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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 512**

**[CMS-5527-F]**

**RIN 0938-AT89**

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

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements two new mandatory Medicare payment models under section 1115A of the Social Security Act—the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model). The RO Model will promote quality and financial accountability for providers and suppliers of radiotherapy (RT). The RO Model will be a mandatory payment model and will test whether making prospective episode payments to hospital outpatient departments (HOPD) and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing Medicare program spending through enhanced financial accountability for RO Model participants. The ETC Model will be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model adjusts Medicare payments on certain dialysis and dialysis-related claims for participating ESRD facilities and clinicians caring for beneficiaries with ESRD

– or Managing Clinicians – based on their rates of home dialysis transplant waitlisting, and living donor transplants. We believe that these two models will test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

**DATES:** These regulations are effective on [insert date 60 days after the date of publication in the **Federal Register].**

**FOR FURTHER INFORMATION CONTACT:**

Rebecca Cole, (410) 786-1589, Rebecca.Cole@cms.hhs.gov, for questions related to General Provisions.

RadiationTherapy@cms.hhs.gov, or 1-844-711-2664 Option 5, for questions related to the Radiation Oncology Model.

ETC-CMMI@cms.hhs.gov, for questions related to the ESRD Treatment Choices Model.

**SUPPLEMENTARY INFORMATION:**

**Current Procedural Terminology (CPT) Copyright Notice**

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## I. Executive Summary and Background

### A. Executive Summary

#### 1. Purpose

The purpose of this final rule is to implement and test two new mandatory models under the authority of the Center for Medicare and Medicaid Innovation (Innovation Center), and to implement certain general provisions that will be applicable to both the RO Model and the ETC Model. Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. Under the Medicare fee-for-service (FFS) program, Medicare generally makes a separate payment to providers and suppliers for each item or service furnished to a beneficiary during the course of treatment. Because the amount of payments received by a provider or supplier for such items and services varies with the volume of items and services furnished to a beneficiary, some providers and suppliers may be financially incentivized to inappropriately increase the volume of items and services furnished to receive higher payments. Medicare FFS may also detract from a provider's or supplier's incentive to invest in quality improvement and care coordination activities if it means those activities will result in payment for fewer items and services. As a result, care may be fragmented, unnecessary, or duplicative.

The goal for these models is to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for model participants. The Model performance period for the RO Model will begin on January 1,

2021, and end December 31, 2025. We will implement the payment adjustments under the ETC Model beginning January 1, 2021 and ending June 30, 2027.

These models will offer participants the opportunity to examine and better understand their own care processes and patterns with regard to beneficiaries receiving RT services for cancer, and beneficiaries with ESRD, respectively. We chose these focus areas for the models because, as discussed in sections III. and IV. of this final rule, we believe that participants in these models will have a significant opportunity to redesign care and improve the quality of care furnished to beneficiaries receiving these services.

We believe the models will further the agency's goal of increasing the extent to which CMS initiatives pay for value and outcomes, rather than for volume of services alone, by promoting the alignment of financial and other incentives for health care providers caring for beneficiaries receiving treatment for cancer or ESRD. Payments that are made to health care providers for assuming financial accountability for the cost and quality of care create incentives for the implementation of care redesign among model participants and other providers and suppliers.

CMS is testing several models, including voluntary models focused specifically on cancer and ESRD. The RO and ETC Models will require the participation of providers and suppliers that might not otherwise participate in these models, and will be tested in multiple geographic areas.

The models will allow CMS to test models with provider and supplier participation when there are differences in: (1) historic care and utilization patterns; (2) patient populations and care patterns; (3) roles within their local markets; (4) volume of services; (5) levels of access to financial, community, or other resources; and (6) levels of population and health care provider

density. As noted in the proposed rule, we believe that participation in these models by a large number of providers and suppliers with diverse characteristics will result in a robust data set for evaluating the models' proposed payment approaches and will stimulate the rapid development of new evidence-based knowledge. Testing these models in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize quality improvement for beneficiaries receiving services for RT and ESRD, which could inform future model design.

We solicited public comment on our proposals, and on any alternatives considered. CMS has made a number of modifications to the formatting and language used in the regulation text (for example, to revise "pursuant to" to "under"; and "shall" to "must") to improve readability. These formatting and language changes are not intended to be substantive. Any substantive change(s) to this final rule is noted in the specific section(s) affected by the change(s).

2. Summary of the Major Provisions

a. General Provisions

The general provisions will be applicable only to participants in the RO Model and the ETC Model. We identified the general provisions based on similar requirements that have been repeatedly memorialized in various documents governing participation in existing model tests. We have made these provisions applicable to both the RO Model and ETC Model, with one exception related to termination of model participants, so that we may eliminate repetition in our regulations at 42 CFR part 512. The general provisions address 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. These provisions are not

intended to comprehensively encompass all the provisions that will apply to each model. Both the RO Model and the ETC Model have unique aspects that will require additional, more tailored provisions, including with respect to payment and quality measurement. Such model-specific provisions are described elsewhere in this final rule.

b. Radiation Oncology (RO) Model

In this rule, we are finalizing the creation and testing of a new payment model for radiation oncology, the RO Model. The intent of the RO Model is to promote quality and financial accountability for episodes of care centered on RT services. While preserving or enhancing the quality of care for Medicare beneficiaries, the RO Model will test whether prospective episode-based payments to physician group practices (PGPs), HOPDs, and freestanding radiation therapy centers for RT episodes of care will reduce Medicare expenditures. We anticipate the RO Model will benefit Medicare beneficiaries by encouraging more efficient care delivery and incentivizing higher value care across episodes of care. The RO Model will have a performance period of 5 calendar years, beginning January 1, 2021, and ending December 31, 2025. The RO Model will capture all complete RO episodes that end during the performance period, which means that the data collection, RO episode payments, and reconciliation will continue into calendar year 2026.

(1) Summary of the RO Provisions

(a) RO Model Overview

RT is a common treatment for patients undergoing cancer treatment and is typically furnished by a physician at either an HOPD or a freestanding radiation therapy center. The RO Model will include prospective payments for certain RT services furnished during a 90-day RO episode for included cancer types for certain Medicare beneficiaries. The included cancer types

will be determined by the following criteria: all are commonly treated with radiation; make up the majority of all incidence of cancer types; and have demonstrated pricing stability. (See section III.C.5.a. of this final rule for more information.) This Model will not account for total cost of all care provided to the beneficiary during the 90 days of an RO episode. Rather, the payment will cover only select RT services furnished during an RO episode. Payments for RO episodes will be split into two components – the professional component (PC) and the technical component (TC). This division reflects the fact that RT professional and technical services are sometimes furnished by separate RT providers and RT suppliers and paid for through different payment systems (namely, the Medicare Physician Fee Schedule and Outpatient Prospective Payment System).

For example, under the RO Model, a participating HOPD must have at least one PGP to furnish RT services at the HOPD. A PGP will furnish the PC as a Professional participant and an HOPD will furnish the TC as a Technical participant. Both will be participants in the RO Model, furnishing separate components of the same RO episode. An RO participant may also elect to furnish both the PC and TC as a Dual participant through one entity, such as a freestanding radiation therapy center. The RO Model will test the cost-saving potential of prospective episode payments for certain RT services furnished during an RO episode and whether shorter courses of RT (that is, fewer doses, also known as fractions) will encourage more efficient care delivery and incentivize higher value care.

(b) RO Model Scope

We are finalizing criteria for the types of cancer included under the RO Model and list 16 cancer types that meet our criteria. These cancer types are commonly treated with RT and, therefore, RT services for such cancer types can be accurately priced for purposes of a

prospective episode payment model. RO episodes will include most RT services furnished in HOPDs and freestanding radiation therapy centers during a 90-day period.

We are finalizing that participation in the RO Model will be mandatory for all RT providers and RT suppliers within selected geographic areas. We will use Core-Based Statistical Areas (CBSAs) delineated by the Office of Management and Budget[1] as the geographic area for the randomized selection of RO participants. We will link RT providers and RT suppliers to a CBSA by using the five digit ZIP Code of the location where RT services are furnished, permitting us to identify RO Model participants while still using CBSA as a geographic unit of selection. In addition, we will exclude certain providers and suppliers from participation under the RO Model as described in section III.C.3.c. of this final rule.

We are including beneficiaries that meet certain criteria under the RO Model. For example, these criteria will require that a beneficiary have a diagnosis of at least one of the cancer types included in the RO Model and that the beneficiary receive RT services from a participating provider or supplier in one of the selected CBSAs. Beneficiaries who meet these criteria will be included in RO episodes.

(c) RO Model Overlap with Other CMS Programs and Models

We expect that there could be situations where a Medicare beneficiary included in an RO episode under the RO Model is also assigned, aligned, or attributed to another Innovation Center model or CMS program. Overlap could also occur among RT providers and RT suppliers at the individual or organization level, such as where a radiation oncologist or his or her PGP participates in multiple Innovation Center models. We believe that the RO Model is compatible

[1] See https://www.census.gov/programs-surveys/metro-micro/about/omb-bulletins.html

with existing models and programs that provide opportunities to improve care and reduce spending, especially episode payment models like the Oncology Care Model. However, we will work to resolve any potential overlaps between the RO Model and other CMS models or programs that could result in repetitive services, or duplicative payment of services, and duplicative counting of savings or other reductions in expenditures.

(d) RO Model Episodes and Pricing Methodology

We are setting a separate payment amount for the PC and the TC of each cancer type included in the RO Model. The payment amounts will be determined based on national base rates, trend factors, and adjustments for each participant's case-mix, historical experience, and geographic location. The payment amount will also be adjusted for withholds for incorrect payments, quality, and starting in the third performance year (PY3), patient experience. The standard beneficiary coinsurance amounts (typically 20 percent of the Medicare-approved amount for services) and sequestration will remain in effect. RO participants will have the ability to earn back a portion of the quality and patient experience withholds based on their reporting of clinical data, their reporting and performance on quality measures, and as of PY3, performance on the beneficiary-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Radiation Therapy Survey.

(e) RO Model Quality Measures and Reporting Requirements

We are adopting four quality measures and will collect the CAHPS® Cancer Care Radiation Therapy Survey for the RO Model. Three of the four measures are National Quality Forum (NQF)-endorsed process measures that are clinically appropriate for RT and are approved

for the Merit-based Incentive Payment System (MIPS).[2,3] We selected all measures based on clinical appropriateness for RT services spanning a 90-day period. These measures will be applicable to the full range of included cancer types and provide us the ability to accurately measure changes or improvements in the quality of RT services. Further, we believe that these measures will allow the RO Model to apply a pay-for-performance methodology that incorporates performance measurement with a focus on clinical care and beneficiary experience with the aim of identifying a reduction in expenditures with preserved or enhanced quality of care for beneficiaries.

RO participants will be paid for reporting clinical data in accordance with our reporting requirements (as discussed in section III.C.8.e. of this final rule), and paid for performance on aggregated quality measure data on three quality measures and pay-for-reporting on one quality measure (for PY1 and PY2) (as discussed in section III.C.8.f. of this final rule). We are adding a set of patient experience measures based on the CAHPS® Cancer Care Survey for Radiation Therapy for inclusion as pay-for-performance measures. We will also require Professional participants 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 (for example, not just Medicare beneficiaries or beneficiaries receiving care for RO episodes).

(f) RO Model Data Sharing Process

We will collect quality and clinical data for the RO Model. We intend to share certain data with RO participants to the extent permitted by the Health Insurance Portability and

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[2] NQF endorsement summaries: http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx

[3] See the CY 2018 QPP final rule (82 FR 53568).

Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We are establishing data privacy compliance standards for RO participants. We are establishing requirements around the public release of patient de-identified information by RO participants. We will offer RO participants the opportunity to request a claims data file that contains patient-identifiable data on the RO participant's patient population for clinical treatment, care management and coordination, and quality improvement activities. Also, we will permit the data to be reused by RO participants for provider incentive design and implementation, and we believe it may be of use in RO participants' review of our calculation of their participant-specific episode payment amounts and reconciliation payment amounts or repayment amounts, as applicable. Thus, we expect that the data offered under the RO Model will be used by RO participants and CMS to better understand Model effects, establish benchmarks, and monitor participant compliance. Again, as previously described, the data uses and sharing will be allowed only to the extent permitted by the HIPAA Privacy Rule and other applicable law.

When using or disclosing such data, the RO participant will be required to make "reasonable efforts to limit" the information to the "minimum necessary" as defined by 45 CFR 164.502(b) and 164.514(d) to accomplish the intended purpose of the use, disclosure, or request. The RO participant will be required to further limit its disclosure of such information to what is permitted by applicable law, including the regulations promulgated under the HIPAA and the Health Information Technology for Economic and Clinical Health (HITECH) laws at 45 CFR part 160 and subparts A and E of part 164. Further discussion of data sharing can be found in section III.C.13. of this final rule.

(g) RO Model Beneficiary Protections

We are requiring Professional participants and Dual participants to notify RO

beneficiaries of the beneficiary's inclusion in this Model through a standardized written notice to each RO beneficiary during the treatment planning service. We intend to provide a notification template, which RO participants may personalize with contact information and logos, but must otherwise not be changed. Further explanation of the beneficiary notification can be found in section III.C.15. of this final rule.

(h) RO Model Program Policy Waivers

We believe it will be necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the RO Model under section 1115A(b) of the Act. We will issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Each of the waivers is discussed in detail in section III.C.10. of this final rule, and codified in our regulations at § 512.280.

c. ESRD Treatment Choices (ETC) Model

The ETC Model will be a mandatory payment model, focused on encouraging greater use of home dialysis and kidney transplants for ESRD Beneficiaries among ESRD facilities and Managing Clinicians located in Selected Geographic Areas. The ETC Model will include two payment adjustments. The first payment adjustment, the Home Dialysis Payment Adjustment (HDPA), will be a positive adjustment on certain home dialysis and home dialysis-related claims during the initial 3 years of the model. The second payment adjustment, the Performance Payment Adjustment (PPA), will be a positive or negative adjustment on dialysis and dialysis-related Medicare payments, for both home dialysis and in-center dialysis, based on ESRD facilities' and Managing Clinicians' rates of home dialysis, and of kidney transplant waitlisting and living donor transplantation, among attributed beneficiaries during the applicable MY. We

are implementing the payment adjustments under the ETC Model beginning January 1, 2021, and ending June 30, 2027.

(1) Summary of the ETC Model Provisions

(a) ETC Model Overview

Beneficiaries with ESRD generally require some form of renal replacement therapy, the most common being hemodialysis (HD), followed by peritoneal dialysis (PD), or a kidney transplant. Most beneficiaries with ESRD receive HD treatments in an ESRD facility; however, other renal replacement modalities – including dialyzing at home or receiving a kidney transplant – may be better options than in-center dialysis for more beneficiaries than currently use them. We are finalizing the ETC Model to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians – clinicians who furnish and bill the Monthly Capitation Payment (MCP) for managing ESRD Beneficiaries – to encourage greater utilization of home dialysis and kidney transplantation, support beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. We believe ESRD facilities and Managing Clinicians are the key providers and suppliers managing the dialysis care and treatment modality options for ESRD Beneficiaries and have a vital role to play in beneficiary modality selection and assisting beneficiaries through the transplant process. We are adjusting payments for home dialysis and home dialysis-related claims with claim service dates from January 1, 2021, through December 31, 2023 through the HDPA. We also will assess the rates of home dialysis and of kidney transplant waitlisting and living donor transplantation, among beneficiaries attributed to ETC Participants during the period beginning January 1, 2021, and ending June 30, 2026, with the PPA based on those rates applying to claims for dialysis and

dialysis-related services with claim service dates beginning July 1, 2022, and ending June 30, 2027.

(b) ETC Model Scope

The ETC Model will be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants for ESRD Beneficiaries. The rationale for a mandatory model for ESRD facilities and Managing Clinicians within Selected Geographic Areas is that we seek to test the effect of payment incentives on availability and choice of treatment modality among a diverse group of providers and suppliers. We will randomly select Hospital Referral Regions (HRRs) for inclusion in the Model, and also include all HRRs with at least 20 percent of ZIP Codes located in Maryland in addition to those selected through randomization in conjunction with the Maryland Total Cost of Care Model currently being tested in the state of Maryland. Managing Clinicians and ESRD facilities located in these Selected Geographic Areas will be required to participate in the ETC Model and will be assessed on their rates of home dialysis, and of kidney transplant waitlisting and living donor transplantation, among their attributed beneficiaries during each MY; CMS will then adjust certain of their Medicare payments upward or downward during the corresponding Performance Payment Adjustment Period (PPA Period). Managing Clinicians and ESRD facilities located in the Selected Geographic Areas will also receive a positive adjustment on their home dialysis and home dialysis-related claims for the first 3 years of the ETC Model to support home dialysis provision before the PPA begins to apply.

(c) Home Dialysis Payment Adjustment (HDPA)

We will make upward adjustments to certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and will

make upward adjustments to the MCP paid to participating Managing Clinicians on home dialysis-related claims. The HDPA will apply to claims with claim service dates beginning on January 1, 2021, and ending on December 31, 2023.

(d) Home Dialysis and Transplant Performance Assessment and Performance Payment Adjustment (PPA)

We will assess ETC Participants' rates of home dialysis, and transplant waitlisting and living donor transplantation, during a MY, which will include 12 months of performance data. Each MY will overlap with the previous MY, if any, and the subsequent MY, if any, for a period of 6 months. Each MY will have a corresponding PPA Period—a 6-month period, which will begin 6 months after the conclusion of the MY. We will adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY. We will be measuring rates of home dialysis, and of transplant waitlisting and living donor transplantation, for ESRD facilities and Managing Clinicians using Medicare claims data, Medicare administrative data including enrollment data, and the Scientific Registry of Transplant Recipients (SRTR) data. We will measure home dialysis rates for ESRD facilities and Managing Clinicians in the ETC Model by calculating the number of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received dialysis at home, plus one half the total number of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received self dialysis in center. We will measure transplant rates for ESRD facilities and Managing Clinicians by calculating the number of attributed beneficiary years during the MY for which attributed beneficiaries were on the kidney transplant waitlist and by calculating the number of attributed beneficiary years during the MY

for which attributed beneficiaries received living donor transplants. The ETC Model will make upward and downward adjustments to certain payments to participating ESRD facilities under the ESRD PPS and to the MCP paid to participating Managing Clinicians based upon the ETC Participant's home dialysis rate and transplant rate. The magnitude of the positive and negative PPAs for ETC Participants will increase over the course of the Model. These PPAs will apply to claims with claim service dates beginning July 1, 2022, and ending June 30, 2027.

(e) ETC Model Overlaps with Other Innovation Center Models and CMS Programs

The ETC Model will overlap with several other CMS programs and models, including initiatives specifically focusing on dialysis care. We believe the ETC Model will be compatible with other dialysis-focused CMS programs and models. However, we will work to resolve any potential overlaps between the ETC Model and other CMS models or programs that could result in repetitive services or duplicative payment for services. The payment adjustments made under the ETC Model will be counted as expenditures under the Medicare Shared Savings Program and other shared savings initiatives. Additionally, ESRD facilities will remain subject to the quality requirements in ESRD Quality Incentive Program (QIP), and Managing Clinicians who are MIPS eligible clinicians will remain subject to MIPS unless otherwise excluded.

(f) ETC Model Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA, we will need to waive certain Medicare program requirements. In particular, we will waive certain requirements of the Act for the ESRD PPS, ESRD QIP, and Medicare Physician Fee Schedule only to the extent necessary to make the payment adjustments under the ETC Model for ETC Participants. In addition, we will waive certain requirements such that the payment adjustments made under the ETC Model will not change beneficiary cost-sharing from

the regular Medicare program cost-sharing for the related Part B services that were paid for beneficiaries who receive services from ETC Participants.

It will also be necessary to waive certain Medicare payment requirements of section 1861(ggg) of the Act and implementing regulations at 42 CFR 410.48, regarding the use of the Kidney Disease Education (KDE) benefit, solely for the purposes of testing the ETC Model. The purpose of such waivers will be to give ETC Participants additional access to the tools necessary to ensure beneficiaries select their preferred kidney replacement modality. As education is a key component of assisting beneficiaries with making such selections, we will waive select requirements regarding the provision of the KDE benefit, including waiving the requirement that certain health care provider types must furnish the KDE service to allow additional staff to furnish the service, waiving the requirement that the KDE service be furnished to beneficiaries with Stage IV CKD to allow ETC Participants to furnish these services to beneficiaries in later stages of kidney disease, and waiving certain restrictions on the KDE curriculum to allow the content to be tailored to each beneficiary's needs.

We will issue these waivers using our waiver authority under section 1115A(d)(1) of the Act.

(g) ETC Model Monitoring and Quality Measures

Consistent with the monitoring requirements in the general provisions, we will closely monitor the implementation and outcomes of the ETC Model throughout its duration. The purpose of this monitoring will be to ensure that the ETC Model is implemented safely and appropriately, the quality or experience of care for beneficiaries is not harmed, and adequate patient and program integrity safeguards are in place.

As part of the monitoring strategy, we will be using two quality measures for the ETC Model: the Standardized Mortality Ratio and the Standardized Hospitalization Ratio. These measures are NQF-endorsed, and are currently calculated at the ESRD facility level for Dialysis Facility Reports and the ESRD QIP, respectively. Therefore, we will require no additional reporting of quality measures by ETC Participants. We intend to propose a beneficiary experience measure in future rulemaking.

(h) ETC Model Beneficiary Protections

The ETC Model will not allow beneficiaries to opt out of the payment adjustments for their ESRD facility or Managing Clinician; however, the Model will not restrict a beneficiary's freedom to choose an ESRD facility or Managing Clinician, or any other provider or supplier, and ETC Participants will be subject to the general provisions protecting beneficiary freedom of choice and access to medically necessary covered services. We also will require that ETC Participants notify beneficiaries of the ETC Participant's participation in the ETC Model by prominently displaying informational materials in ESRD facilities and Managing Clinician offices or facilities where beneficiaries receive care. Additionally, ETC Participants will be subject to the general provisions regarding descriptive model materials and activities.

B. Background

In the July 18, 2019 **Federal Register** (84 FR 34478), we published the proposed rule titled "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures" that would implement two new mandatory Medicare payment models under

section 1115A of the Act—the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model).

As we stated in the proposed rule, we believe that these two models will test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

We received approximately 330 timely pieces of correspondence in response to our solicitation of public comments on the proposed rule. While we are finalizing several of the provisions from the proposed rule, there are a number of provisions from the proposed rule that we intend to address later and a few that we do not intend to finalize. We also note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule we are not addressing most comments received with respect to the provisions of the proposed rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

## II. General Provisions

A. Introduction

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to such programs' beneficiaries. The Innovation Center has designed and tested numerous models governed by participation agreements, cooperative agreements, model-specific addenda to existing contracts with CMS, and regulations. While each of these models has a specific payment methodology, quality metrics, and certain other applicable policies, each model also has general provisions that are very similar, including provisions on monitoring and evaluation; compliance with model requirements and applicable laws; and beneficiary protections.

This section of the final rule finalizes the implementation of some general provisions that will be applicable to both the RO Model and the ETC Model. These general provisions are only applicable to model participants in the RO Model and the ETC Model. The general provisions being finalized here are based on similar provisions that have been repeatedly memorialized in various documents governing participation in existing model tests.

As we noted in the proposed rule, we believe it promotes efficiency to publish in section II. of this final rule certain general provisions in each of these areas that apply to both the RO Model and the ETC Model. This avoids the need to restate the same provisions separately for the two models in this final rule. We will codify these general provisions in a new subpart of the Code of Federal Regulations (42 CFR part 512, subpart A). These provisions are not intended to comprehensively encompass all the provisions that will apply to each model. Both the RO Model and the ETC Model have unique aspects that require additional, more tailored provisions,

including with respect to payment and quality measurement. Such model-specific provisions are described elsewhere in this final rule.

We received approximately 35 timely public comments on the general provisions of the proposed rule. These comments were submitted by individuals and entities with an interest in radiation oncology and kidney diseases. We note that some of these public comments were outside the scope of the proposed rule. These out-of-scope public comments are not addressed with the policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in this section of the final rule under the appropriate headings.

B. Basis and Scope

In § 512.100(a), we proposed to apply the general provisions in section II. of the proposed rule only to the RO Model and the ETC Model, each of which we proposed to refer to as an "Innovation Center model" for purposes of these general provisions. As proposed, this paragraph indicated that these general provisions would not, except as specifically noted in part 512, affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity (such as those in parts 413, 414, 419, 420, and 489 of chapter IV of 42 CFR and those in parts 1001-1003 of chapter V of 42 CFR).

In § 512.100(b), we proposed to apply the general provisions to model participants in the RO Model (with one exception described later in this final rule) and the ETC Model. We proposed to define the term "model participant" to mean an individual or entity that is identified as a participant in an Innovation Center model under the terms of part 512; as proposed, the term "model participant" would include, unless otherwise specified, the terms "RO participant" or

"ETC Participant" as those terms are defined in subparts B and C of part 512. We proposed to define "downstream participant" to mean an individual or entity that has entered into a written arrangement with a model participant pursuant to which the downstream participant engages in one or more Innovation Center model activities. We proposed that a downstream participant may include, but would not be limited to, an individual practitioner, as defined for purposes of the RO Model. We proposed to define "Innovation Center model activities" to mean any activities impacting the care of model beneficiaries related to the test of the Innovation Center model performed under the terms of proposed part 512. While not used in the general provisions, as this term is used for purposes of both the RO Model and the ETC Model, we proposed to define "U.S. Territories" to mean American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

We solicited public comment on our proposals regarding the basis and scope of these general provisions. We received no comments on these proposals and therefore we are finalizing these proposals without modification in our regulations at § 512.100(a). We similarly did not receive comments on our proposed definitions of model participant, downstream participant, or U.S. Territories, and are finalizing these definitions as proposed in our regulation at § 512.110.

C. Definitions

In our regulation at § 512.110, we proposed to define certain terms relevant to the general provisions. We describe these definitions in context throughout section II. of this final rule. To the extent we have received comments on the definitions we proposed, we have responded to those comments throughout section II. of this final rule.

D. Beneficiary Protections

As we design and test new models at the Innovation Center, we believe it is necessary to have certain protections in place to ensure that beneficiaries retain their existing rights and are not harmed by the participation of their health care providers in Innovation Center models. Therefore, as noted in the proposed rule, we believe it is necessary to propose certain provisions regarding beneficiary choice, the availability of services, and descriptive model materials and activities.

For purposes of the general provisions, we proposed to define the term "beneficiary" to mean an individual who is enrolled in Medicare FFS. As we noted in the proposed rule, this definition aligns with the scope of the RO Model and the ETC Model, which include only Medicare FFS beneficiaries. We also proposed to define the term "model beneficiary" to mean a beneficiary attributed to a model participant or otherwise included in an Innovation Center model under the terms of proposed part 512; as proposed, the term "model beneficiary" as defined in this section would include, unless otherwise specified, the term "RO Beneficiary" and beneficiaries attributed to ETC participants under § 512.360. As stated in the proposed rule, we believed it was necessary to propose this definition of model beneficiary so as to differentiate between Medicare FFS beneficiaries generally and those specifically included in an Innovation Center model. We received no comments on these proposed definitions and therefore are finalizing these definitions in our regulation at § 512.110 without modification.

1. Beneficiary Freedom of Choice

A beneficiary's ability to choose his or her provider or supplier is an important principle of Medicare FFS and is codified in section 1802(a) of the Act. To help ensure that this protection is not undermined by the testing of the two Innovation Center models, we proposed to require in § 512.120(a)(1) that model participants and their downstream participants not restrict a

beneficiary's ability to choose his or her providers or suppliers. We proposed that this policy would apply with respect to all Medicare FFS beneficiaries, not just model beneficiaries, because we believe it is important to ensure that the Innovation Center model tests do not interfere with the general guarantees and protections for all Medicare FFS beneficiaries.

Also, in § 512.120(a)(2), we proposed to codify that the model participant and its downstream participants must not commit any act or omission, nor adopt any policy, that inhibits beneficiaries from exercising their freedom to choose to receive care from any Medicare-participating provider or supplier, or from any health care provider who has opted out of Medicare. As we noted in the proposed rule, we believe this requirement is necessary to ensure that Innovation Center models do not prevent beneficiaries from obtaining the general rights and guarantees provided under Medicare FFS. However, because we believe that it is important for model participants to have the opportunity to explain the benefits of care provided by them to model beneficiaries, we further proposed that the model participant and its downstream participants would be permitted to communicate to model beneficiaries the benefits of receiving care with the model participant, if otherwise consistent with the requirements of part 512 and applicable law.

In § 512.110, we proposed to define the terms "provider" and "supplier," as used in part 512, in a manner consistent with how these terms are used in Medicare FFS generally. Specifically, we proposed to define the term "provider" to mean a "provider of services" as defined under section 1861(u) of the Act and codified in the definition of "provider" at 42 CFR 400.202. We similarly proposed to define the term "supplier" to mean a "supplier" as defined in section 1861(d) of the Act and codified at 42 CFR 400.202. As stated in the proposed rule, we believe it is necessary to define "provider" and "supplier" in this way as a means of

noting to the general public that we are using the generally applicable Medicare definitions of these terms for purposes of part 512.

We solicited comments on our proposals related to beneficiary freedom of choice. In this section of this final rule, we summarize and respond to the public comments received on the beneficiary freedom of choice proposal.

Comment: A few commenters thanked CMS for the explicit clarification of beneficiary rights – notably, that beneficiaries maintain their right to choose a health care provider that is not participating in either the RO Model or the ETC Model.

Response: We thank the commenters for their support and for their comments in support of our proposals to maintain beneficiaries' freedom of choice and other beneficiary protections.

Comment: A few commenters requested that CMS strengthen the proposed beneficiary protections so that beneficiaries are adequately educated about any Innovation Center model in which they are included. Specifically, one of the commenters requested that CMS solicit external feedback on the contents of any beneficiary notification letter prior to requiring its use by model participants. A few commenters also expressed concern that RO Model beneficiaries, specifically, would not have access to the same range of benefits as other Medicare beneficiaries.

Response: We disagree with the commenters that additional safeguards are needed to ensure that model beneficiaries will be adequately educated about the Innovation Center models. Specifically, we believe that several of our finalized provisions will provide adequate education to model beneficiaries regarding the models in which the beneficiaries are included, including §§ 512.225 and 512.330 relating to beneficiary notifications for the RO Model and ETC Model, respectively, as well as § 512.120(c) relating to the requirements for materials and activities used to educate, notify, or contact beneficiaries regarding the Innovation Center model (referred to in

this final rule as descriptive model materials and activities). We would note that § 512.120(c) allows model participants to provide additional descriptive model materials and activities to model beneficiaries that could describe in greater detail the Innovation Center Model and its expected impacts on model beneficiaries. We note that this provision requires that all descriptive model materials and activities must not be materially inaccurate or misleading, and all such materials and activities may be reviewed by CMS. With respect to the template beneficiary notifications that RO participants and ETC Participants must furnish, we will not provide a formal process for soliciting feedback on the content of such notifications because such a process may interfere with the model operation timelines. However, we are open to receiving such feedback on an informal basis. We believe the provisions regarding beneficiary notifications and descriptive model materials and activities strike an appropriate balance between the amount of information that may be desired by beneficiaries and the burden of ensuring that such information is accurate and not misleading.

Additionally, as described in this final rule, under our regulations at § 512.120(a) and (b), model beneficiaries will retain the right to receive care from the providers and suppliers of their choice as well as access to the same range of benefits as other Medicare FFS beneficiaries who are not receiving care from an Innovation Center model participant. As such, we believe that our proposed beneficiary protections will establish strong beneficiary safeguards for the two Innovation Center models. However, as described in section II.H. of this final rule, we are also finalizing our proposal to monitor model participant compliance with model terms and other applicable program laws and policies, including requirements related to beneficiary access to services and the providers and suppliers of their choice. If needed, we will propose any modifications to the applicable beneficiary protections through future rulemaking.

After considering public comments, we are finalizing our proposals on beneficiary freedom of choice without modification in our regulation at § 512.120(a). We received no comments on the proposed definitions of provider and supplier and therefore are finalizing these definitions without modification in our regulation at § 512.110.

2. Availability of Services

Models tested under the authority of section 1115A of the Act are designed to test potential improvements to the delivery of and payment for health care to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care for the beneficiaries of these programs. As such, as we noted in the proposed rule, an important aspect of testing Innovation Center models is that beneficiaries continue to access and receive needed care. Therefore, in § 512.120(b)(1), we proposed that model participants and downstream participants are required to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Consistent with the limitation on Medicare coverage under section 1862(a)(1)(A) of the Act, we proposed to define "medically necessary" to mean reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member. Also, we proposed to define "covered services" to mean the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act, which aligns with Medicare coverage standards and the definition of "covered services" used in other models tested by the Innovation Center. Also, we proposed that model beneficiaries and their assignees, as defined in 42 CFR 405.902, would retain their rights to appeal Medicare claims in accordance with 42 CFR part 405, subpart I. As noted in the proposed rule, we believe that model beneficiaries and their assignees should not lose the right to appeal claims for Medicare items

and services furnished to them solely because the beneficiary's provider or supplier is participating in an Innovation Center model.

Also, in § 512.120(b)(2) we proposed to prohibit model participants and downstream participants from taking any action to avoid treating beneficiaries based on their income levels or based on factors that would render a beneficiary an "at-risk beneficiary" as that term is defined for purposes of the Medicare Shared Savings Program at 42 CFR 425.20, a practice commonly referred to as "lemon dropping." For example, 42 CFR 425.20 defines an "at-risk beneficiary" to include, without limitation, a beneficiary who has one or more chronic conditions or who is entitled to Medicaid because of disability. As such, a model participant or downstream participant would be prohibited from taking action to avoid treating beneficiaries with chronic conditions such as obesity or diabetes, or who are entitled to Medicaid because of disability. As noted in the proposed rule, we believe it is necessary to specify prohibitions on avoiding treating at-risk beneficiaries, including those with obesity or diabetes, or who are eligible for Medicaid because of disability, to prevent potential lemon dropping of beneficiaries. Further, we believe prohibiting lemon dropping is a necessary safeguard to counter any incentives created by the Innovation Center models for model participants to avoid treating potentially high-cost beneficiaries who are most in need of quality care. This prohibition has been incorporated into the governing documentation of many current models being tested by the Innovation Center for this same reason. Also, in § 512.120(b)(3), we proposed an additional provision to prohibit model participants from taking any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance, a practice commonly referred to as "cherry-picking." For example, a model participant or downstream participant would be prohibited from

targeting only healthy, well-educated, or wealthy beneficiaries for voluntary alignment, the receipt of permitted beneficiary incentives or other interventions, or the reporting of quality measures.

We solicited comments on our proposals related to availability of services and on whether prohibiting cherry-picking would prevent model participants from artificially inflating their financial or quality performance results. In this section of this final rule, we summarize and respond to the public comments received on these proposals.

Comment: A commenter applauded CMS's proposals to prohibit model participants from "cherry-picking" beneficiaries. This commenter requested additional details on how CMS plans to identify model participants that have "cherry-picked" or "lemon-dropped" beneficiaries.

Response: We appreciate the commenter's support of our proposal to prohibit cherry-picking in Innovation Center models. We will identify model participants that may have "cherry-picked" or "lemon-dropped" beneficiaries through various modes of monitoring set forth in section II.H. (general provisions), section III.C.14. (the RO Model), and section IV.C.10. (ETC Model) of this final rule. In addition, beneficiary complaints may alert us to potentially inappropriate beneficiary selection or avoidance of certain beneficiaries.

After considering public comments, we are finalizing our proposed provisions on the availability of services without modification in our regulation at § 512.120(b). We received no comments on whether prohibiting cherry-picking will prevent model participants from artificially inflating their financial or quality performance results and therefore are not finalizing additional provisions against cherry-picking in this final rule.

3. Descriptive Model Materials and Activities

In order to protect beneficiaries from potentially being misled about Innovation Center models, we proposed at § 512.120(c)(1) to prohibit model participants and their downstream participants from using or distributing descriptive model materials and activities that are materially inaccurate or misleading. For purposes of part 512, we proposed to define the term "descriptive model materials and activities" to mean general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding the Innovation Center model. Further, we proposed that the following communications would not be descriptive model materials and activities: communications that do not directly or indirectly reference the Innovation Center model (for example, information about care coordination generally); information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of "marketing" as that term is defined at 45 CFR 164.501. The potential for model participants to receive certain payments under the two Innovation Center models may be an incentive for model participants and their downstream participants to engage in marketing behavior that may confuse or mislead beneficiaries about the Innovation Center model or their Medicare rights. Therefore, as noted in the proposed rule, we believe it is necessary to ensure that those materials and activities that are used to educate, notify, or contact beneficiaries regarding the Innovation Center model are not materially inaccurate or misleading because these materials might be the only information that a model beneficiary receives regarding the beneficiary's inclusion in the model. Additionally, we understand that not all communications between the model participant

or downstream participants and the model beneficiaries would address the model beneficiaries' care under the model. As such, we would note that this proposed prohibition would in no way restrict the ability of a model participant or its downstream participants to engage in activism or otherwise alert model beneficiaries to the drawbacks of mandatory models in which they would otherwise decline to participate, provided that such statements are not materially inaccurate or misleading. We did not propose to regulate information or communication unrelated to an Innovation Center model because it would not advance the purpose of the proposed prohibition, which is to protect model beneficiaries from being misled about their inclusion in an Innovation Center model or their Medicare rights generally. Accordingly, we proposed to define the term "descriptive model materials and activities" such that materials unrelated to the Innovation Center model are not subject to the requirements of § 512.120(c)(1).

Also, in § 512.120(c)(4) we proposed to reserve the right to review, or have our designee review, descriptive model materials and activities to determine whether the content is materially inaccurate or misleading; this review would not be a preclearance by CMS, but would take place at a time and in a manner specified by CMS once the materials and activities are in use by the model participant. As noted in the proposed rule, we believe it would be necessary for CMS to have this ability to review descriptive model materials and activities in order to protect model beneficiaries from receiving misleading or inaccurate materials regarding the Innovation Center model. Furthermore, to facilitate our ability to conduct this review and to monitor Innovation Center models generally, we proposed at § 512.120(c)(3) to require model participants and downstream participants, to retain copies of all written and electronic descriptive model materials and activities and to retain appropriate records for all other descriptive model materials and activities in a manner consistent with § 512.135(c) (record retention).

Also in § 512.120(c)(2), we proposed to require model participants and downstream participants to include the following disclaimer on all descriptive model materials and activities: "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 & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document." We proposed to require the use of this disclaimer so that the public, and beneficiaries in particular, are not misled into believing that model participants or their downstream participants are speaking on behalf of the agency.

We solicited comments on our proposals related to descriptive model materials and activities. We also solicited comment on whether we should propose a different disclaimer that alerts beneficiaries that we prohibit misleading information and gives beneficiaries contact information so they could reach out to us if they suspect the information they have received regarding an Innovation Center model is inaccurate.

In this section of this final rule, we summarize and respond to the public comments received on these proposals.

Comment: A commenter requested that CMS review all marketing materials from model participants prior to those materials being made available to beneficiaries in order to prevent confusion or the dissemination of misleading information. This commenter also supported the proposal that descriptive model materials and activities include the proposed disclaimer.

Response: We thank the commenter for supporting our proposal to require model participants include a disclaimer on all descriptive model materials and activities so that the public, and model beneficiaries in particular, are not misled into believing that model participants are speaking on behalf of CMS. We also appreciate the commenter's

recommendation that CMS review all marketing materials from model participants prior to their distribution; however, we believe that our proposal to reserve the right to review such materials once distributed strikes the appropriate balance. Specifically, our final rule protects beneficiaries from receiving misleading information regarding Innovation Center models without unduly delaying the release of useful information or increasing the burden on model participants and CMS by requiring a thorough review of all marketing materials from all model participants prior to their release.

After considering public comments, we are finalizing our proposed provisions on descriptive model materials and activities without modification in our regulation at § 512.120(c). We did not receive any comments on whether we should propose a different disclaimer that alerts beneficiaries that we prohibit misleading information and gives them contact information so they could reach out to us if they suspect the information they have received regarding an Innovation Center model is inaccurate. Furthermore, we received no comments on these proposed definition of descriptive model materials and activities and therefore are finalizing this definition without modification in our regulation at § 512.110.

E. Cooperation with Model Evaluation and Monitoring

Section 1115A(b)(4) of the Act requires the Secretary to evaluate each model tested under the authority of section 1115A of the Act and to publicly report the evaluation results in a timely manner. The evaluation must include an analysis of the quality of care furnished under the model and the changes in program spending that occurred due to the model. Models tested by the Innovation Center are rigorously evaluated. For example, when evaluating models tested under section 1115A of the Act, we require the production of information that is representative of a wide and diverse group of model participants and includes data regarding potential

unintended or undesirable effects, such as cost-shifting. The Secretary must take the evaluation into account if making any determinations regarding the expansion of a model under section 1115A(c) of the Act.

In addition to model evaluations, the Innovation Center regularly monitors model participants for compliance with model requirements. For the reasons described in section II.H. of this final rule, these compliance monitoring activities are an important and necessary part of the model test.

Therefore, we proposed to codify in § 512.130, that model participants and their downstream participants must comply with the requirements of 42 CFR 403.1110(b) (regarding the obligation of entities participating in the testing of a model under section 1115A of the Act to report information necessary to monitor and evaluate the model), and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act. This participation in the evaluation may include, but is not limited to, responding to surveys and participating in focus groups. Additional details on the specific research questions that the Innovation Center model evaluation will consider for the RO Model and ETC Model can be found in in sections III.C.16. and IV.C.11. of this final rule, respectively. Further, we proposed to conduct monitoring activities according to proposed § 512.150, described later in this final rule, including producing such data as may be required by CMS to evaluate or monitor the Innovation Center model, which may include protected health information as defined in 45 CFR 160.103 and other individually identifiable data.

We solicited public comment on our proposal regarding cooperation with model monitoring and evaluation activities. We received no comments on these proposals and therefore are finalizing these proposals without modification in our regulation at § 512.130.

F. Audits and Record Retention

By virtue of their participation in an Innovation Center model, model participants and their downstream participants may receive model-specific payments, access to payment rule waivers, or some other model-specific flexibility. Therefore, as noted in the proposed rule, we believe that CMS's ability to audit, inspect, investigate, and evaluate records and other materials related to participation in Innovation Center models is necessary and appropriate. In addition, we proposed in § 512.120(b)(1) to require model participants and their downstream participants to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Similarly, in order to expand a phase 1 model tested by the Innovation Center, among other things, the Secretary must first determine that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals. Thus, as discussed in the proposed rule, there is a particular need for CMS to be able to audit, inspect, investigate, and evaluate records and materials related to participation in Innovation Center models to allow us to ensure that model participants are in no way denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the Innovation Center model. We proposed to define "model-specific payment" to mean a payment made by CMS only to model participants, or a payment adjustment made only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers; the term "model-specific payment" would include, unless otherwise specified, the terms "home dialysis payment adjustment (HDPA)," "performance payment

adjustment (PPA)," "participant-specific professional episode payment," or "participant-specific technical episode payment." As noted in the proposed rule, we believe it is necessary in order to distinguish payments and payment adjustments applicable to model participants as part of their participation in an Innovation Center model, from payments and payment adjustments applicable to model participants as well as other providers and suppliers, as certain provisions of proposed part 512 would apply only to the former category of payments and payment adjustments.

We note here and in the proposed rule that there are audit and record retention requirements under the Medicare Shared Savings Program (42 CFR 425.314) and in current models being tested under section 1115A of the Act (such as under 42 CFR 510.110 for the Innovation Center's Comprehensive Care for Joint Replacement Model). Building off those existing requirements, we proposed in § 512.135(a), that the Federal government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. Additionally, in order to align with the policy of current models being tested by the Innovation Center, in § 512.135(b) and (c) we proposed that the model participant and its downstream participants must do the following:

• Maintain and give the Federal government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the Innovation Center model, including, without limitation, documents and other evidence regarding all of the following:

++ Compliance by the model participant and its downstream participants with the terms of the Innovation Center model, including proposed new subpart A of proposed part 512.

++ The accuracy of model-specific payments made under the Innovation Center model.

++ The model participant's payment of amounts owed to CMS under the Innovation Center model.

++ Quality measure information and the quality of services performed under the terms of the Innovation Center model, including proposed new subpart A of part 512.

++ Utilization of items and services furnished under the Innovation Center model.

++ The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

++ Patient safety.

++ Any other program integrity issues.

• Maintain the documents and other evidence for a period of 6 years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the model participant at least 30 days before the normal disposition date; or

++ There has been a termination, dispute, or allegation of fraud or similar fault against the model participant in which case the records must be maintained for an additional six (6) years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the model participant of a special need to retain a record or group of records at least 30 days before the normal disposition date, we proposed that the records must be

maintained for such period of time determined by CMS. If CMS notifies the model participant of a special need to retain records or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, the model participant must notify its downstream participants of the need to retain records for the additional period specified by CMS. As noted in the proposed rule, this provision will ensure that that the government has access to the records.

To avoid any confusion or disputes regarding the timelines outlined in these general provisions, we proposed to define the term "days" to mean calendar days.

We solicited public comment on these proposed provisions regarding audits and record retention.

Historically, the Innovation Center has required participants in section 1115A models to retain records for at least 10 years, which is consistent with the outer limit of the statute of limitations for the Federal False Claims Act and is consistent with the Shared Savings Program's policy outlined at 42 CFR 425.314(b)(2). For this reason, we also solicited public comments on whether we should require model participants and downstream participants to maintain records for longer than 6 years.

We summarize and respond in this section of this final rule to the public comments received on these proposals.

Comment: A few commenters applauded our proposed requirement for model participants and their downstream participants to maintain records for at least six (6) years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation.

Response: We thank the commenters for their support of this proposed policy.

Comment: A few commenters, while generally supporting our proposed record retention requirements, made alternative suggestions for how CMS should collect model-related records from model participants. Specifically, both commenters suggested that CMS expressly allow for e-transmission of model-related records when requested by CMS as this would allow additional flexibility for model participants and be less burdensome for model participants.

Response: We appreciate the commenters' support for our proposed record retention requirements. While we did not propose to prohibit e-transmission of records that are requested by CMS, we are not finalizing a provision that would permit the exclusive use of e-transmission for such records, as we believe that CMS should make case-by-case determinations regarding whether e-transmission is appropriate.

We received no comments on whether CMS should require model participants and downstream participants to maintain records for longer than 6 years. After considering public comments, we are finalizing our proposals on audits and record retention as proposed in our regulation at § 512.135. We received no comments on the proposed definitions for model-specific payments and days; and therefore, are finalizing these definitions without modification in our regulation at § 512.110.

G. Rights in Data and Intellectual Property

To enable CMS to evaluate the Innovation Center models as required by section 1115A(b)(4) of the Act and to monitor the Innovation Center models pursuant to § 512.150, in § 512.140(a) we proposed to use any data obtained in accordance with §§ 512.130 and 512.135 to evaluate and monitor the Innovation Center models. We further proposed that, consistent with section 1115A(b)(4)(B) of the Act, that CMS would be allowed to disseminate quantitative and qualitative results and successful care management techniques, including factors

associated with performance, to other providers and suppliers and to the public. We proposed that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources.

In order to protect the intellectual property rights of model participants and downstream participants, in § 512.140(c) we proposed to require model participants and their downstream participants to label data they believe is proprietary that they believe should be protected from disclosure under the Trade Secrets Act. As we noted in the proposed rule, this approach is already in use in other models currently being tested by the Innovation Center, including the Next Generation Accountable Care Organization Model. Any such assertions would be subject to review and confirmation prior to CMS's acting upon such assertion.

We further proposed to protect such information from disclosure to the full extent permitted under applicable laws, including the Freedom of Information Act. Specifically, in § 512.140(b), we proposed that we would not release data that has been confirmed by CMS to be proprietary trade secret information and technology of the model participant or its downstream participants without the express written consent of the model participant or its downstream participant, unless such release is required by law.

We solicited public comment on these proposals. We received no comments on these proposals and therefore are finalizing these proposals without modification in our regulation at § 512.140.

H. Monitoring and Compliance

Given that model participants may receive model-specific payments, access to payment rule waivers, or some other model-specific flexibility while participating in an Innovation Center

model, as noted in the proposed rule, we believe that enhanced compliance review and monitoring of model participants is necessary and appropriate to ensure the integrity of the Innovation Center model. In addition, as part of the Innovation Center's assessment of the impact of new Innovation Center models, we have a special interest in ensuring that model tests do not interfere with ensuring the integrity of the Medicare program. Our interests include ensuring the integrity and sustainability of the Innovation Center model and the underlying Medicare program, from both a financial and policy perspective, as well as protecting the rights and interests of Medicare beneficiaries. For these reasons, as a part of the models currently being tested by the Innovation Center, CMS or its designee monitors model participants to assess compliance with model terms and with other applicable program laws and policies. As noted in the proposed rule, we believe our monitoring efforts help ensure that model participants are furnishing medically necessary covered services and are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the model or are not in the best interests of the model, the Medicare program, or Medicare beneficiaries.

In § 512.150(b)(1), we proposed to continue this standard practice of conducting monitoring activities for several reasons: (1) to ensure compliance by the model participant and each of its downstream participants with the terms of the Innovation Center model, including the requirements of proposed subpart A of proposed part 512; (2) to understand model participants' use of model-specific payments; and (3) to promote the safety of beneficiaries and the integrity of the Innovation Center model. Such monitoring activities would include, but not be limited to: (1) documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires; (2) audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants;

(3) interviews with members of the staff and leadership of the model participant and its downstream participants; (4) interviews with beneficiaries and their caregivers; (5) site visits to the model participant and its downstream participants, which would be performed in a manner consistent with proposed § 512.150(c), described later in this rule; (6) monitoring quality outcomes and registry data; and (7) tracking patient complaints and appeals. We believe these specific monitoring activities, which align with those currently used in other models being tested by the Innovation Center, are necessary to ensure compliance with the terms and conditions of the Innovation Center model, including proposed subpart A of proposed part 512, and to protect beneficiaries from potential harms that may result from the activities of a model participant or its downstream participants, such as attempts to reduce access to or the provision of medically necessary covered services.

We proposed to codify in § 512.150(b)(2), that when we are conducting compliance monitoring and oversight activities, CMS or its designees would be authorized to use any relevant data or information, including without limitation Medicare claims submitted for items or services furnished to model beneficiaries. As noted in the proposed rule, we believe that it is necessary to have all relevant information available to us during our compliance monitoring and oversight activities, including any information already available to us through the Medicare program.

We proposed to require in § 512.150(c)(1) that model participants and their downstream participants cooperate in periodic site visits conducted by CMS or its designee in a manner consistent with § 512.130, described previously. Such site visits would be conducted to facilitate the model evaluation performed pursuant to section 1115A(b)(4) of the Act and to monitor

compliance with the Innovation Center model terms (including proposed subpart A of proposed part 512).

In order to operationalize this proposal, in § 512.150(c)(2) we proposed that CMS or its designee would provide the model participant or its downstream participant with no less than 15 days advance notice of a site visit, to the extent practicable. Furthermore, to the extent practicable, we proposed that CMS would attempt to accommodate a request that a site visit be conducted on a particular date, but that the model participant or downstream participant would be prohibited from requesting a date that was more than 60 days after the date of the initial site visit notice from CMS. We believe the 60-day period would reasonably accommodate model participants' and downstream participants' schedules while not interfering with the operation of the Innovation Center model. Further, in § 512.150(c)(3) we proposed to require the model participant and their downstream participants to ensure that personnel with the appropriate responsibilities and knowledge pertaining to the purpose of the site visit be available during any and all site visits. As noted in the proposed rule, we believe this proposal is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Also, in § 512.150(c)(4), we proposed that CMS or its designee could perform unannounced site visits to the offices of model participants and their downstream participants at any time to investigate concerns related to the health or safety of beneficiaries or other patients or other program integrity issues, notwithstanding these provisions. Further, in § 512.150(c)(5) we proposed that nothing in proposed part 512 would limit CMS from performing other site visits as allowed or required by applicable law. As noted in the proposed rule, we believe that, regardless of the model being tested, CMS must always have the ability to timely investigate concerns related to the health or safety of beneficiaries or other patients, or program integrity

issues, and to perform functions required or authorized by law. In particular, we believe that it is necessary for us to monitor, and for model participants and their downstream participants to be compliant with our monitoring efforts, to ensure that they are not denying or limiting the coverage or provision of medically necessary covered services to beneficiaries in an attempt to change model results or their model-specific payments, including discrimination in the provision of services to at-risk beneficiaries (for example, due to eligibility for Medicaid based on disability).

Model participants that are enrolled in Medicare will remain subject to all existing requirements and conditions for Medicare participation as set out in Federal statutes and regulations and provider and supplier agreements, unless waived under the authority of section 1115A(d)(1) of the Act solely for purposes of testing the Innovation Center model. Therefore, in § 512.150(a), we proposed to require that model participants and each of their downstream participants must comply with all applicable laws and regulations. We noted in the proposed rule that a law or regulation is not "applicable" to the extent that its requirements have been waived pursuant to section 1115A(d)(1) of the Act solely for purposes of testing the Innovation Center model in which the model participant is participating.

To protect the financial integrity of each Innovation Center model, in § 512.150(d) we proposed that if CMS discovers that it has made or received an incorrect model-specific payment under the terms of an Innovation Center model, CMS may make payment to, or demand payment from, the model participant. We did not propose a deadline for making or demanding such payments, but we stated that we were considering the imposition of some of the deadlines set forth in the Medicare reopening rules at 42 CFR 405.980. Specifically, we sought 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). As noted in the proposed rule, we believe this may be necessary to ensure we have a means and a timeline to make redeterminations on incorrect model-specific payments that we have made or received in conjunction with the proposed Innovation Center models.

We proposed to codify at § 512.150(e) that nothing contained in the terms of the Innovation Center model or proposed part 512 would limit or restrict the authority of the HHS Office of Inspector General (OIG) or any other Federal government authority, including its authority to audit, evaluate, investigate, or inspect the model participant or its downstream participants for violations of any statutes, rules, or regulations administered by the Federal government. This provision simply reflects the limits of CMS authority.

We solicited comments on these proposals related to monitoring and compliance. In this section of this final rule, we summarize and respond to the public comments received on these proposals and comment solicitations.

Comment: A commenter expressed its support for our proposal to permit CMS to make corrections to model-specific payments. This commenter also suggested that RO participants be permitted to initiate requests to make corrections to model-specific payments in the RO Model.

Response: We thank this commenter for their support of the proposed policy. We would note that in section III.C.12. of this final rule, we have finalized the proposed process, with a modification to allow for 45 days instead of the proposed 30 days, for RO participants to notify CMS of suspected errors in the calculation of their reconciliation payment amount or repayment amount or aggregate quality score as reflected on an RO reconciliation report that has not been deemed final. In addition, in section IV.C.5.h. of this final rule, we have finalized the proposed

process for ETC Participants to request a targeted review of the calculation of the Modality Performance Score (MPS).

We understand the commenter to be advocating that RO participants should have the right to request reopening of a model-specific payment determination. By way of background, a reopening is an administrative action taken to change a binding determination or decision that resulted in either an overpayment or underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record (see § 405.980(a)). Under the Medicare reopening rules, a party to an initial determination may request that the determination be reopened in a variety of circumstances, including within one year for any reason and within four years for good cause (as defined at § 405.986). The Medicare reopening rules also permit a CMS contractor to reopen an initial determination on its own motion for a variety reasons, including: (1) within 1 year for any reason; (2) within 4 years for good cause (as defined at § 405.986); and (3) at any time if there is reliable evidence (as defined at § 405.902) that the initial determination was procured by fraud or similar fault (as defined at § 405.902). Under § 405.986, "good cause" may be established when there is new and material evidence that was not available or known at the time of the determination or decision and that may result in a different conclusion or when the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision. Under the existing reopening rules, the decision whether to grant a request for reopening is within the sole discretion of CMS and is not reviewable (see § 405.980(a)(5)).

As noted previously in this final rule, we did not propose any temporal restrictions on when CMS could correct prior payments, but we stated in the proposed rule that we were

considering the imposition of some of the deadlines set forth in the Medicare reopening rules at 42 CFR 405.980. We specifically sought comment regarding 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). After consideration of the public comments, we believe that model participants should have a limited opportunity to request the reopening of a model-specific payment determination. Specifically, we will permit the reopening of a model-specific payment determination, whether on CMS' own motion or at the request of a model participant, for good cause (as defined at § 405.986) within 4 years after the date of the determination. This reopening provision will help to ensure accurate payments under an Innovation Center model, while the temporal and "good cause" limitations will promote efficient use of administrative resources and the eventual finality of payment determinations. In addition, we are finalizing a policy that permits CMS to reopen a model-specific payment determination at any time if there exists reliable evidence (as defined at § 405.902) that the determination was procured by fraud or similar fault (as defined at § 405.902). The purpose of this provision is to remediate fraud and abuse that may not be discovered within four years of the initial payment determination.

Finally, consistent with the existing Medicare reopening rules, the decision to grant or deny a reopening request in an Innovation Center model with respect to a model-specific payment is solely at CMS discretion and not reviewable. For example, for purposes of an Innovation Center Model, CMS may exercise its discretion to reopen a model-specific payment determination to correct a clerical error that constitutes good cause for reopening under §405.986(a)(2). We note that if CMS reopens a model-specific payment determination, the

revised payment determination may be appealed in accordance with the applicable Innovation Center model regulations, including §512.170 (limitations on review).

We do not believe, however, that it is necessary to permit the reopening of a model-specific payment determination for any reason within 1 year after the determination has been made. The reopening rule we are finalizing here adequately protects payment accuracy, especially in light of the review procedures set forth for the RO Model at § 512.290 and for the ETC Model at § 512.390. Moreover, as noted above, this final rule permits CMS to correct clerical errors that it determines constitute "good cause" for reopening. We are finalizing our reopening policy at § 512.150(d).

Comment: A commenter stated that on-site monitoring of RO participants should be conducted by personnel and contractors that can provide RO participants with certification, licensure, or other form of demonstrated knowledge in the specific field of radiation oncology.

Response: We disagree with the commenters' belief that site visits of RO participants must be conducted by personnel and contractors that have certification, licensure, or other form of demonstrated knowledge in the specific field of radiation oncology. We reiterate that the proposed site visits were intended to ensure compliance with the Innovation Center model terms, to facilitate the model evaluation, and to investigate concerns related to the health or safety of beneficiaries or other patients or other program integrity issues.

There are a variety of reasons for us to conduct site visits. While having a certain amount of knowledge of the field of radiation oncology may be necessary to conduct some site visits of RO participants, depending on the nature and purpose of the site visit, knowledge of the RO Model terms as well as general Medicare policies and procedures may be more important. As such, we are not accepting the commenters' suggestion to require the personnel and contractors

conducting site visits to provide RO participants with certification, licensure, or other form of demonstrated knowledge in the specific field of radiation oncology.

After considering public comments, we are finalizing our proposals on monitoring and compliance in our regulation at § 512.150 with modification. Specifically, to align the regulatory text with the proposals discussed in the preamble to the proposed rule, we have modified the regulatory text at § 512.150(b)(1) to reference additional purposes for which CMS may conduct monitoring activities, namely to understand model participants' use of model-specific payments; and to promote the safety of beneficiaries and the integrity of the Innovation Center model. In addition, in response to public comment, we have modified paragraph (d) of §512.150 to codify the reopening process. Specifically, paragraph (d) has been revised to state the following: (1) CMS may reopen a model-specific payment determination, either on its own motion or at the request of a model participant, within four years from the date of the determination for good cause (as defined at § 405.986); (2) CMS may reopen a model-specific payment determination at any time if there exists reliable evidence (as defined in § 405.902) that the determination was procured by fraud or similar fault (as defined in § 405.902); and (3) CMS's decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal. Finally, we have revised paragraph (e) for brevity, which now states that this final rule does not limit or restrict the authority of the OIG or any other Federal government authority to audit, evaluate, investigate, or inspect model participants or their downstream participants for violations of "Federal statutes, rules, or regulations."

I. Remedial Action

As stated in the proposed rule and earlier in this final rule, as part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section

1115A of the Act, we have a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, we monitor for compliance with model terms as well as other Medicare program rules. When we become aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant.

As we noted in the proposed rule, the terms of many models currently being tested by the Innovation Center permit CMS to impose one or more administrative remedial actions to address noncompliance by a model participant. We proposed that CMS would impose any of the remedial actions set forth in proposed § 512.160(b) if we determine that the model participant or a downstream participant--

- Has failed to comply with any of the terms of the Innovation Center model, including proposed subpart A of proposed part 512;
- Has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- Has taken any action that threatens the health or safety of a beneficiary or other patient;
- Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Innovation Center model;
- Has undergone a change in control (as defined in section II.L. of this final rule) that presents a program integrity risk;
- Is subject to any sanctions of an accrediting organization or a Federal, state, or local government agency;
- Is subject to investigation or action by HHS (including the HHS-OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being

subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal government has intervened, or similar action; or

- Has failed to demonstrate improved performance following any remedial action imposed by CMS.

In § 512.160(b), we proposed to codify that CMS may take one or more of the following remedial actions if CMS determined that one or more of the grounds for remedial action described in § 512.160(a) had taken place--

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

• Such other action as may be permitted under the terms of proposed part 512.

As stated in the proposed rule, we noted that because the ETC Model is a mandatory model, we would not expect to use the provision that would allow CMS to terminate an ETC Participant's participation in the ETC Model, except in circumstances in which the ETC Participant has engaged, or is engaged in, egregious actions. We would note that we did not propose and are therefore not finalizing a provision authorizing CMS to terminate RO participants from the RO Model. The types of providers and suppliers selected for participation in the RO Model do not present the same risk of fraud and abuse that has historically been present in the dialysis industry, which includes ESRD facilities, one of the two types of participants in the ETC Model. We plan to monitor the RO Model for program integrity and fraud and abuse issues, and if necessary, we may add a termination provision for RO participants in future rulemaking.

We solicited public comment on these proposals regarding remedial action. We received no comments on these proposals and therefore are finalizing these proposals our regulation at § 512.160.

J. Innovation Center Model Termination by CMS

In the proposed rule, we proposed certain provisions that would allow CMS to terminate an Innovation Center model under certain circumstances. Section 1115A(b)(3)(B) of the Act requires the Innovation Center to terminate or modify the design and implementation of a model, after testing has begun and before completion of the testing, unless the Secretary determines, and the Chief Actuary certifies with respect to program spending, that the model is expected to: improve the quality of care without increasing program spending; reduce program spending without reducing the quality of care; or improve the quality of care and reduce spending.

In § 512.165(a), we proposed that CMS could terminate an Innovation Center model for reasons including, but not limited to, the following circumstances:

- CMS determines that it no longer has the funds to support the Innovation Center model; or
- CMS terminates the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act.

As provided by section 1115A(d)(2)(E) of the Act and proposed § 512.170, we noted in the proposed rule that termination of the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

To ensure model participants had appropriate notice in the case of the termination of the Innovation Center model by CMS, we also proposed to codify at § 512.165(b) that we would provide model participants with written notice of the model termination, which would specify the grounds for termination as well as the effective date of the termination.

We solicited public comment on these proposals regarding the termination of an Innovation Center model by CMS. We received no comments on these proposals; and therefore, are finalizing these proposals without modification in our regulation at § 512.165.

K. Limitations on Review

In § 512.170, we proposed to codify the preclusion of administrative and judicial review under section 1115A(d)(2) of the Act.

Section 1115A(d)(2) of the Act states that there is no administrative or judicial review under section 1869 or 1878 of the Act or otherwise for any of the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites, or participants to test models selected.

• The elements, parameters, scope, and duration of such models for testing or dissemination.

• Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.

• The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.

• Determinations about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such section.

We proposed to interpret the preclusion from administrative and judicial review regarding the Innovation Center's selection of organizations, sites, or participants to test models selected to preclude from administrative and judicial review our selection of a model participant, as well as our decision to terminate a model participant, as these determinations are part of our selection of participants for Innovation Center model tests.

In addition, we proposed to interpret the preclusion from administrative and judicial review regarding the elements, parameters, scope, and duration of models for testing or dissemination, to preclude from administrative and judicial review the following CMS determinations made in connection with an Innovation Center model:

• The selection of quality performance standards for the Innovation Center model by CMS.

• The assessment by CMS of the quality of care furnished by the model participant.

• The attribution of model beneficiaries to the model participant by CMS, if applicable.

We solicited comments on these proposals regarding limitations on review. In this section of this final rule, we summarize and respond to the public comments received on these proposals.

Comment: A commenter suggested that model participants be afforded the opportunity to challenge any adverse assessments relating to that model participant's quality of care through administrative or judicial review.

Response: We reiterate that the limitations on administrative and judicial review established in section 1115A(d)(2) of the Act include a preclusion from review for the elements, parameters, scope, and duration of such models for testing or dissemination. We proposed to interpret this provision as precluding from review the assessment by CMS of the quality of care furnished by the model participant. However, after reviewing this language in light of the concern flagged by the commenter, we realize that our proposed regulatory text was confusing. Our intent was to interpret the preclusion in section 1115A(d)(2)(C) of the Act related to the elements, parameters, scope, and duration of a model to apply to the methodology used to assess the quality of care furnished by a model participant, as this is an element of the design of an Innovation Center model. We did not intend to preclude from review a determination regarding how that methodology is applied to a particular model participant. We are therefore modifying the text of § 512.170(c)(2) to refer to the methodology used by CMS to assess of the quality of care furnished by the model participant. For the same reason, we are modifying the text of § 512.170(c)(3) to similarly refer to the methodology used by CMS to attribute model beneficiaries to the model participant, if applicable. We believe it is appropriate to codify the statutory limitations on judicial and administrative review in our regulations and that our interpretations thereof, with these clarifications, are consistent with the statute. We also agree

with the commenter's assertion that model participants should be allowed to challenge adverse assessments that are not precluded, and have laid out a policy specifically allowing this for the RO Model (section III.C.12. of this final rule) and the ETC Model (section IV.C.5.h. of this final rule).

After considering public comments, we are finalizing our proposals on limitations on review in our regulation at § 512.170 with the modifications described previously in this final rule.

L. Miscellaneous Provisions on Bankruptcy and Other Notifications

Models currently being tested by the Innovation Center usually have a defined period of performance, but final payment under the model may occur long after the end of this performance period. In some cases, a model participant may owe money to CMS. As we noted in the proposed rule, we recognize that the legal entity that is the model participant may experience significant organizational or financial changes during and even after the period of performance for an Innovation Center model. To protect the integrity of the Innovation Center models and Medicare funds, we proposed a number of provisions to ensure that CMS is made aware of events that could affect a model participant's ability to perform its obligations under the Innovation Center model, including the payment of any monies owed to CMS.

First, in § 512.180(a), we proposed that a model participant must promptly notify CMS and the local U.S. Attorney Office if it files a bankruptcy petition, whether voluntary or involuntary. Because final payment may not take place until after the model participant ceases active participation in the Innovation Center model or any other model in which the model participant is participating or has participated (for example, because the period of performance for the model ends, or the model participant is no longer eligible to participate in the model), we

further proposed that this requirement would apply until final payment has been made by either CMS or such model participant under the terms of each model in which the model participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

Specifically, we proposed that the notice of the bankruptcy must be sent by certified mail within 5 days after the bankruptcy petition has been filed and that the notice must contain a copy of the filed bankruptcy petition (including its docket number) and a list of all models tested under section 1115A of the Act in which the model participant is participating or has participated. To minimize the burden on model participants, while ensuring that CMS obtains the information necessary from model participants undergoing bankruptcy, we proposed that the list need not identify a model in which the model participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the model participant and CMS have been fully and finally resolved with respect to that model. We proposed that the notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3-01-24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified for purposes of receiving such notices on the CMS website.

As we noted in the proposed rule, by requiring the submission of the filed bankruptcy petition, CMS would obtain information necessary to protect its interests, including the date on which the bankruptcy petition was filed and the identity of the court in which the bankruptcy petition was filed. We recognize that such notices may already be required by existing law, but CMS often does not receive them in a timely fashion, and they may not specifically identify the models in which the individual or entity is participating or has participated. The failure to

receive such notices on a timely basis can prevent CMS from asserting a claim in the bankruptcy case. We are particularly concerned that a model participant may not furnish notice of bankruptcy after it has completed its performance in a model, but before final payment has been made or administrative or judicial proceedings have been resolved. As we noted in the proposed rule, we believe our proposal is necessary to protect the financial integrity of the Innovation Center models and the Medicare Trust Funds. Because bankruptcies filed by individuals and entities that owe CMS money are generally handled by CMS regional offices, we stated that we were considering (and we solicited comment on) whether we should require model participants to furnish notice of bankruptcy to the local CMS regional office instead of, or in addition to, the Baltimore headquarters.

Second, in § 512.180(b), we proposed that the model participant, including model participants that are individuals, would have to provide written notice to CMS at least 60 days before any change in the model participant's legal name became effective. The notice of legal name change would have to be in a form and manner specified by CMS and include a copy of the legal document effecting the name change, which would have to be authenticated by the appropriate state official. As we stated in the proposed rule, the purpose of this notice requirement is to ensure the accuracy of our records regarding the identity of model participants and the entities to whom model-specific payments should be made or against whom payments should be demanded or recouped. We solicited comment on the typical procedure for effectuating a legal entity's name change and whether 60 days advance notice of such a change is feasible. Alternatively, we considered requiring notice to be furnished promptly (for example, within 30 days) after a change in legal name has become effective. We solicited public comment on this alternative approach.

Third, in § 512.180(c), we proposed that the model participant would have to provide written notice to CMS at least 90 days before the effective date of any change in control. We proposed that the written notification must be furnished in a form and manner specified by CMS. For purposes of this notice obligation, we proposed that a "change in control" would mean any of the following: (1) the acquisition by any "person" (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the model participant by any individual or entity; (3) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant; or (4) the approval and completion of a plan of liquidation of the model participant, or an agreement for the sale or liquidation of the model participant. We noted in the proposed rule that the proposed requirement and definition of change in control are the same requirements and definition used in certain models that are currently being tested under section 1115A authority. We further noted that we believe this notice requirement is necessary to ensure the accuracy of our records regarding the identity of model participants and to ensure that we pay and seek payment from the correct entity. For this reason, we proposed that if CMS determined in accordance with § 512.160(a)(5) that a model participant's change in control would present a program integrity risk, CMS could take remedial action against the model participant under § 512.160(b). In addition, to ensure payment of

amounts owed to CMS, we proposed that CMS may require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

We solicited comments on these proposals. Also, we solicited comment as to whether the requirement to provide notice regarding changes in legal name and changes in control are necessary, or are already covered by existing reporting requirements for Medicare-enrolled providers and suppliers. In this section of this final rule, we summarize and respond to the public comments received on the proposal to require model participants to notify CMS of a change in legal name.

Comment: A few commenters generally supported the proposed procedure for notifying CMS of a name change. However, the commenters noted that they would prefer that the model participant be required to notify CMS 30 days after a legal name change, instead of 60 days before, as they believe that would reduce the administrative burden of complying with the proposed requirement for model participants.

Response: We solicited comment on whether to require the model participant to provide CMS with written notice 30 days after a legal name change. We agree with the commenters' assertion that notifying CMS of a legal name change 30 days after the name change occurs would be less burdensome for model participants. We further believe that written notice received within 30 days after the name change occurs would provide CMS with sufficient notice to ensure the accuracy of our records.

We did not receive comments regarding our proposals to require the model participant to notify CMS regarding bankruptcy or a change in control. After considering public comments, we are finalizing our proposals on bankruptcy and other notifications in our regulation at § 512.180, with modification to § 512.180(b) to change the timeline under which a model

participant must provide written notice to CMS regarding a legal name change from 60 days in advance of a legal name change to 30 days after the legal name change occurs. We have also made a non-substantive modification to our regulation text at § 512.110 to correct a drafting error in the final rule that removes the duplicative text from the definition of change in control.

## III. Radiation Oncology Model

### A. Introduction

As discussed in the proposed rule (84 FR 34478), we proposed to establish a mandatory Radiation Oncology Model (RO Model), referred to throughout section III. of this final rule as "the Model", to test whether prospective episode-based payments for radiotherapy (RT) services,[4] (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. As radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions, as we stated in the proposed rule, we believe that radiation oncology is well-suited for testing a prospective episode payment model. Under the RO Model proposals, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. We proposed that the base payment amounts for RT services included in the Model would be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. We proposed that the performance period for the RO Model would be 5 performance years (PYs), beginning in 2020, and ending December 31, 2024, with final data submission of clinical data elements and quality measures in 2025 to account for episodes ending in 2024 (84 FR 34493 through 34503).

We included the following proposals for the Model in the proposed rule: (1) the scope of the Model, including required participants and episodes under the Model test; (2) the pricing

[4] *Radiotherapy (RT) services* (also referred to as radiation therapy services) are services associated with cancer treatment that use high doses of radiation to kill cancer cells and shrink tumors, and encompass treatment consultation, treatment planning, technical preparation and special services (simulation), treatment delivery, and treatment management.

methodology under the Model and necessary Medicare program policy waivers to implement such methodology; (3) the quality measures selected for the Model for purposes of scoring a participant's quality performance; (4) the process for payment reconciliation; and (5) data collection and sharing. We solicited comments on these proposals.

B. Background

1. Overview

CMS is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs. Accordingly, as part of that effort, we have in recent years undertaken a number of initiatives to improve cancer treatment, most notably with our Oncology Care Model (OCM). As we stated in the proposed rule (84 FR 34490), we believe that a model in radiation oncology will further these efforts to improve cancer care for Medicare beneficiaries and reduce Medicare expenditures.

RT is a common treatment for nearly two thirds of all patients undergoing cancer treatment[5, 6] and is typically furnished by a radiation oncologist. As we discussed in the proposed rule (84 FR 34490), we analyzed Medicare FFS claims between January 1, 2015, and December 31, 2017, to examine several aspects (including but not limited to modalities, number of fractions, length of episodes, Medicare payments and sites of service, as described in this section) of radiation services furnished to Medicare beneficiaries during that period. We used HOPD and Medicare Physician Fee Schedule (PFS) claims, accessed through CMS' Chronic Conditions Data Warehouse (CCW), to identify all FFS beneficiaries who received any radiation treatment delivery services within that 3-year period. These radiation treatment delivery services

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

[6] 2012/13 Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

included various types of modalities.[7] Such modalities included external beam radiotherapy (such as 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. As discussed in the proposed rule (84 FR 34490), we conducted several analyses of radiation treatment patterns using that group of beneficiaries and their associated Medicare Part A and Medicare Part B claims.

Our analysis, as discussed in the proposed rule (84 FR 34490), showed that from January 1, 2015 through December 31, 2017, HOPDs furnished 64 percent of episodes nationally, while freestanding radiation therapy centers furnished the remaining 36 percent of episodes. In the proposed rule we stated that our intention was to make this data publically accessible in a summary-level, de-identified file titled the "RO Episode File (2015-2017)," on the RO Model's website, and we posted it for commenters' reference in conjunction with the publication of the proposed rule. In the proposed rule (84 FR 34490), we discussed that our analysis also showed that, on average, freestanding radiation therapy centers furnished (and billed for) a higher volume of RT services within such episodes than did HOPDs. Based on our analysis of Medicare FFS claims data from that time period, episodes of care in which RT was furnished at a freestanding radiation therapy center were, on average, paid approximately $1,800 (or 11 percent) more by Medicare than those episodes of care where RT was furnished at an HOPD. As we stated in the proposed rule (84 FR 34490), we are not aware of any clinical rationale that explains these differences, which persisted after controlling for diagnosis, patient case mix (to

[7] Modality refers to various types of radiotherapy, which are commonly classified by the type of radiation particles used to deliver treatment.

the extent possible using data available in claims), geography, and other factors. These differences also persisted even though Medicare payments are lower per unit in freestanding radiation therapy centers than in HOPDs. Upon further analysis, as we noted in the proposed rule (84 FR 34490), we observed that freestanding radiation therapy centers use more IMRT, a type of RT associated with higher Medicare payments, and perform more fractions (that is, more RT treatments) than HOPDs.

2. Site-Neutral Payments

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 component of the services are paid under the PFS. As we discussed in the proposed rule (84 FR 34490 through 34491), differences in the underlying rate-setting methodologies used in the OPPS and PFS to establish payment for RT services in the HOPD and in the freestanding radiation therapy centers respectively help to explain why the payment rate for the same RT service could be different depending on the setting in which it is furnished. This difference in payment rate, which is commonly referred to as the site-of-service payment differential, may incentivize Medicare providers and suppliers to deliver RT services in one setting over another, even though the actual treatment and care received by Medicare beneficiaries for a given modality is the same in both settings. We proposed to test a site-neutral payment in the RO Model rather than implementing a payment adjustment in the OPPS or PFS because--

● The Secretary of Health and Human Services has limited authority to adjust payments only within established payment methodologies such as under section 1848 of the Act governing the PFS;

● The Practice Expense (PE) component of the PFS is determined based on resource inputs (labor, equipment, and supplies) and input price estimates from entities paid under the PFS only, which means the PE calculation does not consider HOPD cost data that the RO Model proposed to use as the basis for national base rates;

● Further, the PE methodology itself calculates a PE amount for each service relative to all of the other services paid under the PFS in a budget neutral manner and consistent with estimates of appropriate division of PFS payments between PE, physician work, and malpractice resource costs; and

● Under the PFS and OPPS, the same payment rate applies for a service, irrespective of the diagnosis, whereas the proposed rule for the RO Model would establish different payments by cancer type.

● Neither the PFS nor OPPS payment systems would allow flexibility in testing new and comparable approaches to value-based payment outside of statutory quality reporting programs.

As we stated in the proposed rule (84 FR 34490 through 34491), we believe a site-neutral payment policy will address the site-of-service payment differential that exists under the OPPS and PFS by establishing a common payment amount to pay for the same services regardless of where they are furnished. In addition, we stated our belief that site-neutral payments would offer RT providers and RT suppliers more certainty regarding the pricing of RT services and remove incentives that promote the provision of RT services at one site of service over another. The RO Model is designed to test these assumptions regarding site-neutrality.

3. Aligning Payments to Quality and Value, Rather than Volume

As discussed in the proposed rule (84 FR 34491), for some cancer types, stages, and characteristics, a shorter course of RT treatment with more radiation per fraction may be appropriate. For example, several randomized controlled trials have shown that shorter treatment schedules for low-risk breast cancer yield similar cancer control and cosmetic outcomes as longer treatment schedules.[8,9,10,11] As another example, research has shown that radiation oncologists may split treatment for bone metastases into 5 to 10 fractions, even though research indicates that one fraction is often sufficient.[12,13,14,15] In addition, recent clinical trials have demonstrated that, for some patients in clinical trials with low- and intermediate-risk prostate

[8] Whelan, T.J. et al. Long-term Results of Hypofractionated Radiation Therapy for Breast Cancer. N. Engl. J. Med. 2010 Feb. 11; 362(6):513-20. https://www.ncbi.nlm.nih.gov/pubmed/20147717.

[9] Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial A of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. Lancet Oncol. 2008 Apr.; 9(4):331-41. https://www.ncbi.nlm.nih.gov/pubmed/18356109.

[10] Bentzen, S.M. et al. The UK Standardisation of Breast Radiotherapy (START) Trial B of Radiotherapy Hypofractionation for Treatment of Early Breast Cancer: A Randomised Trial. Lancet Oncol. 2008 Mar. 29; 371(9618): 1098-107. https://www.ncbi.nlm.nih.gov/pubmed/18355913.

[11] Haviland, J.S. et al. The UK Standardisation of Breast Radiotherapy (START) Trials of Radiotherapy Hypofractionation for Treatment Of Early Breast Cancer: 10-Year Follow-Up Results of Two Randomised Controlled Trials. Lancet Oncol. 2013 Oct.; 14(11): 1086-94. https://www.ncbi.nlm.nih.gov/pubmed/24055415.

[12] Sze, W.M. et al. Palliation of Metastatic Bone Pain: Single Fraction Versus Multifraction Radiotherapy – A Systematic Review of The Randomised Trials. Cochrane Database Syst. Rev. 2004; (2):CD004721. https://www.ncbi.nlm.nih.gov/pubmed/15106258.

[13] Chow, E. et al. Update on the Systematic Review of Palliative Radiotherapy Trials for Bone Metastases. Clin. Oncol. (R. Coll. Radiol.). 2012 Mar;24 (2):112-24. https://www.ncbi.nlm.nih.gov/pubmed/22130630.

[14] Chow, Ronald et al. Efficacy of Multiple Fraction Conventional Radiation Therapy for Painful Uncomplicated Bone Metastases: A Systematic Review. Radiotherapy & Oncology: March 2017 Volume 122, Issue 3, Pages 323-331. http://www.thegreenjournal.com/article/S0167-8140(16)34483-8/abstract.

[15] Lutz, Stephen et al. Palliative Radiation Therapy for Bone Metastases: Update of an ASTRO Evidence-Based Guideline. Practical Radiation Oncology (2017) 7, 4-12. http://www.practicalradonc.org/article/S1879-8500(16)30122-9/pdf.

cancer, courses of RT lasting 4 to 6 weeks lead to similar cancer control and toxicity as longer courses of RT lasting 7 to 8 weeks.[16,17]

Based on our review of claims data, we discussed our belief that the current Medicare FFS payment systems may incentivize selection of a treatment plan with a high volume of services over another medically appropriate treatment plan that requires fewer services. Each time a patient requires radiation, providers and suppliers can bill for RT services and an array of necessary planning services to make the treatment successful.[18] We discussed that this structure may incentivize providers and suppliers to furnish longer courses of RT because they are paid more for furnishing more services. Importantly, however, the latest clinical evidence suggests that shorter courses of RT for certain types of cancer would be equally effective and could improve the patient experience, potentially reduce cost for the Medicare program, and lead to reductions in beneficiary cost-sharing.

As discussed in the proposed rule (84 FR 34491), there is also some indication that the latest evidence-based guidelines are not incorporated into practices' treatment protocols in a timely manner.[19] For example, while breast cancer guidelines have since 2008 recommended that radiation oncologists use shorter courses of treatment for lower-risk breast cancer (3 weeks versus 5 weeks), an analysis found that, as of 2017, only half of commercially insured patients actually received the shorter course of treatment.[20]

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[16] D. Dearnaley, I. Syndikus, H. Mossop, et al. Conventional versus hypofractionated high-dose intensity-modulated radiotherapy for prostate cancer: 5-year outcomes of the randomised, non-inferiority, phase 3 CHHiP trial. Lancet Oncol, 17 (2016), pp. 1047-1060 http://www.sciencedirect.com/science/article/pii/S1470204516301024.

[17] W.R. Lee, J.J. Dignam, M.B. Amin, et al. Randomized phase III noninferiority study comparing two radiotherapy fractionation schedules in patients with low-risk prostate cancer. J Clin Oncol, 34 (2016), pp. 2325-2332 http://ascopubs.org/doi/full/10.1200/JCO.2016.67.0448.

[18] These planning and technical preparation services include dose planning, treatment aids, CT simulations, and other services.

[19] http://www.npr.org/sections/health-shots/2017/10/21/558837836/many-breast-cancer-patients-receive-more-radiation-therapy-than-needed.

[20]https://www.practicalradonc.org/cms/10.1016/j.prro.2018.01.012/attachment/775de137-63cb-4c5d-a7f9-95556340d0f6/mmc1.pdf.

4. CMS Coding and Payment Challenges

In the proposed rule (84 FR 34491 through 34492) we identified several coding and payment challenges for RT services. Under the PFS, payment is set for each service using resource-based relative value units (RVUs). The RVUs have three components: clinician work (Work), practice expense (PE), and professional liability or malpractice insurance expense (MP). In setting the PE RVUs for services, we rely heavily on voluntary submission of pricing information for supplies and equipment, and we have limited means to validate the accuracy of the submitted information. As a result, it is difficult to establish the cost of expensive capital equipment, such as a linear accelerator, in order to determine PE RVUs for physicians' services that use such equipment.[21]

Further, as we discussed in the proposed rule (84 FR 34492), we examined RT services and their corresponding codes under our potentially misvalued codes initiative based on their high volume and increasing use of new technologies. Specifically, we reviewed codes for RT services for Calendar Years (CYs) 2009, 2012, 2013, and 2015 as potentially misvalued services. In general, when a code is identified as potentially misvalued, we use notice and comment rulemaking to propose and finalize the code as misvalued, and then review the Work and PE RVU inputs for the code. As a result of the review, we may engage in further rulemaking to adjust the Work or PE inputs either upward or downward. The criteria for identifying potentially misvalued codes are set forth in section 1848(c)(2)(K)(ii) of the Act.

As described in the proposed rule (84 FR 34492), through annual rulemaking for the PFS, we review and adjust values for potentially misvalued services, and also establish values for new and revised codes. We establish Work and PE RVU inputs for new, revised, and potentially

[21] CY 2014 PFS final rule with comment period (78 FR 43296, 43286 through 43289, and 43302 through 43311).

misvalued codes based on a review of information that generally includes, but is not limited to, recommendations received from the American Medical Association's RVS Update Committee (AMA/RUC), Health Care Professional Advisory Committee (HCPAC), Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; a comparison of the work for other codes within the PFS; and consultation with other physicians and health care professionals within CMS and other federal government agencies. We also consider the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations.

Through the annual rulemaking process previously described, we have reviewed and finalized payment rates for several RT codes over the past few years. The American Medical Association identified radiation treatment codes for review because of site of service anomalies. We first identified these codes as potentially misvalued services during CY 2012 under a screen called "Services with Stand-Alone PE Procedure Time." We observed significant discrepancies between the 60-minute procedure time assumptions for IMRT and public information which suggested that the procedure typically took between 5 and 30 minutes. In CY 2015, the American Medical Association CPT® Editorial Panel revised the entire code set that describes RT delivery. CMS proposed values for these services in the CY 2016 proposed rule but, due to challenges in revaluing the new code set, finalized the use of G-codes that we established to largely mirror the previous radiation treatment coding structure.[22] The Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114-115), enacted on December 28, 2015, addressed

[22] *See generally*, CY 2015 PFS final rule with comment period (79 FR 67547); CY 2016 PFS final rule with comment period (80 FR 70885); and CY 2016 PFS correcting amendment (81 FR 12024).

payment for certain RT delivery and related imaging services under the PFS, 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. (The PAMPA and BBA of 2018 are discussed in detail in this rule).

Despite the previously discussed challenges related to information used to establish payment rates for RT services, the proposed rule (84 FR 34492) noted that we have systematically attempted to improve the accuracy of payment for these codes under the PFS. While the potentially misvalued code review process is essential to the PFS, some stakeholders have expressed concern that changes in Work and PE RVUs have led to fluctuations in payment rates. Occasionally, changes in PE RVUs for one or more CPT® codes occur outside of the misvalued code review cycle if there are updates to the equipment and supply pricing. Any changes to CPT® code valuations, including supply and equipment pricing changes, are subject to public comment and review.

The proposed rule further explained that although the same code sets generally are used for purposes of the PFS and OPPS, there are differences between the codes used to describe RT services under the PFS and the OPPS, and those in commercial use more broadly (84 FR 34492). We continue to use some CMS-specific coding, or HCPCS codes, in billing and payment for RT services under the PFS, while we generally use CPT® codes under the OPPS. As a result of coding and other differences, these payment systems utilize different payment rates and reporting rules for the same services, which contribute to site-of-service payment differentials. These differences in payment systems can create confusion for RT providers and RT suppliers, particularly when they furnish services in both freestanding radiation therapy centers and HOPDs.

Finally, as noted in the proposed rule (84 FR 34492), there are coding and payment challenges specific to freestanding radiation therapy centers. Through the annual PFS rulemaking process, we receive comments from stakeholders representing freestanding radiation therapy centers and physicians who furnish services in freestanding radiation therapy centers. In recent years, these stakeholder comments have noted the differences and complexity in payment rates and policies for RT services between the PFS and OPPS; expressing particular concerns about differences in payment for RT services furnished in freestanding radiation therapy centers and HOPDs despite the fact that the fixed, capital costs associated with linear accelerators that are used to furnish these services do not differ across settings; and raising certain perceived deficiencies in the PFS rate-setting methodology as it applies to RT services delivered in freestanding radiation therapy centers.[23] It is also important to note that even if we were able to obtain better pricing information for inputs, PFS rates are developed to maintain relativity among other PFS office-based services, and generally without consideration of OPPS payment rates.

As previously noted, the PAMPA addressed payment for certain RT delivery and related imaging services under the PFS. Specifically, section 3 of the PAMPA directed CMS to maintain the 2016 code definitions, Work RVU inputs, and PE RVU inputs for 2017 and 2018 for certain RT delivery and related imaging services; prohibited those codes from being considered as potentially misvalued codes for 2017 and 2018; and directed 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. Section 51009 of the BBA of 2018 extended these payment policies through 2019. In November 2017,

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[23] *See generally*, CY 2018 PFS final rule with comment period, 82 FR 52976; CY 2015 PFS final rule with comment period, 79 FR 67547; CY 2014 PFS final rule with comment period, 78 FR 43296.

we submitted the Report to Congress as required by section 3(b) of the PAMPA.[24] In the report, we discussed the current status of RT services and payment, and reviewed model design considerations for a potential APM for RT services.

In the proposed rule (84 FR 34493), we described how the Innovation Center, in preparing the Report to Congress, conducted an environmental scan of current evidence and held a public listening session followed by an opportunity for RT stakeholders to submit written comments about a potential APM. A review of the applicable evidence cited in the Report to Congress demonstrated that episode payment models can be a tool for improving quality of care and reducing expenditures. Episode payment models pay a fixed price based on the expected costs to deliver a bundle of services for a clinically defined episode of care. In the proposed rule, we stated our belief that radiation oncology is a promising area of health care for episode payments, in part, based on the findings in the Report to Congress. While the report discusses several options for an APM, in the proposed rule, we proposed what the Innovation Center has determined to be the best design for testing an episodic APM for RT services.

The following is a summary of comments we received on the proposed goals of the RO Model and the issues addressed in section III.B. of the proposed rule and our responses to these comments:

Comment: Many commenters supported most aspects of the proposed RO Model and expressed commitment to fully participating in a value-based care model. A commenter recommended that CMS finalize the RO Model as mandatory, site-neutral, and inclusive of all proposed modalities. Several commenters expressed their support and encouraged CMS to have

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[24] United States Department of Health and Human Services Report to Congress: *Episodic Alternative Payment Model for Radiation Therapy Services*. (Nov. 2019). https://innovation.cms.gov/resources/radiationapm-pubforum.html

value-based programs that allow health care providers, through shared decision-making with their patients, to determine appropriate and convenient delivery options. A few commenters noted appreciation for CMS' commitment to providing participants with stable rates. Some commenters expressed support for clinical episode-related payments and the removal of payment on a per fraction basis. A few of these commenters also expressed their support of the transition to value-based care solutions.

Response: We thank these commenters for their support of our efforts to move forward with the RO Model. We are finalizing the RO Model as mandatory (see section III.C.3.a. of this final rule) with the modification of a low volume opt-out (see section III.C.3.c. of this final rule), site-neutral (see section III.C.6.c. of this final rule), and inclusive of all proposed modalities except for IORT (see section III.C.5.d. of this final rule).

Comment: A commenter expressed concern that CMS has not provided enough evidence to indicate that RT services for cancer are over utilized and to support the application of a standard set of RT services for cancer patients through a bundled payment program.

Response: We understand this commenter's concerns. However, we disagree with this commenter. We have performed extensive research, and we have received numerous stakeholders' requests to create an alternative payment model in the radiotherapy space. For more information on our research and rationale, please see sections III.B.3. and III.B.4. of this final rule, and 84 FR 34491 through 34493 of the proposed rule.

Comment: A commenter suggested that CMS allow RT providers and RT suppliers to select appropriate radiation modalities based on nationally recognized clinical guidelines to ensure that beneficiaries receive evidence-based care.

Response: The Model encourages the use of nationally recognized, evidence-based clinical treatment guidelines. We will monitor the use of guidelines during the Model.

Comment: A commenter requested that CMS take on more risk sharing, reduce the savings targets, reimburse administrative costs of participation, and have absolute scoring and setting or thresholds for payment linked to quality measures.

Response: We have addressed these comments throughout the applicable sections of this final rule, including in, but not limited to, sections III.C.6., C.6.f, and C.8. of this final rule.

Comment: A commenter expressed concern for overall payment stability because disruptions to payment may have unintended consequences such as the closure of radiotherapy centers which could result in a loss of access to care for Medicare beneficiaries.

Response: One of the objectives of this Model is to provide site-neutral, more predictable payments to RO participants. We believe that the payment methodology as finalized in section III.C.6. of this final rule accomplishes this goal of providing more predictable or foreseeable payments to RO participants. We further believe that having more predictable payments may mitigate closures of viable radiotherapy centers. Additionally, we will be monitoring for beneficiary access issues throughout the Model (see section III.C.14).

Comment: A few commenters raised concerns that the lack of telehealth discussion in this Model meant that such connected health technologies would not have a role in the RO Model. A commenter requested that CMS utilize every opportunity to remove barriers to the use of advanced technologies within a connected healthcare system.

Response: Although several Innovation Center models and programs include the use of telehealth services, at this time, there are no permanent Medicare telehealth codes included in the list of included RT services in section III.C.5.c. We note that HCPCS Code 77427 has been

temporarily added to the list of Medicare telehealth codes for the public health emergency (PHE) for the COVID-19 pandemic. RT services can only be furnished via telehealth to the extent permitted under the Medicare telehealth coverage and payment rules. Participants can continue to furnish telehealth services in accordance with current coverage and payment guidelines. We are taking this comment into consideration for future rulemaking.

Comment: Some commenters expressed concerns with the episode-based payment concept and indicated that such programs may put patients' safety at risk (for example, increased radiation exposure to healthy tissues). One of these commenters requested that CMS prioritize total-cost-of-care models over other episode-based payment programs.

Response: We believe that the RO Model will best meet its objectives of delivering site-neutral payments for included radiation therapy modalities through episode-based payments rather than total-cost-of-care because radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions. We also believe that providers and suppliers will not compromise their patients' safety or deviate from the standard practice of care in an attempt to "game" the system. We believe that the monitoring and compliance requirements will mitigate gaming by RO participants. In addition, we believe that there are sufficient safeguards in place to prevent providers and suppliers from engaging in acts that will harm their patients, including but not limited to the requirements to actively participate with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback on treatment plans) (see section III.C.14).

Comment: Several commenters requested that the site neutral payment policy be abandoned. A few commenters stated that a site neutral payment approach assumes that care is

equivalent in all settings. A commenter argued that the site neutral policy ignores the higher cost of providing services in an HOPD setting as compared to the physician office setting of freestanding radiation therapy centers as HOPDs provide wraparound services, such as translators and other social services that are not otherwise billable, and face requirements set by regulators and accreditors to which physician offices are not subject.

Response: As we documented in the proposed rule and in the November 2017 Report to Congress (see section III.B.4 of the proposed rule at 84 FR 34491 through 34493 and this final rule for background on the November 2017 Report to Congress), differences in the underlying methodologies used in the OPPS and PFS for rate setting often result in differences in the payment rate for the same RT service depending on whether the service is furnished in a freestanding radiation therapy center paid under the PFS, or an HOPD paid under the OPPS. We refer to this as the site-of-service payment differential, and we believe that such differentials 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. Therefore, we are using HOPD payment rates to create the RO Model national base rates. For a detailed discussion of this Model's Pricing Methodology see section III.C.6 of this final rule.

Comment: A commenter stated that CMS does not have authority to implement site-neutral payments and is using section 1115A to adopt a policy preference that CMS otherwise could not adopt.

Response: We disagree with this commenter, and believe that we are operating within our authority. Section 1115A of the Social Security Act authorizes the Secretary to test innovative payment and service delivery models expected to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's

Health Insurance Program (CHIP) beneficiaries. Section 1115A(b) provides a non-exhaustive list of models to be tested. Under this authority, CMS has broad discretion to design its payment and service delivery models. For more discussion about CMS' statutory authority to conduct the RO Model under section 1115A of the Act, please reference section III.C.3.a of this final rule.

Comment: A few commenters requested that we abandon the proposal to have site-neutral payments because different sites of care have different operating costs.

Response: We believe that site-neutral payment is a necessary component of the RO Model test to avoid establishing an incentive for RO participants to deliver RT services in one setting over another, even though the actual treatment and care received by Medicare beneficiaries for a given modality is the same in both settings.

Comment: A commenter stated that the proposed RO Model's site-neutral payments do not go far enough and that these payments should be applied to all providers and suppliers, regardless of the Core-Based Statistical Areas (CBSAs) in which they furnish RT services. This commenter also does not believe that a 5-year test is necessary to conclude that payment rates for RT services under the OPPS and MPFS should be equalized.

Response: We agree that payment rates under the RO Model should be site-neutral, and are proceeding with the 5-year test of this Model, with CBSAs selected for participation to understand the impact of site-neutral payments on cost and quality of care. We believe that the Model performance period of 5 years, as opposed to a shorter duration, is necessary to obtain sufficient data to compute a reliable impact estimate and to analyze the data from the Model to determine next steps regarding potential expansion or extension of the Model. Further, we believe that a test period of 5 years is necessary to address and mitigate any potential

implementation issues or unintended consequences. For a discussion of the Model performance period, please see section III.C.1. of this final rule.

Comment: A commenter requested clarification on how the RO Model will impact the budget neutrality requirements under the OPPS and PFS.

Response: With respect to the budget neutrality requirements under the Medicare Physician Fee Schedule (PFS) and Outpatient Prospective Payment System (OPPS), absent any further adjustment, we would expect the RO Model to pull utilization out of the traditional fee-for-service payment systems. The Center for Medicare will monitor this issue through the duration of the Model test and account for utilization for services included in the RO Model under the PFS and OPPS as appropriate. In essence, we believe that this Model will, in time, reduce program expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

Comment: A couple of commenters opposed paying for radiotherapy services based on the proposed prospective payment approach in the RO Model, and instead suggested that payment continue to be made on a fee-for-service basis, with a reduction in the reimbursement for fractions that are beyond the average for a particular diagnosis.

Response: The commenters' suggested approach, as we understand it, would require ongoing adjustments to fee-for-service payments based on changing averages for a particular diagnosis. We believe that the proposed prospective episode-based payment tested under this Model would be preferable as this approach will test whether a modality agnostic, bundled payment will lead to more appropriate courses of radiation treatment for certain cancer types.

Comment: A commenter urged CMS to establish policies that encourage participants' investment in care transformation to achieve the agency's long-term goal of improving quality of care while reducing costs.

Response: We believe that this Model embraces our goal of improving quality of care while reducing costs (see section III.C.14 of this final rule for the Model's monitoring and compliance requirements). We also believe that this Model, as finalized, will encourage RO participants to transform their care.

Comment: A commenter voiced concern that participants with fewer resources would attempt high dose hypofractionation without adequate equipment and that the proposed rule did not have a mechanism in place to test the "fitness" of the hypofractionation equipment.

Response: At this time, we are unable to perform such a test as we do not believe that testing equipment falls within the Innovation Center's authority to test payment and service delivery models. However, we will be using Peer Review and patient surveys, among other monitoring measures (see section III.C.14 of this final rule), to assess whether RO participants are engaging in such egregious behaviors.

Comment: A few commenters discussed concerns with hypofractionation. These commenters generally noted that data supporting fractionation is limited across cancer types. A commenter used prostate cancer as an example, concluding that the RO Model might make hypofractionated treatment the only economically viable option for treating men with low- and intermediate-risk prostate cancer. This commenter believed such a move would be premature, as the benefits of hypofractionation for prostate cancer are unclear.

Another commenter highlighted that testing whether hypofractionation lowers costs and improves quality will require providers and suppliers to upgrade their technology to provide

lower and more precise fractions of RT. For this reason, the commenter recommended that CMS publish the science underlying its belief that hypofractionation would be appropriate for this range of cancer types.

A commenter shared specific recommendations and evidence for RT hypofractionation in breast cancer, prostate cancer, head and neck cancer, and Central Nervous System (CNS) cancers, as well as in bone and brain metastases.

A commenter emphasized that hypofractionated treatments may increase acute toxicity and that patients with pre-existing conditions like ulcerative colitis or collagen-vascular disorder are poor candidates for these types of hypofractionated treatments.

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

Comment: A commenter expressed concern with the high cost of treating patients in a rural treatment facility.

Response: We believe that the policies as finalized in this final rule will help to address this commenter's concerns. In particular, we refer readers to section III.C.3.c of this final rule for the optional opt-out for low-volume RO participants, as well as section III.C.3.d that describes how CBSAs exclude extreme rural geographic areas, and section III.C.3.c that discusses the exclusion of critical access hospitals.

Comment: A commenter expressed the desire to maintain current valuations for Radiation Therapy G-codes under the PFS (HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017), and requested that these valuations be stable throughout the Model.

Response: The purpose of the RO Model is to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures and preserve or enhance quality of care for beneficiaries. Additionally, the RO Model is designed to test a site-neutral and modality agnostic approach to payment for RT services. Therefore, we do not believe that continuing to make payment based on the current valuations for certain G-codes under the PFS aligns with the intent of this Model test. Please refer to section III.C.5.c of this final rule for a discussion of our included RT services as well as section III.C.6 for details regarding the specific RO Model codes that will be used during this Model and how their value will be calculated in each performance year.

C. RO Model Regulations

In the proposed rule at 84 FR 34493, we discussed our policies for the RO Model, including model-specific definitions and the general framework for implementing the RO Model. We defined "performance year" (PY) as the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period. We proposed to codify the term "performance year" at § 512.205 of our regulations.

In the proposed rule, we included our proposed policies for each of the following: (1) the scope of the RO Model, including the RO participants, beneficiary population, and episodes that would be included in the test; (2) the pricing methodology under the Model and the Medicare program policy waivers necessary to implement such methodology; (3) the measure selection for

the Model, including performance scoring methodology and applying quality to payment; (4) the process for payment reconciliation; and (5) data collection and sharing.

In the proposed rule, we discussed codifying RO Model policies at 42 CFR part 512, subpart B (§§ 512.200 through 512.290). In addition, as we explained in section II. of the proposed rule, the general provisions codified at §§ 512.100 through 512.180 would apply to the RO Model.

1. Model Performance Period

We proposed to test the RO Model for five PYs. We proposed to define "Model performance period" to mean January 1, 2020, the date the Model begins, through December 31, 2024, the last date during which episodes under the Model must be completed (84 FR 34493). Alternatively, we also considered delaying implementation to April 1, 2020 to give RO participants and CMS additional time to prepare. As we discussed, an April 2020 start date would only affect the length of PY1 which would be 9 months. All other PYs would be 12 months. For all episodes to be completed by December 31, 2024, we proposed that no new episodes may begin after October 3, 2024. We solicited public comments on the Model performance period and potential participants' ability to be ready to implement the RO Model by January 1, 2020. We also solicited comments on delaying the start of the Model performance period to April 1, 2020. The following is a summary of comments received on these proposals and our responses:

Comment: Many commenters provided feedback related to the Model's start date for the RO Model. Almost all of the commenters were opposed to the RO Model beginning on January 1, 2020. Some commenters recommended that CMS consider delaying the implementation of the Model until the alternatively proposed date of April 1, 2020, but many still believed that this date

would not allow sufficient time to prepare. Commenters believed the April 1, 2020 Model's start date fell short of providing adequate preparation time for RO participants and proposed alternative start dates of late spring or early summer of 2020; July 1, 2020; August 1, 2020; October 1, 2020; and January 1, 2021. Commenters recommended a delay from when the RO Model is finalized or when the CBSAs selected for participation are announced to when it would begin; a couple of commenters recommended a 6-month delay, some commenters requested a 9-month delay, and a few commenters recommended a 12-month delay.

Response: We appreciate these commenters' concerns. Regarding commenters' use of the term "implementation date," we understand commenters are referring to the beginning of the Model performance period. After reviewing these concerns, we agree with commenters that both the January 1, 2020 and April 1, 2020 start dates would not provide RO participants with sufficient time to operationalize the RO Model requirements. We intended to start the RO Model on July 1, 2020, but as we were completing this final rule, the United States began responding to an outbreak of respiratory disease, referred to as "Coronavirus disease 2019", which created a serious public health threat greatly impacting the U.S. health care system. The Secretary of the Department of Health and Human Services, Alex M. Azar II, declared a Public Health Emergency ("PHE") on January 31, 2020, retroactively effective from January 27, 2020, to aid the nation's healthcare community in responding to the Coronavirus disease 2019 pandemic. On July 23, 2020, Secretary Azar renewed, effective July 25, 2020, the determination that a PHE exists which he had previously renewed on April 21, 2020.

In light of this unprecedented PHE, which continues to strain health care resources, we are finalizing the RO Model's Model performance period to begin on January 1, 2021. We understand that RO participants may have limited capacity to meet the RO Model requirements

in 2020. To ensure that participation in the RO Model does not further strain RO participants' capacity, potentially hindering the delivery of safe and efficient health care to beneficiaries receiving RT services, we are finalizing the RO Model's Model performance period to begin on January 1, 2021.

We also believe that finalizing the Model performance period to begin January 1, 2021 will give RO participants sufficient time to learn and understand the RO billing requirements, train staff on new procedures, prepare to report on quality measures and clinical data elements, evaluate and adjust their budgets to prepare for the RO Model, and to allow EHR vendors to begin to develop mechanisms to comply with the Model.

Therefore, we are finalizing our proposed Model performance period at § 512.205, with the modification that the Model performance period begin on January 1, 2021, where each PY will consist of a 12-month period beginning on January 1 and ending on December 31. For all episodes to be completed by December 31, 2025, we are finalizing that no new RO episodes may begin after October 3, 2025. The 5-year performance period will run from January 1, 2021, through December 31, 2025.

Comment: One commenter recommended that CMS issue an Interim Final Rule with comment period, identify the selected RO Model participants in the Interim Final Rule, and ensure selected participants have at least six months of advanced notice before the RO Model begins.

Response: An interim final rule with comment period ("IFC") would be inappropriate for purposes of finalizing the RO Model, as the proposed rule for the RO Model was published July 18, 2019 (84 FR 34478). Further, we believe the selected RO participants will have sufficient time to prepare for a Model performance period that begins January 1, 2021. To ensure that RO

participants have sufficient preparation time, we are publishing this final rule more than 60 days prior to the beginning of the Model performance period.

Comment: Many commenters stated that RO participants would face considerable administrative burden, and would not have the appropriate time to plan for implementation until the final rule was issued – noting that 60 days or fewer would be insufficient. These commenters identified many reasons for requesting more time, including that EHR vendors would need ample time to design, develop, build, test, validate, and implement the software to allow RO participants to fulfill the requirements of the RO Model in a streamlined manner through their EHR platforms. Some of these commenters specified that it could take 12 to 18 months for EHR vendors to complete software development cycles. A few commenters pointed out that successful implementation of the RO Model would require many RO participants as well as software vendors to change EHR configurations, organizational policies, and end user workflows. A commenter stated that radiation oncology departments utilize specific electronic medical record and record-and-verification systems that are linked to their linear accelerators, and the vendors that support those information systems would not be prepared for implementation in January 2020. A commenter also stated that hospitals and other participants need time to plan for budget requests and approvals relating to equipment upgrades and IT support. A few commenters expressed concern that EHR vendors would need to develop and implement complicated changes to collect information on clinical data elements in a short period of time because CMS has yet to publish the Model-specific clinical data elements.

Response: We agree with commenters' concerns that EHR vendors will need more time to design, develop, build, test, validate, and implement the software to allow RO participants to fulfill the requirements of the RO Model in a streamlined manner through their EHR platforms.

We understand that successful implementation of the RO Model will require many RO participants as well as software vendors to change EHR configurations, organizational policies, and end user workflows. We also understand that some radiation oncology departments utilize specific electronic medical record and record-and-verification systems that are linked to their linear accelerators, and the vendors that support those information systems would not have been prepared for implementation in January 2020. We further understand that hospitals and other participants need time to plan for budget requests and approvals relating to equipment upgrades and IT support. Based on these concerns and the PHE, we are finalizing the Model performance period to begin on January 1, 2021. The Model requirements, including measure data collection and the use of certified EHR technology (CEHRT), will begin in PY1 (which begins on January 1, 2021). We believe that the period of time between publication of this final rule and the beginning of the Model performance period will provide EHR vendors with sufficient time to implement the software that RO participants may need to adhere to the RO Model requirements.

Comment: Many commenters stated that RO participants would need adequate time to prepare for the new reporting of quality measures and clinical data required by the RO Model. These commenters stated that they would need considerable time to develop and build a specific clinical infrastructure to meet the increased quality data collection and reporting requirements mandated by the RO Model. A commenter emphasized that such a delay would be particularly important for those RO participants treating Medicare beneficiaries with prostate, breast, or lung cancers as well as bone and brain metastases, given CMS' proposal to require those participants to collect and report clinical information not currently available in claims or captured in the proposed quality measures.

Response: We understand commenters' concerns that they will need considerable time to develop and build a specific clinical infrastructure to meet the increased quality data collection and reporting requirements mandated by the RO Model. We also understand that RO participants and Medicare contractors in the CBSAs selected for participation would need adequate time to prepare for the RO Model requirements, and to successfully modify operations. We believe that finalizing the Model performance period on January 1, 2021 provides sufficient time for selected RO participants to develop and build the necessary infrastructure to meet reporting requirements of the RO Model.

Comment: Many commenters requested that the RO Model be delayed so that RO participants and Medicare contractors in the CBSAs selected for participation would have adequate time to prepare for the RO Model requirements, and to successfully modify operations.

Response: We believe that finalizing the Model performance period to begin on January 1, 2021 will provide adequate time for RO participants to prepare for the RO Model and to modify their operations to meet the Model requirements. The Medicare Administrative Contractors in the CBSAs selected for participation will be prepared when the Model begins on January 1, 2021.

Comment: Many commenters requested more time to implement the RO Model, because RO participants would need adequate time to operationalize the RO Model's coding and billing requirements. Many commenters stated that they would need to hire additional staff, and to train and educate new and existing staff and clinicians on RO Model procedures, requirements, billing and other systems. A few commenters stated that they would need sufficient time to educate and engage clinical and operational staff about the RO billing practices and processes, and for these participants to learn and understand changes to coding, claims generation, claims processing,

participant-specific modifiers and adjustments, withhold calculations, and payment programming. A couple of commenters expressed concern about the administrative burden of learning a new billing system under the RO Model while simultaneously maintaining a separate billing system for privately insured patients. One of these commenters stated that the billing staff would be burdened with the need to identify which patients are in the Model and which are not in order to appropriately bill claims because the billing would differ significantly for each patient and insurer. Many commenters stated that RO participants would need more time to make budgetary accommodations to offset the perceived additional expenses related to participation in the RO Model and to re-evaluate practice budgets to accommodate for changes in cash flow as a result of participation in the Model.

Response: We believe that finalizing the Model performance period to begin on January 1, 2021 will provide RO participants with sufficient time to prepare to meet the billing and coding requirements, to re-evaluate practice budgets to accommodate for changes in the Model, to hire new staff and educate existing staff, and to address concerns regarding the administrative burden of learning a new billing system under the RO Model. The Model requirements, codified at § 512.220, will start on January 1, 2021.

For concerns regarding changes in billing and coding requirements, we believe that the finalized billing process that will be easily implemented within current systems because it is based on how FFS claims are currently submitted. Section III.C.7 of this final rule provides information on billing and coding changes under the RO Model. Additional guidance on billing and coding will be made available to RO participants before the beginning of the Model performance period through resources such as the Medicare Learning Network (MLN Matters) publications, Model-specific webinars, and/or the RO Model website.

Comment: A few commenters stated that they would need to operationalize the billing requirements of the RO Model in a shortened time frame, as they would not be notified of their selection until the publication of the final rule.

Response: We believe that finalizing the Model performance period to begin on January 1, 2021 will provide RO participants adequate time to operationalize the Model's billing requirements which are based on the current FFS claims systems.

Comment: A commenter stressed that it would take time to operationalize the beneficiary notification requirement.

Response: We will provide RO Model participants with a beneficiary notification letter template that RO participants may personalize with their contact information and logo. RO participants must provide this beneficiary notification letter to each beneficiary during the initial treatment planning session. We refer readers to section III.C.15 of this final rule for details regarding the beneficiary notification letter. We do not believe that the beneficiary notification letter, which will require minimal modification by the RO participant, will warrant significant additional time to operationalize.

Comment: A commenter requested additional time for participants to receive and review CMS data to better understand their current care processes and drive care transformation under the Model.

Response: We plan to allow RO participants, to the extent permitted by HIPAA and other applicable laws, to request claims data from CMS for purposes of care coordination and/or quality improvement work. Please see section III.C.13.d for more information. To request this data, RO participants will submit a Participant Data Request and Attestation (DRA) form, which will be available on the Radiation Oncology Administrative Portal (ROAP).

Comment: A few commenters suggested that CMS include a performance year 0 (PY0) for the RO Model. This PY0 could serve as a baseline measurement and preparation period that would allow RO participants to make practice transformations; change workflow; review, analyze, and act on data received from CMS; understand Model reporting requirements; and receive additional education from CMS on Model parameters and objectives. A couple of these commenters further suggested that RO participants could submit no-pay claims for the PY0 episodes while continuing their normal billing practices.

Response: We are finalizing the Model performance period that will include performance years (PYs) one through five (PY1-PY5), and it will not include a PY0. PY1 of the RO Model will begin on January 1, 2021. We believe that finalizing the Model performance period to begin on January 1, 2021 makes a PY0 unnecessary because RT providers and RT suppliers will have several months to prepare for the RO Model and its requirements.

Comment: A few commenters recommended reducing the number of performance years. A commenter requested that the duration of the Model be reduced to three years. This commenter stated that a reduction in both duration and number of episodes, coupled with voluntary participation, would provide sufficient information for CMS to assess the viability of the Model and to then scale the Model nationally if it had achieved its goals of improving care and reducing costs.

Response: We proposed that the performance period for the RO Model to be five performance years because at least five performance years are necessary to sufficiently test the proposed prospective payment approach, stimulate the development of new evidence-based knowledge, acquire additional knowledge relating to patterns of inefficient utilization of health care services, and to formulate methods to incentivize the improvement of high-quality delivery

of RT services. Based upon our analyses we do not believe that three years will be sufficient to test the proposed payment approach. We believe that a Model performance period of five years is necessary to address implementation issues and for the evaluation to obtain sufficient data to compute a reliable impact estimate, and to determine next steps regarding potential expansion or extension of the Model. Notably, the evaluation will analyze data on the impact of the Model on an ongoing basis, so to the extent that evaluation results are definitive sooner than the end of the Model, we will consider next steps at that time rather than waiting until the Model ends. For these reasons, we believe that a Model performance period of five years is necessary, and we will not reduce the Model performance period to less than five years.

We also would like to clarify that we proposed that the RO Model would cover 40 percent of all eligible RO episodes in eligible CBSAs nationwide in order to have a nationally representative sample of RT providers and suppliers that is sufficiently large enough to confidently show the impacts of the Model within five years (84 FR34496). As discussed in section III.C.3.d, we are finalizing a policy that includes 30 percent of all eligible RO episodes in eligible CBSAs nationwide, and determined that we will still be able to maintain confidence in estimating the impacts of the RO Model. Finalizing a Model performance period to anything less than five years would not allow us to maintain that confidence necessary to show the impacts of the RO Model.

Regarding the commenters suggesting that the RO Model should be voluntary, please reference section III.C.3.a of this final rule for further discussion of why we believe a mandatory design is necessary for the testing of the RO Model.

After considering public comments, we are finalizing our proposal with modification to the Model performance period. Specifically, we are revising the regulations at § 512.205 to

define the Model performance period to mean January 1, 2021, through December 31, 2025, the last date during which RO episodes must be completed, with no new RO episodes beginning after October 3, 2025, in order for all RO episodes to be completed by December 31, 2025. We are also codifying at § 512.205 that performance year (PY) means the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period.

2. Definitions

In the proposed rule, we proposed to define certain terms for the RO Model at § 512.205. We described these proposed definitions in context throughout section III of the proposed rule. In the proposed rule, we solicited public comments on our proposed definitions. To the extent we have received comments relating to the definitions that we had proposed, we have responded to those comments in context throughout section III of this final rule.

3. Participants

In the proposed rule, we discussed how certain Medicare participating HOPDs, physician group practices (PGPs), and freestanding radiation therapy centers that furnish RT services (RT providers or RT suppliers) in Core-Based Statistical Areas (CBSAs) randomly selected for participation, would be required to participate in the RO Model either as "Professional participants," "Technical participants," or "Dual participants" (as such terms are defined at 84 FR 34494). We defined "RO participant" at § 512.205 of the proposed rule as a PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model pursuant to the criteria that we proposed to establish at § 512.210 (see section III.C.3.b in the proposed rule and in this final rule). In addition, we noted that the proposed definition of "model participant," includes an RO participant. In the proposed rule, we discussed our proposals 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

In the proposed rule (84 FR 34493 through 343494), we discussed how certain RT providers and RT suppliers that furnish RT services within CBSAs randomly selected for participation would be required to participate in the RO Model (as discussed in sections III.C.3.b and III.C.3.d of this final rule). To date, the Innovation Center has tested one voluntary prospective episode payment model, Bundled Payments for Care Improvement (BPCI) Model 4 that attracted only 23 participants, of which 78 percent withdrew from the initiative. In the proposed rule, we discussed our interest in testing and evaluating the impact of a prospective payment approach for RT services in a variety of circumstances. We stated our belief that by requiring the participation of RT providers and RT suppliers, we would have access to more complete evidence of the impact of the Model.

As discussed in the proposed rule, we believe a representative sample of RT providers and RT suppliers for the proposed Model would result in a robust data set for evaluation of this prospective payment approach, and would stimulate the rapid development of new evidence-based knowledge (84 FR 34493). Testing the Model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy. Therefore, we proposed a broad representative sample of RT providers and RT suppliers in multiple geographic areas (see section III.C.3.d of both the proposed rule and this final rule for a discussion regarding the Geographic Unit of Selection). We proposed the best method for obtaining the necessary diverse, representative group of RT providers and RT

suppliers would be random selection. This is because a randomly selected sample would provide analytic results that will be more generally applicable to all Medicare FFS RT providers and RT suppliers and would allow for a more robust evaluation of the Model.

In addition, in the proposed rule at 84 FR 34493 through 34494, we discussed actuarial analysis suggesting that the difference in estimated price updates for rates in the OPPS and PFS systems from 2019 through 2023, in which the OPPS rates are expected to increase substantially more than PFS rates, would result in few to no HOPDs electing to voluntarily participate in the Model. Further, those actuarial estimates suggested that freestanding radiation therapy centers with historically lower RT costs compared to the national average would most likely choose to participate, but those with historically higher costs would be less likely to voluntarily participate. We discussed how requiring participation in the RO Model would ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers and to help support a statistically robust test of the prospective episode payments made under the RO Model.

For these reasons, we believed that a mandatory model design would be the best way to improve our ability to detect and observe the impact of the prospective episode payments made under the RO Model. Therefore, we proposed that participation in the RO Model would be mandatory for all RT providers and RT suppliers furnishing RT services within the CBSAs randomly selected for participation (84 FR 34493 through 34494).

We solicited public comments on our proposal for mandatory participation. The following is a summary of comments received on this proposal and our responses to these comments:

Comment: CMS received many comments related to the proposed mandatory participation of the Model. One commenter agreed with CMS' decision to make participation in this Model mandatory for CBSAs randomly selected for participation.

Response: We appreciate the commenter's support. As explained in the proposed rule (84 FR 34493 through 34496) and in this final rule, mandatory participation eliminates selection bias, ensures participation from HOPDs, provides a representative sample of RT providers and RT suppliers, and facilitates a comparable evaluation comparison group. We maintain that the mandatory design for the RO Model is necessary to enable CMS to detect change reliably in a generalizable sample of RT providers and RT suppliers to support a potential model expansion.

Comment: A few commenters stated that the mandatory nature of the RO Model would force some RT providers and RT suppliers to participate in the Model that are not operationally ready while at the same time excluding others that are well prepared. This could create challenges for beneficiary access and could lead to operational issues for practices.

Response: Mandatory participation and random selection of participants are integral to the design and evaluation of this Model. However, we believe that finalizing the Model performance period to on January 1, 2021 will allow RT providers and RT suppliers sufficient time to prepare for the RO Model's requirements.

Comment: Some commenters stated that mandatory participation would have negative consequences on Medicare beneficiaries, such as depriving beneficiaries of their freedom to choose where they receive RT services, reducing access to care, and increasing financial and logistical burdens for beneficiaries that believe they need to travel outside of their CBSA to receive care from a non-RO participant.

Response: We would like to clarify that the RO Model will not interfere with the general guarantees and protections for all Medicare FFS beneficiaries. We support Medicare beneficiaries' rights to seek care wherever they choose, and we are codifying at § 512.120(a)(1) the requirement that RO participants not restrict a beneficiary's ability to choose his or her provider(s) and/or supplier(s). Further, we are using CBSAs as the unit of selection for the RO Model. We selected CBSAs, as opposed to larger geographic units of selection, in order to allow beneficiaries to travel to another area to receive RT services, if they so wished.

Comment: A couple of commenters stated that mandatory participation is a departure from the agency's previous approach to model participation, and these commenters believed that CMS had previously indicated that mandatory models would only be used judiciously or when the agency could not guarantee enough participation or would have an adverse selection for voluntary models.

Response: We believe that the RO Model meets these circumstances. As discussed throughout this section and in Section III.C.3.d, we designed the RO Model to require participation by RT providers and RT suppliers in order to avoid selection bias. Further, as discussed earlier in this section, our actuarial analysis suggests that without mandatory participation in the RO Model, there will be limited to no participation from HOPDs.

Comment: Some commenters expressed concerns that the proposed mandatory participation would lack upside opportunity for high-performing participants and lead to hospitals and health systems bearing the expense of participation in a complicated program and the burden of generating all of the identified savings associated with the Model.

Response: We would like to note that the RO Model is an Advanced APM and a MIPS APM. As such, eligible clinicians who are Professional participants and Dual participants may

potentially become Qualifying APM Participants (QPs) who earn an APM Incentive Payment and are excluded from the MIPS reporting requirements and payment adjustments. Under the current Quality Payment Program rules, those who are not excluded from MIPS as QPs or Partial QPs will receive a final score and payment adjustment under MIPS, unless otherwise excepted. We believe these aspects of the RO Model as an Advanced APM and a MIPS APM will provide eligible participants with an example of the upside opportunity for high-performing participants under the Model stated by the commenters. The RO Model also affords all RO participants the opportunity to actively participate in the effort of moving toward and incentivizing value-based RT care, offering to make certain data available that RO participants can request for use in care coordination and quality improvement, which would potentially increase beneficiary satisfaction.

Comment: Many commenters suggested that other unintended consequences could result from mandatory participation in the RO Model. These commenters listed the following potential consequences: a competitive disadvantage for participants who are subject to new and uncertain pricing; unfair financial hardship for participating practices; a disproportionate effect on cancer centers with a predominantly Medicare patient base; Medicare patients being exposed to unnecessary excess radiation; stifled innovation; and a decrease in overall quality of care.

Response: We will conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences of the Model, as finalized in section III.C.16. Please also refer to sections III.C.3.d. and III.C.14 of this final rule for more discussion about how we will monitor for unintended consequences under the RO Model.

Specifically regarding the comment about Medicare patients being exposed to unnecessary excess radiation, we rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As for concerns regarding stifled innovation under the RO Model, we

believe these concerns will be mitigated by the fact that new technologies, upon receiving an assigned HCPCS code, would be paid FFS until such time that they could be proposed for the RO Model through future rulemaking. We also believe these concerns about stifled innovation under the RO Model will be mitigated by the trend factor, which will reflect updates to input prices as reflected in updated PFS and OPPS rates. Please refer to section III.C.6 of this final rule for further discussion about this.

We do not believe that RO participants will be at a competitive disadvantage, or subject to uncertain pricing, because the RO Model pricing methodology employs a trend factor, which is applied to an established national base rate, that is based on updated PFS and OPPS rates and ensures that spending under the RO Model will not diverge too far from spending under the FFS that non-participants will receive for the underlying bundle of services had they been in the Model. See section III.C.6.d for more information.

Regarding the comment that the Model would have a disproportionate effect on cancer centers with a predominantly Medicare patient base, we disagree. Episode payments will be largely determined by what an RO participant was historically paid. As described in section III.C.6, the pricing methodology as finalized will blend together the national base rate with an RO participant's unique historical experience. If the RO participant is historically less efficient than the national average, the blend in PY1 will be 90 percent of the RO participant's historical payments and 10 percent of the national base rate. This means that prior to applying the discount factor and withholds, payments under the Model will be between 90 and 100 percent of the RO participant's historical payments. For historically inefficient RO participants, the blend shifts over time to a 70/30 blend in PY5. For historically efficient RO participants, the blend for the Model performance period is fixed at 90/10 blend.

Regarding the comment that the mandatory nature of the RO Model will result in a decrease in overall quality of care, we disagree. We specifically designed the Model to preserve or enhance quality of care, and we are putting in place measures, like the collection of quality measures and clinical data elements, to help us to quantify the impact of the RO Model on quality of care. See section III.C.8 of this final rule for more information regarding our finalized provisions for the quality measures and clinical data elements that will be collected for the RO Model.

Comment: Many commenters suggested that participation in the Model be voluntary, or that participants have the option to opt-in or opt-out of the Model. Many commenters provided operational suggestions should the Model be voluntary, including that participants could choose to participate for the entirety of the Model performance period. Many commenters referenced other voluntary models, namely the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model and the Oncology Care Model (OCM), and suggested that these models have significant health care provider interest and participation, and have demonstrated that the RO Model could be successful and garner sufficient participation as a voluntary model. The commenters suggested that a voluntary model would provide an opportunity to mitigate unintended consequences prior to expanding to a mandatory model. Many commenters stated that making the RO Model voluntary would reduce the potential risk, disruption, and financial hardships to RO participants.

As an alternate recommendation, many commenters 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. One of these commenters 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 voluntary participation for the first performance year (PY) with a transition to limited mandatory participation in the subsequent performance years. Another commenter recommended voluntary participation with a gradual phase in of additional participants through expansion of the Model by 10 percent each year.

Another commenter suggested that providers and suppliers in the selected geographic areas be allowed to opt out of participation in the first year of the Model, and that CMS remove downside risk for those that do participate. Then, in the remaining four years of the Model, all providers and suppliers in the selected geographic areas would be required to participate with two-sided risk. A few commenters recommended that CMS initiate the Model on a voluntary basis with little to no risk, and then transition to a risk-based Model with opt-in and opt-out provisions to take place over a period of time. These commenters compared this suggested risk approach to those implemented in both the Comprehensive Care for Joint Replacement (CJR) Model and OCM. A few commenters recommended that CMS consider a voluntary Model for the first four years with incentives for participants, and then subsequently transition to a limited mandatory Model. Another commenter suggested that the RO Model be voluntary for the initial three years, and then move to mandatory in PY4 and PY5.

Many commenters recommended that the Model have voluntary participation throughout the Model performance period. A 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. This commenter recommended that these tests be conducted with interested RT providers and RT suppliers before CMS scaled it to the size proposed in the NPRM. Another commenter

suggested implementing the Model nationally as a voluntary model and utilizing the approach of evaluating the impact through an interrupted time series approach rather than a control group. A commenter recommended voluntary participation with a 10 percent reimbursement lift to allow participants to ramp up for the program and have the internal administrative and clinical operations necessary to support and succeed in the Model.

These commenters provided a variety of reasons for their recommendations of a voluntary, phase in approach to the RO Model. A commenter believed this approach would promote an equitable opportunity for success and ensure accurate and useful results from the Model. Another commenter believed this process would allow practices to transition to the coding and billing requirements and allow time to build infrastructures to collect data. A couple of commenters stated that this approach would support CMS' objectives, as well as allow CMS to build the infrastructure to administer this program effectively and to then scale it as additional participants joined. A few commenters suggested that this approach would be more consistent with the processes that previous CMS models have followed. One of these commenters stated that this approach would provide participants with more feasible pathways to value-based payment by allowing for flexibility and time to adjust practice patterns to best meet the Model's requirements. Another commenter stated that this process would be fairer to providers and suppliers that are currently unprepared to participate, and would avoid penalties on participants that are unequipped to provide value-based care and require additional time to prepare a plan for a successful transformation.

Response: We appreciate commenters' suggested alternatives to mandatory participation for the RO Model. However, as explained in the proposed rule (84 FR 34493 through 34496) and in this final rule, we believe that if the Model is voluntary for all RT providers and RT suppliers

or allow for a phased-in approach, then we will face complications in our ability to accurately evaluate the RO Model.

Regarding the comment about voluntary participation with a 10 percent reimbursement lift to allow participants to ramp up for the program and have the internal administrative and clinical operations necessary to support and succeed in the Model, we believe, although we are not sure as more detail was not provided by the commenter, that the commenter is suggesting that payments be increased for participants by 10 percent. We would like to note that we would not be able to maintain or reduce costs under this type of design.

Regarding the comment suggesting that we implement the Model nationally as a voluntary model and utilize the approach of evaluating the impact through an interrupted time series approach rather than a control group, as discussed throughout this section of the final rule, we maintain that the mandatory design for the RO Model is necessary. We have decided not to use an interrupted time series design for the RO Model because the use of a comparison group not exposed to the intervention improves our ability to make causal inferences. A time series analysis is only necessary in circumstances when a comparison group does not exist, and under the RO Model, a control group of nonparticipants will exist.

While we will not allow for voluntary participation for the Model, after considering the concerns raised by the commenters, including potential financial hardship for practices under the RO Model, we are modifying the proposed policy to include an opt-out option for RT providers and RT suppliers that are low volume (see section III.C.3.c of this final rule for additional information). While we appreciate the commenters' suggestions to employ a phase in process for the RO Model, we believe that allowing a phase in process for participants would create a selection bias in the early years of the Model that would hinder robust evaluation. As we stated

in the proposed rule and in this final rule, actuarial analysis suggests that the difference in estimated price updates for rates in the OPPS and PFS systems from 2019 through 2023, in which the OPPS rates are expected to increase substantially more than PFS rates, would result in few to no HOPDs electing to voluntarily participate in the Model. These actuarial estimates also suggest that freestanding radiation therapy centers with historically lower RT costs compared to the national average would most likely choose to participate, but those with historically higher costs would be less likely to volunteer to participate. Therefore, we believe that requiring participation in the RO Model, without a voluntary phase in option, is necessary to ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, and obtain a diverse, representative sample of RT providers and RT suppliers that will allow a statistically robust test of the prospective episode payments made under the RO Model.

Comment: Some commenters questioned CMS' statutory authority to implement the RO Model using section 1115A of the Act. A few of these commenters stated that the proposal requiring mandatory participation of approximately 40 percent of radiation oncology episodes represents a major policy change, and not a test of payment and service delivery models, which is what CMS is authorized to do in section 1115A of the Act. A few commenters stated that Innovation Center models should be implemented on a voluntary basis as the statute does not authorize CMS to mandate participation in any Innovation Center model, and any agency interpretation that the statute permits mandatory models raises issues of impermissible delegation of lawmaking authority where none was intended and is inconsistent with the expressed mandate of section 1115A. A commenter stated that making the Model a mandatory requirement could be found potentially unlawful and is unprecedented. A commenter surmised that the RO Model was not developed by the Innovation Center, that the Secretary does not have the authority to waive

Medicare provisions or any requirements of the Medicare statute under the RO Model, and that the RO Model violates section 3601 of the Patient Protection and Affordable Care Act ("the ACA").

Response: We disagree with these commenters. The Innovation Center designed and developed the RO Model, and we will be testing the RO Model, consistent with section 1115A of the Act. We believe that we have the legal authority to test the RO Model and to require the participation of all RT providers and RT suppliers in the CBSAs selected for participation, and that this does not constitute an impermissible delegation of lawmaking authority that is inconsistent with section 1115A of the Act. First, we note that the RO Model will not be the first Innovation Center model that requires participation under the authority of section 1115A of the Act; we refer readers to the Comprehensive Care for Joint Replacement (CJR) Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services Final Rules, and the Home Health Prospective Payment System (HHPPS) Final Rules implementing the Home Health Value-Based Purchasing (HHVBP) Model. Hospitals in selected Metropolitan Statistical Area (MSAs) were required to participate in the CJR Model beginning in April 2016, and home health agencies in selected states were required to participate in the HHVBP Model beginning in January 2016.

We believe that both section 1115A of the Act and the Secretary's existing authority to operate the Medicare program authorize us to finalize mandatory participation in the RO Model as we have proposed. Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving quality of care. The statute does not require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality. Although

section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, the Secretary is not limited to those models. Rather, as specified in section 1115A(b)(1) of the Act, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Here, the RO Model addresses a defined population (FFS Medicare beneficiaries who receive included RT services) for which there are potentially avoidable expenditures (arising from the lack of site neutrality for payments, incentives that encourage volume of services over the value of services, and coding and payment challenges in the PFS). We designed the RO Model to require participation by RT providers and RT suppliers in order to avoid the selection bias inherent to any model in which providers and suppliers may choose whether or not to participate. Such a design will ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers that will allow a statistically robust test of the prospective episode payments made under the RO Model. We believe this is the most prudent approach for the following reasons. Under the mandatory RO Model, we will test and evaluate a Model across a wide range of RT providers and RT suppliers, representing varying degrees of experience with episode payment. The information gained from testing the mandatory RO Model will allow CMS to comprehensively assess whether RO episode payments are appropriate for a potential expansion in duration or scope, including on a nationwide basis. Thus, the RO Model meets the criteria required for Phase I model tests.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of Medicare. Specifically, the Secretary has authority under sections 1102 and 1871 of the Act to implement regulations as necessary to administer Medicare, including testing

this Medicare payment and service delivery model. We note that the RO Model is not a permanent feature of the Medicare program; the Model will test different methods for delivering and paying for services covered under the Medicare program, which the Secretary has clear legal authority to regulate. The proposed rule went into detail about the provisions of the proposed RO Model, enabling the public to understand how the proposed Model was designed and could apply to affected RT providers and RT suppliers. As permitted by section 1115A of the Act, we are testing the RO Model within specified limited geographic areas. The fact that the Model will require the participation of certain RT providers and RT suppliers does not mean it is not a Phase I Model test. If the Model test meets the statutory requirements for expansion, and the Secretary determines that expansion is appropriate, we would undertake rulemaking to implement the expansion of the scope or duration of the Model to additional geographic areas or for additional time periods, as required by section 1115A(c) of the Act.

Furthermore, we wholeheartedly disagree that the RO Model is in violation of section 3601 of the ACA. Section 3601 of the ACA requires that nothing in the provisions of or amendments to the ACA, including models being designed and tested by the Innovation Center, may result in a reduction of guaranteed Medicare benefits. The RO Model is designed not to result in a reduction of guaranteed Medicare benefits, and in fact as finalized in section II.D.2 and codified at § 512.120(b)(1), we are specifically requiring RO participants to continue to make medically necessary covered services available to beneficiaries to the extent required by law. Further, we will monitor compliance with the Model requirements through monitoring activities that 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 participants and clinicians on the individual practitioner list; interviews with beneficiaries and their caregivers; site visits; monitoring quality outcomes and clinical data, if applicable; and tracking patient complaints and appeals. Please see section III.C.14 of this final rule for further discussion on monitoring activities.

After considering public comments, we are finalizing our proposal for mandatory participation with modification. Specifically, we are codifying at § 512.210(a) that any Medicare-enrolled 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.

Further, after considering the concerns raised by the commenters regarding the mandatory nature of the RO Model, we are finalizing 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), 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). We believe that these modifications address some of the commenters' concerns regarding the mandatory nature of the RO Model, including those relating to potential financial hardship as well as the size and scope of the Model (see section III.C.3.d of this final rule for more information).

As stated in the proposed rule and in this final rule, we believe that by requiring the participation of RT providers and RT suppliers, we would have access to more complete evidence of the impact of the Model. We also believe that a representative sample of RT providers and RT suppliers would result in a robust data set for evaluation of this prospective payment approach, and would stimulate the development of new evidence-based knowledge. Testing the Model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for RT services. This learning could potentially inform future Medicare payment policy. Therefore, we are finalizing as proposed the selection of a broad, representative sample of RT providers and RT suppliers in multiple geographic areas (see 84 FR 34495 through 34496, and section III.C.3.d. of this final rule for a discussion regarding the Geographic Unit of Selection) for RO Model participation. However, in response to comments, we are reducing the scale of the RO Model from the proposed approximately 40 percent of episodes to approximately 30 percent of eligible episodes (please reference section III.C.3.d. of this final rule for more information).

We have determined that the best method for obtaining the necessary diverse, representative group of RT providers and RT suppliers is random selection. This is because a randomly selected sample would provide analytic results that will be more generally applicable to all Medicare FFS RT providers and RT suppliers and will allow for a more robust evaluation of the Model. As we explained in the proposed rule and in this final rule, because actuarial analysis suggests that the difference in estimated price updates for rates in the OPPS and PFS systems from 2019 through 2023, in which the OPPS rates are expected to increase substantially more than PFS rates, would result in few to no HOPDs electing to voluntarily participate in the Model and that freestanding radiation therapy centers with historically lower RT costs

compared to the national average would most likely choose to participate, but those with historically higher costs would be less likely to voluntarily participate, we believe that requiring participation in the RO Model will ensure sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers that will allow a statistically robust test of the prospective episode payments made under the RO Model.

For the previously identified reasons, we believe that a mandatory model design would be the best way to improve our ability to detect and observe the impact of the prospective episode payments made under the RO Model. We therefore are finalizing our proposal with modification that participation in the RO Model will be mandatory.

b. RO Model Participants

An RO participant, a term that we defined in the proposed rule at § 512.205, would be a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that is required to participate in the RO Model pursuant to § 512.210 of the proposed rule. As discussed in the proposed rule at 84 FR 34494 through 34495, an RO participant would participate in the Model as a Professional participant, Technical participant, or Dual participant.

In the proposed rule, we proposed to define the term "Professional participant" as an RO participant that is a Medicare-enrolled physician group practice (PGP), identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component of RT services at either a freestanding radiation therapy center or an HOPD. We proposed at 84 FR 34494 that Professional participants would be required annually to attest to the accuracy of an individual practitioner list provided by CMS, of all of the eligible clinicians who furnish care under the Professional participant's TIN, as discussed in section III.C.9 of this final rule. We

proposed to define the term "individual practitioner" to mean a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and have reassigned his/her billing rights to the TIN of an RO participant (84 FR 34494). We further proposed that an individual practitioner under the RO Model would be considered a downstream participant, as discussed in section II.B. of the proposed rule and this final rule.

We proposed at 84 FR 34494 to define the term "Technical participant" to mean an 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 of RT services. Finally, we proposed at 84 FR 34494 to define "Dual participant" to mean an RO participant that furnishes both the professional component and technical component of an episode for RT services through a freestanding radiation therapy center, identified by a single TIN. We proposed to codify the terms "Professional participant," "Technical participant," "Dual participant" and "individual practitioner" at § 512.205.

We also explained in the proposed rule at 84 FR 34494 that an RO participant would furnish at least one component of an episode, which would have two components: a professional component and a technical component. We proposed to define the term "professional component (PC)" to mean the included RT services that may only be furnished by a physician. We proposed to define the term "technical component (TC)" to mean the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and costs related to RT services. (See section III.C.5.c of the proposed rule at 84 FR 34494 through for a discussion regarding our proposed included RT services.) We proposed to codify the terms "professional component (PC)" and "technical component (TC)" at § 512.205 of the proposed rule.

In the proposed rule, we proposed that an episode of RT under the RO Model would be furnished by either: (1) two separate RO participants, that is, 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 the PC and TC of an episode. For example, if a PGP furnishes only the PC of an episode at an HOPD that furnishes the TC of an episode, then the PGP would be a Professional participant and the HOPD would be a Technical participant. In other words, the PGP and HOPD would furnish separate components of the same episode and would be separate participants under the Model.

The following is a summary of the public comments received on these proposed definitions related to RO participants and our responses to those comments:

Comment: A commenter supported these key participant distinctions, appreciated that CMS recognized that RT services can be delivered at different sites of service, and stated that this participant construct lends itself well to the establishment of separate professional and technical payment components.

Response: We appreciate this commenter's support on our proposed definitions for the Professional, Technical, and Dual participants in the RO Model.

Comment: A commenter requested clarification on how RO participants will be defined if there are multiple sites of service during an episode. This commenter provided an example where a physician delivers EBRT in a freestanding setting and then chooses to deliver brachytherapy in the hospital outpatient department (HOPD) setting. This commenter asked whether the physician in this example would be considered a Dual participant such that there would be no technical component payment issued to the HOPD. This commenter suggested that

CMS should provide clarification regarding how these types of situations will be handled and reimbursed within the Model.

Response: As stated in the proposed rule at 84 FR 34494, a Professional participant is an RO participant that is a Medicare-enrolled physician group practice (PGP), identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component of RT services at either a freestanding radiation therapy center or an HOPD. A Technical participant is an 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 of RT services. A Dual participant is an RO participant that furnishes both the professional component and technical component of an RO episode for RT services through a freestanding radiation therapy center, identified by a single TIN. Professional participant, Technical participant and Dual participant are similar to the proposed definitions, RT provider and RT supplier. In the proposed rule, an RT provider is defined as a Medicare-enrolled HOPD that furnished RT service in a 5-digit ZIP Code linked to a CBSA selected to participate, and an RT supplier is defined as a Medicare –enrolled PGP or freestanding radiation therapy center that furnishes RT services in a 5-digit ZIP Code linked to a CBSA selected to participate. These definitions taken together with other proposed definitions, RO participant, Professional participant, Technical participant and Dual participant, are duplicative. For clarification, we are finalizing proposed definitions for the Professional, Technical, and Dual participants in the RO Model without modification, and finalizing the proposed definitions for RT provider and RT supplier with modification. RT provider will mean any Medicare-enrolled HOPD that furnishes RT services and RT supplier will mean any Medicare-enrolled PGP or freestanding radiation therapy center that furnishes RT services.

As for the specific example the commenter presented, the freestanding radiation therapy center would be considered a Dual Participant for delivery of EBRT, and the HOPD delivering brachytherapy would bill traditional Medicare fee-for-service as described in section III.C.7. In the example described, FFS payments made to the HOPD would be considered duplicate payments during reconciliation as described in section III.C.11.

Comment: Some commenters were concerned with the possibility that health systems could have some of their practices participating in the RO Model and their remaining practices operating outside of the Model. These commenters stated that it is common for large health systems to have a single TIN covering multiple locations, and that the proposed RO Model design could allow practices within the same health system to fall into different CBSAs. This may cause challenges for both RT providers and RT suppliers and patients as well as cause avoidable complexity in rare situations where patients shift between care locations. These commenters, therefore, recommended that CMS make accommodations for health systems with multiple sites, where practices that span multiple CBSA's with a single TIN can request to opt-in or opt-out of the Model.

Response: We recognize that this scenario could occur where practices under the same TIN could fall into different CBSAs whereas some are either in the Model and others are out of the Model. As stated in the proposed rule in section III.C.3.d (84 FR 34495 through 34496), we are using CBSAs as the geographic unit of selection for the RO Model for various reasons, including that CBSAs are large enough to reduce the number of RO participants in close proximity to other RT providers and RT suppliers that would not be required to participate in the Model. As we have chosen the method of using randomly selected stratified CBSAs in the RO Model, it is unavoidable that some practices within the same TIN may fall into different CBSAs,

though we anticipate that the numbers will be limited. As noted in the commenters' letters, situations where a beneficiary changes treatment locations is rare in radiation oncology, and we believe that our billing policies would allow sufficient flexibility to accommodate these uncommon instances, where the first treatment provider or supplier would be paid through the Model and a subsequent provider or supplier would bill FFS. We appreciate the commenters' concerns on this matter, and we will monitor this situation for any issues or complications that may arise from this policy.

After considering public comments, we are finalizing our proposed provisions on the RO Model participant definitions without change. Specifically, we will codify at § 512.205 to define an RO participant as a Medicare-enrolled physician group practice (PGP), freestanding radiation therapy center, or HOPD that is required to participate in the RO Model pursuant to § 512.210. We are further finalizing our proposal to define the term "Professional participant" at § 512.205 as an RO participant that is a Medicare-enrolled PGP identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component of an RO episode. We are also finalizing our proposal define the term "Technical participant" at § 512.205 to mean an 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 of an episode. Finally, we are finalizing our proposal to define "Dual participant" at § 512.205 to mean an RO participant that furnishes both the professional component and technical component of an RO episode through a freestanding radiation therapy center, identified by a single TIN.

c. RO Model Participant Exclusions

In the proposed rule at 84 FR 34493 through 34494, we proposed to exclude from RO Model participation any PGP, freestanding radiation therapy center, or HOPD that—

• Furnishes RT only in Maryland;

• Furnishes RT only in Vermont;

• Furnishes RT only in U.S. Territories;

• Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or

• Participates in or is identified as eligible to participate in the Pennsylvania Rural Health Model.

The proposed rule specified that these exclusion criteria would apply during the entire Model performance period. If an RO participant undergoes changes such that one or more of the exclusion criteria becomes applicable to the RO participant during the Model performance period, then that RO participant would be excluded from the RO Model (that is, it would no longer be an RO participant subject to inclusion criteria). For example, if an RO participant moves its only service location[25] from a CBSA randomly selected for participation in Virginia to Maryland, it would be excluded from the RO Model from the date of its location change. Conversely, if a PGP, freestanding radiation therapy center, or HOPD satisfies the exclusion criteria when the Model begins, and subsequently experiences a change such that the exclusion criteria no longer apply and the PGP, freestanding radiation therapy center, or HOPD is located in one of the CBSAs selected for participation, then participation in the RO Model would be

[25] Service location means the site of service in which an RO Participant or any RT provider or RT supplier furnishes RT services.

required. For example, if an HOPD is no longer classified as a PPS-exempt hospital and the HOPD is located in one of the CBSAs selected for participation, then the HOPD would become an RO participant from the date that the HOPD became no longer classified as a PPS-exempt hospital.

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

We proposed to exclude RT providers and RT suppliers in Maryland due to the unique statewide payment model being tested there (the Maryland Total Cost of Care Model), in which Maryland hospitals receive a global budget. We noted in the proposed rule that this global budget includes payment for RT services and as such would overlap with the RO Model payment. Thus, we proposed to exclude Maryland HOPDs to avoid double payment for the same services. We proposed to extend the exclusion to all RT providers and RT suppliers in Maryland to avoid creating a gaming opportunity where certain beneficiaries could be shifted away from PGPs and freestanding centers to HOPDs.

In the proposed rule, we proposed to exclude RT providers and RT suppliers in Vermont due to the Vermont All-Payer ACO Model, which is a statewide model in which all-inclusive population-based payments (AIPBPs) are currently made to the participating ACO for Medicare FFS services furnished by all participating HOPDs and an increasing number of participating PGPs. Given the scope of this model as statewide and inclusive of all significant payers, we

explained in the proposed rule that we believe excluding RT providers and RT suppliers in Vermont from the RO Model is appropriate to avoid any potential interference with the testing of the Vermont All-Payer ACO Model.

We also proposed to exclude HOPDs that are participating in or eligible to participate in the Pennsylvania Rural Health Model from the RO Model. Hospitals and CAHs that are participating in the Pennsylvania Rural Health Model receive a global budget, much like hospitals participating in the Maryland Total Cost of Care Model. Further, we proposed to extend the exclusion to HOPDs that are eligible to participate in the Pennsylvania Rural Health Model because additional hospitals and CAHs may join that model in the future or may be included in the evaluation comparison group for that model. We stated in the proposed rule that we would identify the hospitals and CAHs that are participating in or are eligible to participate in the Pennsylvania Rural Health Model on a list to be updated quarterly and made available on the Pennsylvania Rural Health Model's website at https://innovation.cms.gov/initiatives/pa-rural-health-model/.

We designed the proposed RO Model to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures by providing savings for Medicare while preserving or enhancing quality. In the proposed rule, we discussed our belief that it would be inappropriate to include these entities for the reasons previously described. Also, we proposed to exclude ASCs and RT providers and RT suppliers located in the U.S. Territories, at § 512.210, due to the low volume of RT services that they provide. In addition, we proposed to exclude CAHs and PPS-exempt cancer hospitals due to the differences in how they are paid by Medicare.

As a result, we proposed that RT services furnished by these RT providers and RT suppliers would be excluded from the RO Model. We also stated that if in the future we determine that providers and suppliers in these categories should be included in the RO Model, we would revise our inclusion criteria through rulemaking.

We proposed to codify these policies at § 512.210 of our regulations. We solicited comments on the proposals related to RO participant exclusions. The following is a summary of the comments received on these proposals and our responses to those comments:

Comment: A commenter supported CMS' decision to exclude from the Model providers and suppliers that furnish RT services only in Maryland, Vermont, or U.S. Territories; that are participating in or eligible to participate in the Pennsylvania Rural Health Model; or that are classified as an ambulatory surgery center, CAH, or PPS-exempt cancer hospital.

Response: We thank this commenter for the support on our proposed exclusions from the RO Model; we are finalizing these exclusions without modification.

We would like to clarify that we recognize HOPDs are not standalone institutions and, as such, may not, independent of a hospital or CAH, participate in or be eligible for participation in the Pennsylvania Rural Health Model. We will use the list on the Pennsylvania Rural Health Model's website at https://innovation.cms.gov/initiatives/pa-rural-health-model/, which is updated quarterly, to identify the hospitals and CAHs eligible to participate in the Pennsylvania Rural Health Model, and therefore identify the specific HOPDs that are excluded from participation in the RO Model. We would also like to clarify that this exclusion of HOPDs associated with hospitals and CAHs eligible to participate in the Pennsylvania Rural Health Model from the RO Model will apply only during the period of such eligibility. If the Pennsylvania Rural Health Model is terminated or if the HOPD is no longer eligible to

participate in the Pennsylvania Rural Health Model as part of an eligible hospital or CAH, and the HOPD otherwise meets the definition of an RO participant, then the HOPD will be required to participate in the RO Model.

Comment: A commenter supported CMS' decision to exclude CAHs from the RO Model, and stated that they appreciated CMS' recognition of the potential negative impact the Model could have on CAHs. This commenter also requested that CMS clarify whether a clinician who provides cancer treatment services at a CAH would be considered a Professional participant under the RO Model. This commenter also suggested that CMS ensure that the technical and professional services are aligned, and further recommended that if a treatment center is excluded from the Model, then the clinicians providing services at that treatment center should also be excluded.

A few commenters requested clarification on CMS' proposed policy regarding an exclusion for PPS-exempt cancer hospitals (PCHs) in the Model. A commenter requested clarification on whether radiation oncology physicians who work for a PCH but bill under a practice TIN, would be considered a Professional or Dual participant.

Another commenter requested clarification on how the professional reimbursement will be handled for physicians practicing in a PCH, but not employed by that legal entity. The commenter asked for clarification on whether the physicians would also be exempt. This commenter further stated that the same physicians may also practice at other non-PCH, and it is not uncommon for radiation oncologists to rotate through multiple facilities in a given week, depending on the size of the physician practice and the number of facilities where they practice.

Response: To clarify, a physician who provides cancer treatment services at a CAH, PCH, or ASC, and also provides services in a freestanding radiation therapy center or HOPD that

is located in a CBSA selected for participation, in addition to their services at a CAH, PCH, or ASC, will be considered either a Dual participant or Professional participant, respectively, under the RO Model. We also want to clarify that a physician who provides RT services at a PCH, regardless of their employment status at the PCH, and also provides only the professional component of an RO episode for RT services in a freestanding radiation therapy center or HOPD that is located in a CBSA selected for participation will be considered a Professional participant under the RO Model. Similarly, a physician who provides RT services at a PCH, and also furnishes both the professional component and technical component of an RO episode for RT services through a freestanding radiation therapy center, identified by a single TIN, will be considered a Dual participant under the RO Model. In contrast, a physician who provides RT services only at an exempt facility (PCH, CAH, or ASC) will not be an RO participant. RT services that are furnished at an exempt facility (PCH, CAH, or ASC) will be paid through FFS, while RO episodes that are furnished at a PGP, freestanding radiation therapy center, or HOPD that is in a CBSA selected for participation will be paid under the RO Model payment methodology.

Comment: A few commenters agreed with CMS' proposal to exclude from the Model PCHs, which some commenters also referred to as DRG-exempt cancer hospitals. A commenter agreed that PCHs should be excluded from the Model, and further requested that all of the physicians practicing in these PCHs be exempted from the RO Model because these physicians practice in the PCHs as well as eligible community practices and they all bill under the same TIN. The commenter indicated that this would complicate data submission and analysis as well as billing practices. A couple of commenters suggested that CMS expand the exclusion list to include all National Cancer Institute (NCI) Designated Comprehensive Cancer Centers. One of

these commenters stated that this policy would align with CMS' proposal to exempt PCHs. Another commenter stated that NCI-designated centers deliver innovative cancer treatments to patients in communities across the United States, and dedicate significant resources toward developing multidisciplinary programs and facilities that lead to better and innovative approaches to cancer prevention, diagnosis, and treatment. This commenter stated that introducing an APM based on complex calculations and historical rates would represent a significant burden that would negatively impact the innovation and discovery missions of NCI-designated centers.

Response: We appreciate these commenters' support of our proposal to exclude PCHs from the RO Model. With regard to the comment requesting that all physicians practicing in a PCH be exempted from the RO Model because these physicians practice in the PCHs as well as eligible community practices and they all bill under the same TIN, we would like to clarify that the physicians will be exempted from the RO Model if they only provide RT services at a PCH. However, if the physician also provides RT services at any other freestanding radiation therapy center and/or HOPD that is included in a CBSA selected for participation, they will be considered a Dual participant and/or Professional participant under the RO Model. We disagree with commenters' requests to expand the PCH exclusion list to include all National Cancer Institute (NCI) Designated Comprehensive Cancer Centers as PCHs are reimbursed on a "reasonable cost" basis instead of the OPPS FFS methodology, and we are excluding entities that are paid via reasonable cost or cost-reporting, and including all HOPDs that are currently paid through the OPPS/FFS methodology. Thus, we will be finalizing our policy as proposed and without modification to exclude from the RO Model any PGP, freestanding radiation therapy

center, or HOPD that is classified as a PCH. However, the RO Model will include PGPs, freestanding radiation therapy centers and HOPDs that are paid under FFS.

Comment: Conversely, some commenters disagreed with the proposal to exclude PCHs from the Model. Of those who disagreed, a couple of commenters stated that PCHs should be incentivized to reduce costs, and pointed to a Government Accountability Office (GAO) report that advised that the payment method for PCHs should be revised to promote efficiency and reduce costs to Medicare. Another commenter inquired why PCHs are exempted when they are among the best resourced institutions and are considered high cost centers due to emerging technologies. Another commenter sought clarification on why CMS decided to exclude a set of RT providers and RT suppliers that specifically treat the targeted conditions in the RO Model, and stated that the largest cancer treatment centers should not be excluded from a model that seeks to address utilization for cancer services. Another commenter stated that it is difficult to understand why PCHs would be excluded from the RO Model on the basis of payment methodology when payment methodology is the primary basis of the Model. Another commenter stated the 11 PCH have large amounts of grant money, have many staff, and receive significant Medicare payments, and accordingly should be included in the Model. A commenter stated that the 11 PCHs should not be excluded from Model because these hospitals have developed financial relationships with many community hospitals that give those hospitals both a financial and a marketing advantage. This commenter stated that if a CBSA is selected for participation and has one of these exempt hospitals, that facility will have a significant advantage over the other sites of service in that area, and this would allow that facility to more heavily market and to purchase upgraded equipment, which would threaten the viability of other programs and decrease access and choice for Medicare beneficiaries needing RT services.

Response: The RO Model is designed to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures by providing savings for Medicare while preserving or enhancing quality of care. We proposed to exclude PCHs because of the differences in how these hospitals are paid by Medicare. That is, they are not paid through traditional FFS payments (see, generally, the Social Security Amendments of 1983 (P.L. 98-21), the Balanced Budget Act of 1997 (P.L. 105-33), and the Omnibus Reconciliation Act of 1989 (P.L. 101-239)), and the RO Model is designed to test and evaluate the change from traditional FFS payments to prospective episode based payments. Regarding the commenter's concern about PCHs and their community hospital partners potentially having a financial and marketing advantage, we will monitor the Model for the occurrence of any such advantages, by monitoring for changes in referral patterns. Based on this monitoring, if we determine to modify the excluded categories of RT providers and RT suppliers, including PCHs, we would revise the RO Model inclusion criteria through future notice-and-comment rulemaking. Therefore, we are finalizing our policy as proposed without modification to exclude from RO Model participation any PGP, freestanding radiation therapy center or HOPD that is classified as a PPS-exempt cancer hospital.

Comment: A commenter suggested that CMS should exclude sole community hospitals (SCH) and Medicare dependent hospitals (MDH). These hospitals are generally rural, small, and highly dependent on Medicare and/or Medicaid funding. This commenter does not believe it would be appropriate to include these hospitals in the RO Model as it could significantly impact the financial viability of these hospitals or lead to a reduction in available services for the community.

Response: We did not propose to exclude MDH or SCH entities from the RO Model because, unlike CAHs, these entities are full service hospitals. If MDH and SCH entities believe they qualify for the RO Model's low volume opt-out option, please reference the discussion on the low volume opt-out option in this section of the final rule for more information. We will monitor the extent to which these hospitals are selected for participation in the Model, and we will monitor the impact the RO Model may have on these types of entities.

Comment: A commenter requested an exemption to the RO Model for practices that serve socioeconomically disadvantaged populations. This commenter stated that these practices tend to have higher costs of care because patients present with advanced stages of disease often due to the lack of access to preventative services, and these practices should not be penalized due to circumstances that are out of their control.

Response: We did not propose to exclude practices that serve socioeconomically disadvantaged populations, and we will not be creating an exemption of this nature at this time. While we understand the commenter's concern, we believe that the RO Model pricing methodology, through the historical experience and case mix adjustments, will account for differences in RO participants' historical care patterns and the demographic characteristics of their patient populations. We will monitor the effect that the RO Model may have on RO participants that serve these populations.

Comment: Many commenters stated that a mandatory RO Model will present operational, administrative, and financial challenges for many RT providers and RT suppliers, and therefore requested a low-volume or hardship exemption to allow participants to opt out of the RO Model. Many commenters disagreed with CMS' decision to not include a model participation hardship exemption for any providers or suppliers, and requested an exemption from Model participation

specifically for low-volume providers and suppliers. These commenters argued that failure to include a low-volume exemption could result in unintended consequences, such as smaller providers and suppliers incurring significant financial losses and potentially ending their programs due to lower payment through the RO Model. Additionally, some of these commenters suggested that that the RO Model should be limited to large groups (30 physicians or more), and that the Model should be limited to large hospitals with employed physicians.

A couple of commenters stated that a low-volume exemption is critical in a shared risk-based model of care, and should therefore be included in the RO Model. Another commenter supported CMS' proposal to exclude ASCs and RT providers and suppliers located in the U.S. Territories due to the low volume of RT services that they provide because of the commenter's belief that such providers and suppliers lack the infrastructure and support to achieve efficiencies. However, the commenter requested that CMS fully exclude from the Model providers and suppliers who furnished fewer than 60 attributed episodes during the 2015-2017 period, rather than just making adjustments to their episode payments. This commenter further stated that its analysis found that there is considerable variation in episode spending relative to payment amounts for providers and suppliers that perform a very low volume of RT, and the commenter maintained that this analysis suggests that episode pricing for these providers and suppliers would be highly random and, therefore, very difficult to manage. The commenter finally concluded that excluding these and other low-volume providers and suppliers would have a minimal impact on the RO Model test, but doing so would prevent these providers and suppliers from being inappropriately penalized by being required to participate in the Model.

Response: We appreciate the commenters' comments and feedback regarding low-volume entities under the RO Model. We understand the commenters' concerns regarding

administrative, financial, and infrastructural challenges for low-volume providers and suppliers under the RO Model. In response to stakeholder comments, we are finalizing our mandatory participation proposal, with a modification for an opt-out option for low-volume entities, which we are codifying 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. Please reference the end of this section for more information on the low volume opt-out option.

Regarding the commenters suggested that that the RO Model should be limited to large groups (30 physicians or more), we would like to note that most RT providers and suppliers have fewer than 30 oncologists, so this number would not provide a feasible threshold for the RO Model.

We agree in part with the commenter who suggested that we add an exclusion of entities with fewer than 60 episodes over the full baseline period of three years. We are focusing on entities with fewer than 20 episodes in the most recent year with available claims data, and we believe this corresponds with this commenter's suggestion. However, instead of excluding such entities, we believe that allowing entities with fewer than 20 episodes to opt-out achieves the right balance of allowing very small entities to opt-out if they believe the burden from participation in the Model would outweigh the possibility of benefits from model participation (for example, potential for care improvements or increased payments), while also maintaining a variety of participant types in the RO Model to promote generalizability (to the extent possible) of any impact results. Further, as discussed in section III.C.6.e(4), we do not apply adjustments to RO participant episode payments for participants that have less than 60 episodes in the last

three years of data. Thus, the opt-out option for entities with fewer than 20 episodes aligns with the threshold set for the historical experience and case mix adjustments. The low volume opt-out option is intended to allow RO participants furnishing a small volume of RT services in the CBSAs selected for participation in the Model to opt out if they so choose given the investment required to implement the Model versus the benefit of participating in the Model for a limited frequency of RT services.

Comment: Some commenters suggested that CMS apply the MIPS low-volume threshold or the CJR Model low-volume exemption as low-volume participation thresholds for mandatory RO Model participation.

Response: For the 2020 MIPS performance period, the MIPS low-volume threshold excludes from the definition of a MIPS eligible clinician an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period (consisting of two 12-month segments during 10/1/18 – 9/30/19 and 10/1/19 – 9/30/20), has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B–enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B–enrolled individuals. RT providers and RT suppliers tend to see smaller numbers of patients but at a higher price per patient than the average MIPS eligible clinician. Therefore, we estimate that using the MIPS low-volume threshold as a threshold for mandatory participation in the RO Model would result in a nearly 50 percent reduction in the number of RO participants. As stated in section III.C.3.d of this final rule, the number of RO participants must remain above a certain level in order to maintain statistical power for Model evaluation, and to generate sufficient savings. We are finalizing our mandatory participation proposal, with a modification for an opt-out option for low-volume entities as

described in this final rule. Similar to the CJR Model's policy, this option would allow any PGP, freestanding radiation therapy center, or HOPD that furnishes fewer than 20 episodes in the most recent year with available claims data within one or more of the CBSAs randomly selected for participation to opt-out of the RO Model, if they so choose. For more information on this final policy please see this section of this rule. There are notable differences between the CJR and RO Models' low volume opt-out options. The CJR Model's low-volume policy was a one-time opt-in option for participants, while the RO Model will make the low volume opt-out option available to eligible participants annually, prior to each year of the Model.

After considering public comments, we are finalizing, with one modification, our proposed provisions on RO Model participant exclusions. As proposed, we are finalizing our policy, and codifying at § 512.210(b), to exclude from RO Model participation any PGP, freestanding radiation therapy center, or HOPD that furnishes RT services only in Maryland; furnishes RT services only in Vermont; furnishes RT services only in U.S. Territories; is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model.

In response to public comments, we are finalizing with one modification our proposal regarding mandatory participation in the Model. A PGP, freestanding radiation therapy center, or HOPD which would otherwise be required to participate in the RO Model under § 512.210(a) may choose to opt-out of the RO Model on an annual basis if the PGP, freestanding radiation therapy center, or HOPD furnishes fewer than 20 episodes across all CBSAs selected for participation in the most recent calendar year with available claims data. We are codifying this modified policy at § 512.210(c) of the final rule.

Each RO participant's episode volume will be assessed at the TIN and CCN level across all CBSAs randomly selected for participation, not according to how many episodes an RO participant furnishes in a single CBSA. For example, if an RO participant furnished 30 episodes in two different CBSAs and both CBSAs are selected for participation in the Model, then the RO participant would not be eligible for the low volume opt-out option, even if the RO participant furnished fewer than 20 episodes in each of those CBSAs. If, however, an RO participant only furnished 15 episodes in only one CBSA selected to participate in the Model, then this RO participant would be eligible for the low volume opt-out option.

RO participants that qualify for the low volume opt-out may still choose to participate in the Model, as our data show that many of these RT providers and RT suppliers may see increased payments (compared to historical payments) and improvements in quality of care under the RO Model despite having a low volume of episodes. Thus, we believe it is important to allow them the option of participating in the RO Model if they so choose.

Prior to the start of each RO Model PY, we will identify which RO participants would be eligible to opt out of the Model (including the RO Model payments and participation requirements) based on the most recently available claims data. For PY1 (January 1, 2021, through December 31, 2021), we will use 2019 episode data, for PY2 (January 1, 2022 through December 31, 2022), we will use 2020 episode data, and so on. The most current episode data is two years removed from the period to which it applies for two reasons. First, as described in the pricing methodology section in section C.III.6, if an RO episode straddles calendar years, the RO episode and its claims are counted in the calendar year for which the initial treatment planning service is furnished. This means that an RO episode could carry 89 days into the next performance year. Second, we will allow for at least one month of claims run-out after all RO

episodes have been completed. A longer claims run-out is not necessary since the low volume opt-out is based on a count of complete episodes and not on volume of services during those RO episodes. For these reasons, the most current episode data is two years removed from the period to which it applies. Broadening the assessment period to multiple years would even further remove the opt-out option from current practice patterns.

We will use only the most recent year with available claims data rather than a 3-year baseline to identify low-volume RO participants. This policy would allow us to better recognize low-volume RO participants over time and avoid creating a permanent opt out for new entities. At the same time, we want to minimize the possibility that RT providers and RT suppliers would have an incentive to create a new billing identifier each year to get out of the Model. Thus, we would monitor for this scenario by examining whether new TINs/CCNs in the Model geographic area have the same address as a previous TIN/CCN to ensure that our policy is serving its intent.

Eligibility for the opt-out option will be assessed annually. A participant may qualify for the opt-out option in one performance year, but not in another. At least 30 days prior to the start of each PY, we will notify participants eligible for the opt-out option as it concerns that upcoming PY. Those RO participants eligible to opt-out of the RO Model must attest to the intention of opting out of the Model prior to the start of the applicable PY (that is, on or before December 31 of the prior PY in which the opt-out would occur). We will provide further instructions on submitting this attestation through subregulatory channels of communication, such as model-specific webinars, and the RO Model website. This process would be repeated prior to each performance year of the Model. This could result in some RO participants being eligible for the opt-out option in some years and not others, that is, an RO participant could be able to opt out in one year and then be required to participate in the subsequent year. We will

notify participants to remind them to verify their eligibility for the opt-out option prior to each performance year.

d. Geographic Unit of Selection

We proposed at 84 FR 34495 through 34496 that the geographic unit of selection for the RO Model would be OMB's Core-Based Statistical Areas (CBSAs). Due to geographic data limitations on Medicare claim submissions, we proposed to link RT providers and RT suppliers to a CBSA by using the five-digit ZIP Code of the location where RT services are furnished. This will permit us to identify RO participants (see section III.C.3.c of the proposed rule and this final rule for a discussion of RO Model participant exclusions for the RT providers and RT suppliers we proposed to exclude from this Model) while still using CBSA as a geographic unit of selection. We proposed to codify the term "Core-Based Statistical Area (CBSA)" at § 512.205 of our regulations.

The proposed rule explained that CBSAs are delineated by the Office of Management and Budget and published on Census.gov.[26] 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). CBSAs are ideal for use in statistical analyses because they are sufficiently numerous to allow for a robust evaluation and are also large enough to reduce the number of RO participants in close proximity to other RT providers and RT suppliers that would not be required to participate in the Model. CBSAs do not include the extreme rural regions, but there are very

[26] See OMB Bulletin No. 18-04 entitled "Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas," https://www.census.gov/programs-surveys/metro-micro/about/omb-bulletins.html

few RT providers and RT suppliers in these areas such that, if included, the areas would likely not generate enough episodes to be included in the statistical analysis; further, CBSAs do contain rural RT providers and RT suppliers as designated by CMS and Health Resources and Services Administration (HRSA). Therefore, CBSAs would capture the diversity of RT providers and RT suppliers who may be affected by the RO Model, and, consequently, we did not propose to include non-CBSA geographies in the RO Model test.

However, as noted in the proposed rule, most RT providers and RT suppliers may not know in what CBSA they furnish RT services. In order to simplify the notification process to inform RT providers and RT suppliers whether or not they furnish RT services in a CBSA selected for participation, we 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 for participation and CBSAs selected for comparison under the Model.

As explained in the proposed rule, not all five-digit ZIP Codes fall entirely within OMB delineated CBSA boundaries, resulting in some five-digit ZIP Codes assigned to two different CBSAs. Approximately 15 percent (15%) of five-digit ZIP Codes have portions of their addresses located in more than one CBSA. If each ZIP Code was assigned only to the CBSA with the largest portion of delivery locations in it, about 5 percent of all delivery locations in ZIP Codes would be assigned to a different CBSA. Rather than increase health care provider burden by requiring submission of more detailed geographic data by RT providers and RT suppliers, we 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 event that

the portion of total addresses within the five-digit ZIP Code is equal across CBSAs and cannot be used to make the link, we proposed that the greater portion of business addresses would take precedence to link the five-digit ZIP Code to the CBSA.

We proposed to use a five-digit ZIP Code to CBSA crosswalk found in the Housing and Urban Development (HUD) ZIP to CBSA Crosswalk file[27] to link each five-digit ZIP Code to a single CBSA. The HUD ZIP to CBSA Crosswalk file lists the ZIP Codes (which come from the United States Postal Service) that correspond with the CBSAs (which are Census Bureau geographies) in which those ZIP Codes exist, allowing these two methods of geographic identification to be linked.

We indicated in the proposed rule that we believed that linking a five-digit ZIP Code to a single CBSA would not substantially impact statistical estimates for the RO Model. In addition, we believed that using a service location's five-digit ZIP Code to determine whether an RT provider or RT supplier must participate in the Model will avoid potential RT provider or RT supplier burden by avoiding an additional requirement that they submit claims using more detailed geographic information. We proposed to provide a look-up tool that includes all five-digit ZIP Codes linked to CBSAs selected for participation in accordance with our selection policy described in this final rule. This tool will be located on the RO Model website, as proposed.

In the proposed rule, we discussed how using CBSAs to identify RO participants would enable CMS to analyze groups of RT providers and RT suppliers in areas selected to participate in the Model and compare them to groups of RT providers and RT suppliers not participating in

[27] Datasets and documentation for HUD USPS Zip Code Crosswalk Files (which includes the previously mentioned HUD ZIP-CBSA crosswalk file) can be found here: https://www.huduser.gov/portal/datasets/usps_crosswalk.html

the Model (84 FR 34496). To the extent that CBSAs act like or represent markets, these group analyses would allow CMS to observe potential group level, market-like effects. We have found group level effects important as context for understanding the results of other models tested under section 1115A of the Act. For example, stakeholders questioned whether a model changed the overall volume of services related to the specific model in a given area. As noted in the proposed rule, we will not be able to address this issue for the RO Model without using a geographic area as the unit of analysis.

With respect to selecting CBSAs for participation and comparators under the Model, we proposed to use a stratified sample design based on the observed ranges of episode counts in CBSAs using claims data from calendar years 2015-2017. We proposed to 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[28] test of the Model is reached. We noted that the primary purpose of the evaluation is to estimate the impact of the Model across all participating organizations. Larger sample sizes decrease the chances that the evaluation will produce mistakes, that is, show 'no effect' when an effect is actually present (for example, when a smoke detector fails to sound an alarm even though smoke is actually present) or show 'an effect' when no effect is actually present (for example, when a smoke detector is sounding an alarm that suggests smoke is detected when actually no smoke is present). Given that we proposed to sample approximately 40 percent of all eligible RO episodes in eligible CBSAs nationwide (as discussed in section III.C.5 of the proposed rule and this final rule), we believe we should be sufficiently powered (that is, the sample size and the expected size of the effect of

[28] 'Robust' in statistical terminology means that we can have high confidence in the test results under a broad range of conditions, for example, lower quality data, a shortened test period, or other unexpected complications.

the Model are both large enough at a given significance level) to confidently show the impact of the Model. The comparison group would consist of RT providers and RT suppliers from randomized CBSAs within the same strata as the selected RO participants from the participant group, resulting in a comparison group of an approximately equal number of CBSAs and episodes as in the participant group that would allow for the effects of the RO Model to be evaluated. We proposed that strata would be divided into five quintiles based on the total number of episodes within a given CBSA. The stratification would improve the balance between the CBSAs selected for participation and the CBSAs selected for comparison by limiting uneven numbers of RT provider and RT supplier and episodes within the CBSAs selected for participation and of CBSAs selected for comparison that could result from a simple random sample. We proposed that if a CBSA were randomly selected to the participant group, then the RT providers and RT suppliers who furnish RT services in that CBSA selected for participation would be RO participants. If the CBSA were randomly assigned to the comparison group, then the providers and suppliers who furnish RT services in that CBSA selected for comparison would not be RO participants, but the claims they generate and the episodes constructed from those claims would be used as part of the RO Model's evaluation.

As discussed in the proposed rule, after determining the sampling framework, we conducted the necessary power calculations (statistical tests to determine the minimum sample size of the participant and comparison groups in the Model, designed in order to produce robust and reliable results) using Medicare FFS claims from January 1, 2015 through December 31, 2017, to construct episodes and then identify a sufficient sample size so that results would be precise and reliable. We stated in the proposed rule that we determined that approximately 40 percent of eligible episodes (as discussed in section III.C.5 of the proposed rule and this final

rule) in eligible CBSAs nationally would allow for a rigorous test of the RO Model that would produce evaluation results that we can be confident are accurately reflecting what actually occurred in the Model test. We also stated that this size would limit the number of episodes expected in the participant group to no more than is needed for a robust statistical test of the projected impacts of the Model.

The proposed rule explained that using randomly selected stratified CBSAs would ensure that the CBSAs selected for participation and CBSAs selected for comparison each contain approximately 40 percent of all eligible episodes nationally. We proposed that the CBSAs selected for comparison would be used to evaluate the impact of the RO Model on spending, quality, and utilization. Further, we proposed that CBSAs would be randomly selected and the ZIP Codes linked to those CBSAs selected for participation would be published on the RO Model website once the final rule is displayed.

The following is a summary of comments we received related to the proposed geographic unit of selection and our responses to those comments:

Comment: A couple of commenters believed that approximately 40 percent of episodes constituted more than a test and a few requested a reduction in the scale of the proposed Model. CMS received many comments related to the proposed size of the RO Model, where CMS proposed to include approximately 40 percent of episodes in the Model. All of the commenters who submitted feedback on this issue were opposed to the size of the Model, and many commenters suggested that the size of the Model should be decreased from approximately 40 percent of all eligible episodes annually. These commenters suggested many alternatives to CMS' proposal to include approximately 40 percent of all eligible episodes, most of which

suggested a range of 7 percent to 25 percent of episodes to be included in the Model; some suggested a gradual phase in of additional RO participants over the course of the Model.

Response: Incorporating some public commenters' request for a reduced size of the Model while ensuring sufficient sample for a robust evaluation, we have determined that a reduced scale from approximately 40 percent of eligible episodes to approximately 30 percent of eligible episodes, is sufficient to produce robust evaluation results for the finalized Model. By requiring approximately 30 percent of eligible episodes to be included in the Model, we expect to be able to detect a savings of 3.75 percent or greater at a significance level of 0.05 and with a power of 0.8.

Based on the comments received, we are finalizing 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. We note that this decision is supported by additional power calculations incorporating updated episode data from 2016-2018 FFS claims data that was not available for reliable analysis at the time of the proposed rule but became available during the fall of 2019 in order to confirm the appropriateness of the minimal sample size that would incorporate the finalized design of the RO Model.

Comment: Many commenters were opposed to mandatory participation of RT providers and RT suppliers located in a random sample of core-based statistical areas (CBSAs). A commenter was concerned that random selection of participants did not account for vulnerable beneficiary populations or vulnerable providers and suppliers. Another commenter expressed concern on the potential of certain RT provider and RT supplier sites being selected in the Model and the potential payment reductions they may face due to the Model, which would prevent them from subsidizing more rural locations which currently do not cover the costs of care.

Response: As we explained in the proposed rule and this final rule, due to concerns about a voluntary model being subject to: (1) selection bias from limited to no participation from HOPDs; (2) an even larger geographic scope requirement for a model with optional participation to account for the projected bias and lower participation rates; (3) the ability of such a model with optional participation to achieve savings; and (4) a reduced likelihood of reliably detecting change to support Model expansion, we proposed to require participation of RT providers and RT suppliers located in a random sample of core-based statistical areas (CBSAs). Mandatory participation among randomly selected providers and suppliers ensures that the evaluation results about the RO Model will be robust (both reliable, in that the effects in savings we would see are not due to chance and not biased due to selection of participants that are not representative of all RT providers and RT suppliers), so that these results can provide for the Chief Actuary of CMS to certify that expansion of the Model would reduce (or would not result in any increase in) net program spending in the future if the Department chooses to pursue expansion under 1115A(c) of the Act. Therefore, we will not be modifying our proposal to randomly select CBSAs to identify RT providers and RT suppliers that are required to participate in the Model through a stratified sample design.

The well-being of potentially vulnerable patients is always of primary concern to CMS. As such, we will examine and monitor vulnerable populations and providers and suppliers for any unintended consequences of the random selection of RO participants in the Model. CMS expects that the payments to providers and suppliers under the RO Model will appropriately cover the costs of standard operations and profits for RT providers and suppliers. We appreciate the possibility of instances where RT providers and suppliers are cross-subsidizing finances from high-earning locations to lower-earning locations, but this is not directly under CMS control –

these are external financing practices which CMS does not have authority over. HHS has additional programs which provide help with financing for potentially vulnerable populations and providers and suppliers (such as HRSA programs for the vulnerable and underserved). Additionally, for certain low volume RT providers and RT suppliers, we are providing a low volume opt-out option, as discussed in section III.C.3.c of this final rule.

Comment: Some commenters expressed concern that the use of Core-Based Statistical Areas (CBSAs) to identify RO participants could result in unintended consequences, such as picking 'winners and losers' in markets. These comments largely focused on 'patient overlap' and the potential incentive for patients to travel, depending on the patient's preference, in order to see a RT provider or RT supplier who either is an RO participant or a RT provider or RT supplier not selected to participate in the Model. Comments appeared to suggest that all RT providers and RT suppliers in a particular market be selected to be RO participants or not. A commenter stated that patients could be negatively impacted by the Model as beneficiaries seeking RT services in included ZIP Codes must also participate in the Model or travel to a geographic area not included in the Model for care (regardless of their ability to do so). A commenter was worried about the potential differences between CBSAs selected for participation and CBSAs selected for comparison with respect to treating prostate cancer if there was an uneven incidence of prostate cancer cases between RO participants and comparators – the comment cited the 'greater levels of technology', such as IMRT (intensity-modulated radiation therapy) that is often used to treat prostate cancer. The commenter was similarly concerned with the potential for lower-risk patients to be used as a benchmark in comparison CBSAs while higher-risk patients would be in the CBSAs selected for participation, particularly with regards to race.

One commenter fully agreed with proposed geography-based randomization process, stating that the proposed process was fair and unbiased. A commenter suggested that site-neutral payments be applied to all RT providers and RT suppliers and not restrict this payment change to the proposed approximately 40 percent of CBSAs selected for participation.

Response: In designing the Model, a driving principle for us was patients being able to continue to access high-quality care. As we stated in the proposed rule and in this final rule, there are tradeoffs to consider in the design of a Model with respect to the unit of selection. The mixture of concern and support for the proposed design as expressed through the comments described here is further evidence of those tradeoffs.

We do not have data that definitively delineates markets for RT services. However, we believe by adopting CBSAs as proxies for those markets that we will achieve a reasonable balance among the tradeoffs raised by commenters and discussed in the proposed rule. To the extent that CBSAs act like or represent markets, these group analyses would allow CMS to observe potential group level, market-like effects. We have found group level effects important as context for understanding the results of other models tested under section 1115A of the Act. Please see section III.C.3.d for a discussion of CBSAs as markets due to their high degree of social and economic integration. Because CBSAs can yield market-like effects, CMS believes that CBSAs are the best available option for selection of RT participation.

We shared the concerns with commenters that selection of some CBSAs may create specific situations, such as a health system having practices in multiple locations and/or those located near the border of a CBSA. We understand the concern that the Model could potentially result in health systems having both RO participants and non-participants, as this could produce additional burden for these systems in terms of billing and the ability to manage patients. This

issue is one such tradeoff in the design of the Model. We determined that some systems would have locations providing RT services that experience the Model conditions as an RO participant and other locations providing RT services that are not RO participants. We chose CBSAs to attempt to minimize the number of such occurrences. We would also like to note 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.

We believe that using stratified randomization will minimize potential selection problems and unintended consequences, including other potential imbalances in cancer type (and corresponding modality) or patient risk. We can identify and account for observed imbalances that may result from randomized selection in the evaluation. The Model (and its exclusions) were designed to minimize the potential consequences. We are finalizing the adoption of CBSAs as the geographic unit of selection in the RO Model.

We seek to support Medicare patients' rights to seek care wherever they choose. We do not believe that the changes in health care provider payments in the RO model would justify or lead to beneficiaries travelling to entirely different CBSAs to seek RO care, which involves frequent treatments over a short period. We designed the model with CBSAs to prevent RO participants from shifting patients who require more expensive care to a site of service which would not be included in the RO Model. The CBSAs selected for participation will be in distinctive locations, and we believe the potential effects on patient costs would not substantial. Based on these facts and the frequency needed for radiation therapy treatments, we do not believe that the RO Model would create an incentive for beneficiaries to avoid RO participants. In other words, we do not believe that the RO Model would create a situation where beneficiaries systematically choose to receive RT services from an RT provider or supplier that they would

not otherwise seek care from in absence of the model. We believe the compensation we are providing under this Model is fair and this should not affect where beneficiaries seek RT services.

The RO Model's inclusion of approximately 30 percent (or a greater percent) of all RT providers and suppliers for a finite period of time does not constitute a program change but a model test. In order to test the effect of payments in the RO Model to determine whether they reduce cost while maintaining and/or improving quality of care and patient outcomes, we believe using both a case (participant) and control (non-participant) will provide the most meaningful comparison. We have designed the Model to include a limited sample size (that is, approximately 30 percent of eligible episodes nationwide), while ensuring both sufficient sample size and power to produce robust data that can provide evidence to certify the Model in the future if the Department chooses.

Comment: A few commenters encouraged us to allow public comment on the particular CBSAs selected for participation in the RO Model.

Response: We appreciate the commenters' concerns regarding an opportunity to comment on particular CBSAs selected for participation, but these comments fall outside the scope of our proposed policy. We would like to clarify that we will use the most recently available HUD USPS ZIP Code Crosswalk Files (https://www.huduser.gov/portal/datasets/usps_crosswalk.html#data) to link a new five-digit ZIP Code to a CBSA in the manner as described in section III.C.3.d. Currently, the HUD USPS ZIP Code Crosswalk Files are updated quarterly. If the most recently available HUD USPS ZIP Code Crosswalk File links any additional five-digit ZIP Codes to the CBSAs selected for participation, we will add those ZIP Codes to the ZIP Codes included under the Model. The look-up tool that

includes all of the five-digit ZIP Codes linked to CBSAs selected for participation will be updated with the additional ZIP Codes. Once a five-digit ZIP Code is assigned to a CBSA selected for participation under the Model, it will not be removed from the list of included ZIP Codes.

Comment: A couple of commenters were concerned that the Model design had the potential not to include a sufficient number of proton beam therapy (PBT) centers to be able adequately detect the impact of the Model on proton centers in isolation.

Response: The evaluation of the RO Model will be primarily interested in the impacts of the Model on the overall spending and quality of care across all included RT services at the population level, and not the effects on one RT modality compared to another. While some future evaluation analyses may include differences in costs and quality by modality, we will make no impact estimates on cost nor quality where we do not have suitable sample size of practices or episodes among the participants and non-participant comparators, understanding that any differences we may observe will be observational and not causative.

Comment: A commenter requested that CMS should publish online an explicit list of excluded RT providers and RT suppliers, including their names, addresses, and NPIs to ensure there's no confusion about excluded providers and suppliers. This commenter further stated that it is important for Professional participants to have a CMS-approved list that clearly indicates which RT providers and RT suppliers are excluded despite the fact that they are located within a ZIP Code selected for the RO Model.

Response: We appreciate the commenter's suggestion. A look-up tool that includes all of the five-digit ZIP Codes linked to CBSAs selected for participation in accordance with our finalized selection policy described in this final rule is located on the RO Model website

(https://innovation.cms.gov/initiatives/radiation-oncology-model/). This tool will allow included entities that furnish RT services to identify if they are included or excluded from the RO Model based on their site of service. We will refrain from including personal identification information of specific physicians in the release of the RT providers and suppliers selected to participate. We believe that relevant entities within selected participating ZIP Codes will already be aware if they meet the exclusion criteria for the Model (for example, if they whether they are PPS-exempt cancer hospitals, critical access hospitals (CAHs), or are located within certain exclude states (Maryland, Vermont, U.S. Territories) or are participating in or eligible to participate in the Pennsylvania Rural Health Model as codified at § 512.210. However, any entity who may want to confirm their exclusion will be free to contact the RO Model help desk (RadiationTherapy@cms.hhs.gov).

Comment: A commenter has requested that we select patients randomly to be included in the Model.

Response: The Model design is such that RO participants will be selected through randomized CBSAs: those CBSAs selected for participation and CBSAs selected for comparison. The Model is not designed to randomly select patients from within selected RO participants. CMS chose not to design the RO Model to randomly select patients as this would have created a much greater burden, administratively and operationally, for RT providers and suppliers who see both participating and non-participating beneficiaries within a single site of care who would then need to operationalize 2 different billing systems (one for participating beneficiaries, one for non-participating beneficiaries) within that one site. Additionally, if the sample size (approximately 30 percent of episodes) were calculated at the beneficiary level (rather than RT provider and supplier level), a substantially greater number of RT providers and

suppliers would be included as RO participants to reach the necessary approximately 30 percent sample size. We are finalizing as proposed that patients will be RO beneficiaries if they receive included RT services from an RO participant. The Model will be finalized using the proposed random selection of CBSAs as the method of determining an RT provider's or RT supplier's participation (or not) in the model.

After considering public comments, we are finalizing with modification our proposed provisions on the RO Model's geographic unit of selection. Specifically, we are codifying at § 512.210(d) that we will randomly select CBSAs to identify RT providers and RT suppliers to participate in the Model through a stratified sample design. However, instead of allowing for participant and comparison groups to contain approximately 40 percent of all eligible episodes in eligible geographic areas as we had proposed, we are modifying this provision in the final rule allowing for participant and comparison groups to contain approximately 30 percent of all eligible episodes in eligible geographic areas (that is, CBSAs). The sample size was calculated incorporating the final parameters of the model, and we are using a sample size that we believe is necessary to detect the anticipated impact of the model. Therefore, we are finalizing that approximately 30 percent of eligible episodes will be randomly selected for this Model. For the final rule, we used 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

In the proposed rule at 84 FR 34496, we proposed that a Medicare FFS beneficiary would be included in the RO Model if the beneficiary:

● Receives included RT services in a five-digit ZIP Code, linked to a CBSA selected for participation, from an 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 an RO participant, the beneficiary:

++ Is eligible for Medicare Part A and enrolled in Medicare Part B; and

++ Has traditional Medicare FFS as his or her primary payer.

In addition, we 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 an 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 in a Medicare hospice benefit period;[29] or

• Is covered under United Mine Workers.

We explained in the proposed rule that the RO Model will evaluate RT services furnished to beneficiaries who have been diagnosed with one of the cancer types identified as satisfying our criteria for inclusion in the Model, as discussed in section III.C.5.a of the rule (84 FR 34496 through 34497). Thus, we stated that we believed it would be necessary to include only beneficiaries who have at least one of the identified cancer types and who also receive RT services from RO participants. We also stated that a key objective of the RO Model is to evaluate if and/or how RT service delivery changes, in either the HOPD or freestanding radiation

[29] Please note that this was incorrectly stated in the section III.C.4 of the preamble to the Notice of Proposed Rulemaking, as "Is not in a Medicare hospice benefit period" (at 84 FR 34496), but was correctly stated in the proposed regulatory text at 84 FR 34585. It has been corrected in the preamble to this Final Rule to "Is in a Medicare hospice benefit period."

therapy center setting, as a result of a change in payment systems from FFS to prospectively determined bundled rates for an episode. We proposed these criteria in order to limit RT provider and RT supplier participation in the RO Model to beneficiaries whose RT providers and RT suppliers would otherwise be paid by way of traditional FFS payments for the identified cancer types. We discussed our belief that these eligibility criteria for RO beneficiaries are necessary in order to properly evaluate this change with minimal intervening effects in the proposed rule.

We proposed to define a beneficiary who meets all of these criteria, and who does not trigger any of the beneficiary exclusion criteria, a "RO beneficiary". We proposed to codify the terms "RO beneficiary," "RT provider," and "RT supplier" at § 512.205.

In addition, we 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 of the beneficiary inclusion criteria. The proposed rule provides that we would consider routine costs of a clinical trial to be all items and services that are otherwise generally available to Medicare beneficiaries (that is, there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial.[30] Medicare pays routine costs by way of FFS payments, making it appropriate to include RT services furnished for RO episodes in this case under the RO Model.

We stated that the RO Model's 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

[30] The current Medicare policy on routine cost in clinical trials is described in Routine Costs in Clinical Trials 100-3 section 310.1.

the 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 as discussed in section III.C.6.i of this final rule. Beneficiaries do have the right to choose to receive RT services in a geographic area not included in the RO Model.

We explained in the proposed rule, at 84 FR 34497, that if an RO beneficiary stops meeting any of the eligibility criteria or triggers any of the exclusion criteria before the TC of an episode initiates, then the episode would be an incomplete episode as discussed in section III.C.6.a of the proposed rule (84 FR 34503 through 34504) and this final rule. Payments to RO participants would be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process, as described in section III.C.11 of the proposed rule and this final rule. We proposed that if traditional Medicare stops being an RO beneficiary's primary payer after the TC of the episode has been initiated, then regardless of whether the beneficiary's course of RT treatment was completed, the 90-day period would be considered an incomplete episode, and the RO participant would receive only the first installment of the episode payment. In the event that a beneficiary dies or enters hospice during an episode, then the RO participant would receive both installments of the episode payment, regardless of whether the RO beneficiary's course of RT has ended (see section III.C.7 of the proposed rule and this final rule).

We proposed these beneficiary eligibility criteria for purposes of determining beneficiary inclusion in and exclusion from the Model. The following is a summary of comments received related to our proposal on the RO Model's beneficiary population and our responses to those comments:

Comment: A few commenters requested that all patients enrolled in clinical trials should be excluded from the RO Model. One of these commenters also stated that some Medicare

contractors provide exceptions to providers and suppliers with a history of evidence development and they suggested that the Innovation Center consider this as a basis for exclusion as well.

Response: We thank the commenters for their suggestions. Medicare pays routine costs by way of FFS payments for Medicare beneficiaries participating in clinical trials when there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision, making it appropriate to include these beneficiaries in the RO Model provided that such beneficiary meets all of the proposed beneficiary inclusion criteria. It is important that the RO Model include clinical trials because the goal of the Model is to test whether prospective episode payments for RT services, in lieu of traditional FFS payments, would reduce Medicare expenditures. Therefore, not including clinical trials that are paid through FFS could skew the Model results. With regard to the commenter who suggested that the Innovation Center provide exceptions to providers and suppliers with a history of evidence development, we appreciate the suggestion, however, we believe that less experienced RO participants will benefit from this type of experience through peer-to-peer learning activities and performance reports that will allow for comparison between participants. We also believe that including providers and suppliers with all levels of experience would result in a more robust data set for evaluation of the RO Model's prospective payment approach. We will continue to monitor the Model for a need of this exception in the future.

Comment: A commenter suggested that CMS should open the RO Model to voluntary participation by Medicare Advantage plans and other payers. This commenter stated that limiting the RO Model to Medicare fee-for service would miss an opportunity to allow as many health care providers and payers as possible to explore and assess innovative approaches to delivering care under a bundled payment model.

Response: At this time, we are finalizing as proposed that the RO Model will include only Medicare fee-for-service beneficiaries receiving RT services by RO Participants. This Model was designed to test an alternative payment approach instead of FFS, and is therefore limited to only Medicare FFS beneficiaries and does not include other payers like Medicare Advantage. As we discussed in the NPRM, a key objective of the RO Model would be to evaluate if and/or how RT service delivery changes in either the HOPD or freestanding radiation therapy center setting as a result of a change in payment systems from that of FFS under OPPS or PFS, respectively, to that of prospectively determined bundled rates for an episode as described in section III.C.6.c. We proposed these beneficiary criteria in order to limit participation in the RO Model to beneficiaries whose RT providers and/or RT suppliers would otherwise be paid by way of traditional FFS payments for the identified cancer types. We believe that these eligibility criteria for RO beneficiaries are necessary in order to properly evaluate this change with minimal intervening effects; therefore, we are not including additional payers such as Medicare Advantage to the RO Model in this final rule. We recognize that other payers may be conducting similar alternative payment models. Other payers who are interested in testing an alternative payment system to FFS are welcome to align with our RO Model methodologies. However, we are not soliciting formal partnerships with other payers at this time.

Comment: Another commenter requested clarification on what will happen if a patient joins a Medicare Advantage plan during the fall open enrollment period while in an RO episode. This commenter expressed concern that both systems will assume the other will pay.

Response: In this scenario, if Medicare FFS stops being the primary payer during the 90-day episode, this would be considered an incomplete episode. Please refer to section III.C.6.a of

the proposed rule (84 FR 34503 through 34504) and this final rule for an overview of our incomplete episode policy.

Comment: A commenter stated that patients should always have a choice in their care, and therefore a patient opt-out provision is warranted just as it is in the OCM.

Response: As we stated in the proposed rule, the RO Model's design will not allow RO beneficiaries to "opt out" of the Model's pricing methodology as described in section III.C.6 of the proposed rule, as well as this final rule. Of note, this policy is the same as in OCM, where beneficiaries who receive care from an OCM participant have the same Medicare rights and protections, including the right to choose which health care provider they see, and they may choose a health care provider who does not participate in the OCM. However, just as in OCM, this Model protects beneficiary choice because beneficiaries have the right to choose to receive RT services from a RT provider and/or RT supplier not included in the RO Model.

Comment: A commenter supported the participant criteria with the exception of excluding those in a Medicare hospice benefit (MHB) period. This commenter stated that such patients may benefit from RT services as a palliative measure and so should be allowed to participate in this Model if so. They further stated that while they agreed this is a reimbursement issue for hospices, palliative radiation is by its nature not curative and so should be covered under the MHB, at least for those people with cancer participating in this Model.

Response: We thank the commenter for their recommendation. Medicare beneficiaries will be excluded from the RO Model if they are in a MHB period at the start of their receipt of RT services, because the MHB is not paid FFS. As we previously stated, the goal of the RO Model is to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures; therefore, it is important that non-FFS

beneficiaries be excluded in order to properly evaluate the results of the Model. Traditionally, if a beneficiary receives RT services during a MHB period, the cost of the treatment would be covered under the Medicare hospice per diem. The RO Model allows for RO Model payments to continue (in addition to the Medicare hospice per diem) if a beneficiary selects MHB during an RO episode so as not to dissuade RO participants from making a hospice referral when needed. The Medicare hospice agency will not be responsible for the cost of RT services in this case. This RO Model policy does not intend to imply that the MHB should pay for curative treatment. While we understand the commenter's concern, we will not be creating an exemption of this nature at this time.

Comment: A commenter requested clarification on the definition of an RO beneficiary, specifically they would like clarification on what happens if a patient starts an episode with inpatient treatment and then changes to an outpatient setting, and if a patient changes ZIP Codes during the course of treatment.

Response: To the commenter's question regarding moving from inpatient treatment to outpatient treatment, if a beneficiary starts 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.

For the commenter's question about a patient changing ZIP Codes during the course of treatment, we note that the ZIP Codes are relevant only to the location of the RO participant, not the residence of the beneficiary. If the beneficiary with an included cancer type receives included professional and technical services from one or more RO participants located in one or more ZIP Codes linked to CBSAs selected for participation, then the beneficiary will be an RO beneficiary. If the beneficiary receives professional RT services from an RO participant in a ZIP

Code linked to CBSAs selected for participation, but receives technical RT services from non-participants (or vice versa), the beneficiary will not be in the Model, and this will be an incomplete episode as defined at § 512.205 and as further described in section III.C.6.a of this final rule. Payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process, as described in section III.C.11 of this final rule.

Comment: A commenter did not support our proposal regarding the beneficiaries that will be included and excluded from the RO Model. This commenter stated that linking beneficiaries by ZIP Code could create adverse selection and skew the results of the Model. This commenter requested clarity on whether inclusion and exclusion is linked to the beneficiary's address being in the ZIP Code or the address of the RO participant. This commenter also requested clarification about whether the RO participant is responsible for the entire ZIP Code even if the beneficiary goes out-of-area.

Response: We are clarifying that a beneficiary's address does not determine his or her inclusion in the RO Model, rather it is determined by the address where the RO participant furnished the included RT services. Nor did we propose to link beneficiaries by ZIP Code. Regarding the requested clarification about whether the RO participant is responsible for the entire ZIP Code even if the beneficiary goes "out-of-area", we take the commenter's reference to a beneficiary going "out-of-area" to mean that the beneficiary has switched providers and stopped receiving RT services from the RO participant that initiated the RO episode. This would be considered an incomplete episode. We also note that in the case of incomplete episodes, RO participants are owed beneficiary coinsurance payment of 20 percent of the FFS amounts that would have been paid in the absence of the RO Model, except when the RO beneficiary ceases to

have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier. In that case, the RO participant would be owed beneficiary coinsurance payment would equal 20 percent of the first installment of the episode payment amount. See III.C.6.a of the proposed rule (84 FR 34503 through 34504) and this final rule for an overview of our incomplete episode policy. Payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process, as described in section III.C.11. of this proposed rule.

Comment: A commenter requested clarification about what will occur if a beneficiary refuses to participate in the Model by notifying CMS in writing after treatment is started and the start of episode (SOE) HCPCS is submitted to CMS.

Response: We would like to clarify that under this Model, RO beneficiaries will not provide direct notification to CMS when they do not wish to participate in the Model. If a beneficiary does not wish to "participate" in the Model, (s)he can seek treatment from a non-participant. The notification that we believe this commenter is referring to is in cases where beneficiaries do not wish to have their claims data shared with the RO participant for care coordination and quality improvement purposes under the Model. In such cases, the RO participant must notify CMS in writing within 30 days of when the RO beneficiary notifies the RO participant (see section III.C.15 of the proposed rule and this final rule for more details on this policy).

Comment: A commenter was concerned with the potential for adverse health outcomes for certain vulnerable populations defined by race, income, and the presence of prostate cancer under the Model.

Response: The evaluation of the RO Model will be taking into account, to the extent feasible, any potential adverse health outcomes, and any underlying differences in patient characteristics, severity, and the related differences in technology in the monitoring and evaluation of this Model.

After considering public comments, we are finalizing our proposal on the beneficiary population with modification. We have made additional non-substantive changes to the proposed provisions at § 512.215 in this final rule to improve readability. Specifically, we are finalizing, with modification, the RO Model beneficiary inclusion criteria as codified at § 512.215(a) and illustrated in Figure A. We have made additional non-substantive changes to the proposed provisions at § 512.215 in this final rule to improve readability. We are also finalizing with modification at § 512.215(a) that an individual is an RO beneficiary if the individual receives included RT services from an RO participant that billed the SOE modifier for the PC or TC of an RO episode during the Model performance period for an included cancer type. An individual is an RO beneficiary if, at the time that the initial treatment planning service of an RO episode is furnished by an RO participant, the individual is eligible for Medicare Part A and enrolled in Medicare Part B, the individual has traditional FFS Medicare 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), and if the individual is not in a MHB period. We are further finalizing with modification at § 512.215(b) that any individual enrolled in a clinical trial for RT

services for which Medicare pays routine costs will be an RO Beneficiary if the individual satisfies all of the beneficiary inclusion criteria codified at § 512.215(a).

Additionally, we are finalizing as proposed to codify the terms "RT provider," and "RT supplier" at § 512.205. We are finalizing, 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.

**Figure A: Finalized RO Beneficiary Inclusion Criteria**

| |
|---|
| The individual receives included RT services:<br>• from an RO participant that billed the 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:<br>• Is eligible for Medicare Part A and enrolled in Medicare Part B<br>• 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)<br>• Is not in a Medicare hospice benefit period |

5. RO Model Episodes

We proposed that under the RO Model, Medicare would pay RO participants a site-neutral, episode-based payment amount for all specified RT services furnished to an RO beneficiary during a 90-day episode (84 FR 34497). In section III.C.5 of the proposed rule, we first explained our proposal to include criteria to add or remove cancer types under the Model and their relevant diagnoses codes in the Model as well as the RT services and modalities that would be covered and not covered in an episode payment for treatment of those cancer types.

We then explained our proposal for testing a 90-day episode and proposed the conditions that must be met to trigger an episode.

a. Included Cancer Types

We proposed the following criteria for purposes of 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.

We proposed to codify these criteria for included cancer types at § 512.230(a) of our regulation.

We proposed the following criteria for purposes of removing cancer types under the RO Model.

- 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 base rates; or
- The Secretary determines a cancer type not to be suitable for inclusion in the Model.

We proposed to codify these criteria for removing cancer types at § 512.230(b) of our regulation.

We identified 17 cancer types in Table 1: Identified Cancer Types and Corresponding ICD-9 and ICD-10 Codes of the proposed rule that met our proposed criteria. We explained in the proposed rule 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 are made up of specific ICD-9 and ICD-10 diagnosis codes. For example, as shown in Table 1 of the proposed

rule, there are cancer types for "breast cancer" and "prostate cancer," which are categorical terms that represent a grouping of ICD-9 and ICD-10 codes affiliated with those conditions. To identify these cancer types and their relevant diagnosis codes to include in the Model, we identified cancers that are treated with RT.

As described in the proposed rule, we used the list of cancer types and relevant diagnosis codes, to analyze the interquartile ranges of the episode prices across diagnosis codes within each cancer type to determine pricing stability. We chose to exclude benign neoplasms and those cancers that are rarely treated with radiation because there were not enough episodes for reliable pricing and they were too variable to pool.

We stated in the proposed rule that during our review of skin cancer episodes, we discovered that Current Procedural Terminology® (CPT®) code 0182T (electronic brachytherapy treatment), which was being used mainly by dermatologists to report treatment for non-melanoma skin cancers, was deleted and replaced with two new codes (CPT® code 0394T to report high dose rate (HDR) electronic skin brachytherapy and 0395T to report HDR electronic interstitial or intracavitary treatments) in 2016. Local coverage determinations (LCDs) that provide information about whether or not a particular item or service is covered were created and subsequently changed during this time period. Our analysis suggested that the volume and pricing of these services dropped significantly between 2015 and 2016, with pricing decreasing more than 50 percent. As a result, we did not believe that we could price episodes for skin cancers that accurately reflect the average resource utilization for an episode. Thus, skin cancer was excluded in the proposed rule.

The proposed RO Model's included cancer types are commonly treated with RT and can be accurately priced for prospective episode payments. As proposed, an up-to-date list of cancer types, upon any subsequent revisions, will be kept on the RO Model website.

We proposed to define the term "included cancer types" to mean the cancer types determined by the proposed criteria set forth in § 512.230, which are included in the RO Model test.

We proposed to maintain the list of ICD-10 codes for included cancer types under the RO Model on the RO Model website. We indicated in the proposed rule that any addition or removal of these codes would be communicated via the RO Model website and written correspondence to RO participants. We proposed to notify RO participants of any changes to the diagnosis codes for the included cancer types per the CMS standard process for announcing coding changes and update the list on the RO Model website no later than 30 days prior to each PY.

We solicited comments on the proposed cancer types included in the RO Model. The following is a summary of the public comments received on this proposal and our responses to those comments:

Comment: A couple of commenters expressed support for the inclusion of all 17 cancer types named in the proposed rule, emphasizing that it expands the benefit to the broadest population of patients. A few of these commenters stated that including all 17 cancer types would reduce the overall administrative burden on RO participants, as this scale decreases the burden associated with operationalizing a model for a few key cancer sites and not others. Other commenters emphasized that, since these 17 cancer types are commonly treated with RT services, they can be accurately priced.

Response: We thank the commenters for their support.

Comment: A commenter described how inaccurate coding could lead to misvalued episode payments and included renal cell carcinoma in one of the examples.

Response: Based on further clinical review, kidney cancer is not commonly treated with radiotherapy and as such it does not meeting the criteria for inclusion. Kidney cancer may have been included as an artifact of inaccurate coding and we are therefore excluding it from the RO Model.

Comment: Many commenters expressed concern over the inclusion of cervical cancer. A commenter suggested separate payment for each physician involved in treating cervical cancer. A few commenters recommended using the OPPS Ambulatory Payment Classification (APC) payment rates without the comprehensive APC (C-APC) methodology for the technical component of the national base rate for cervical cancer, because they believe that the C-APC OPPS methodology undervalues the brachytherapy reimbursement. Another 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. This commenter also believed that the RO Episode File misattributed episodes to cervical cancer that ought to have fallen under a different cancer type. This commenter noted episodes that are inconsistent with clinical medicine and could be only partially captured episodes, incorrectly captured delivery codes, or misattributed episodes. Regarding misattribution, the commenter stated that approximately 2 percent of cervical cancer episodes include SRS, yet since SRS is a single fraction of radiation to the brain, these episodes are likely treating a metastatic site rather than treating the primary site of cervical cancer. Regarding partially captured episodes, the commenter asserted that there are 75 episodes from the RO Episode File where fewer fractions were provided than is the established clinical approach.

Response: We believe that the national base rates represent the average of all RT services provided to beneficiaries with a given cancer type, including cervical cancer, and it is probable that there will be individual episodes where there is deviation from the standard treatment given the clinical profile of an individual patient. Our data shows that in addition to episodes with lower numbers of fractions, there are other episodes with higher numbers of fractions than is typically recommended. Over the past few years, we have repeatedly examined the C-APC methodology with regard to brachytherapy and cervical cancer and determined that it provides appropriate reimbursement. For examples, please see the CY 2020 OPPS/ASC final rule with comment period (84 FR 61163) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58843). As such, we believe that the C-APC methodology is appropriate to use in the base rate calculations for the RO Model. We will continue to examine these concerns. Please refer to the pricing methodology in section III.C.6 for further explanation of these points, including rationale related to APCs and C-APCs. We rely on Medicare providers and suppliers to furnish appropriate care to beneficiaries.

Comment: A commenter suggested adding a specific category for an isolated lymph node treated with radiation, emphasizing that this is a common clinical situation.

Response: We thank the commenter for their suggestion. However, we believe that the treatment of an isolated lymph node would likely be part of a treatment plan for an included cancer type. If it is not part of a treatment plan for an included cancer type, the treatment would be paid FFS.

Comment: A few commenters recommended that CMS remove liver cancer from the RO Model. These commenters argued that the treatments for liver cancer are not well-suited for the RO Model as treatment can involve multiple physicians. A few commenters stated that liver

cancer sometimes involves radioembolization treatment using Yttrium-90, and that this therapy frequently involves both a radiation oncologist and an interventional oncologist, most likely in the HOPD. These commenters believed that including this therapy could trigger incomplete episodes, as one physician is typically involved in planning and a second in delivery. These commenters also believed that, when the radiation oncologist triggers the episode, there would be a separate FFS payment to the interventional radiologist for their work, ultimately resulting in a higher payment from the patient.

Other commenters believed that liver cancer should be excluded from the Model, as it is uncommon for a patient to receive more than one session of brachytherapy for liver cancer, thus there is no opportunity to improve efficiency or reduce spending. A couple of commenters added that liver cancer treated with brachytherapy accounts for only 0.29 percent of all episodes included in the Model, and, therefore, any cost savings would be trivial. Another commenter suggested that this low percentage indicated that liver cancer treated with brachytherapy should fall under the "certain brachytherapy surgical services" excluded by the proposed rule due to low volume.

Response: As noted in section III.C.5.c of this final rule, we are removing Yttrium-90 from the RT services included on the list referred to as "RO Model Bundled HCPCS" (Table 2; as such, it may be billed FFS. Liver cancer meets the criteria for inclusion as a cancer type under the RO Model as codified at § 512.230(a). The RO Model is designed to be disease-specific and agnostic to treatment and modality type. Liver cancer is commonly treated with radiation and has associated current ICD-10 codes that demonstrate pricing stability. It is important to note, that when just one treatment is clinically appropriate and furnished, the RO participant will be paid more than they would have under FFS. CMS recognizes that there is no efficiency or

savings to be earned in these instances, but by including liver cancer in the RO Model we will be able to test whether prospective payments for RT services, as opposed to traditional FFS payments, would reduce Medicare expenditures while preserving or enhancing quality of care. Thus, we are finalizing our proposal to include liver cancer in the RO Model.

Comment: Some commenters recommended that CMS implement the Model with fewer cancer types. A commenter suggested that CMS limit the number of cancer types to those for which treatment protocols are the most standardized across patient cohorts and with low propensity for outlier cases. A couple of these commenters expressed concerns that the administrative burden imposed by the sheer number of included cancer types would be too much for RO participants and CMS to manage effectively. A commenter noted the variation in treatment pathways and requested that CMS consider excluding treatments that are extensive or serve as outliers. These commenters indicated that focusing on fewer cancer types would allow providers and suppliers to focus efforts on specific areas of medicine, causing less disruption to RO participants.

A few of these commenters had specific recommendations for which subset of cancer types should be included. A couple of commenters suggested targeting the most prevalent cancer types: breast, colon, lung, and prostate, as treatments for these cancers are often more homogenous and their costs are more predictable. A few other commenters recommended including only cancer types that had sufficient clinical data to support hypofractionation as clinically appropriate care. A few commenters recommended excluding complex cancer types with variable costs, such as cancers of the brain and of the head and neck. Specifically, commenters emphasized that these cancer types frequently require more complicated workup, planning, and technology than others, and must be adjusted as the tumor shrinks or the patient

loses weight. A commenter underscored that, even within these three cancer types, patients may receive treatments that vary widely in cost based on clinical indicators.

A couple of commenters suggested phasing in the 17 cancer types over time, beginning with one or two cancer types and then expanding to the full set of 17 over the Model performance period. A couple commenters suggested reducing the number of cancer types included and analyzing performance data before including all 17 cancer types from the outset of the Model.

Response: The 16 cancer types that we are finalizing for inclusion in the RO Model are cancers commonly treated with RT. The Innovation Center excluded those cancers that are rarely treated with radiation. Once an initial list of cancer types and relevant diagnosis codes were identified, the Innovation Center reviewed them for pricing stability. For example, the Innovation Center analyzed the interquartile ranges of the episode prices across diagnosis codes within cancer types. There will likely be individual episodes where there is deviation from the standard treatment given the clinical profile of an individual patient. Our data shows that, in addition to episodes with lower numbers of fractions, there are other episodes with higher numbers of fractions than is typically recommended, including but not limited to as cancers of the brain and of the head and neck. The final list includes those cancer types that are commonly treated with RT and have demonstrated pricing stability, which allows them to be accurately priced. The diagnoses selected to be included in the RO Model account for over 90 percent of episodes during the time period that was analyzed (2016-2018, as discussed in section III.C.6.d). CMS believes that phasing in the included cancer types would prevent a robust evaluation because doing so would reduce the amount of available data for any cancer types phased in at a later time. As previously stated, we believe that a Model performance period of at least 5 years

is sufficient to obtain data to compute a reliable impact estimate. Please refer to section III.C.1 of the rule for more information on the Model performance period.

Additionally, CMS believes that limiting or phasing in the number of included cancer types would be more burdensome for most RO participants. As previously noted, the included diagnoses accounted for over 90 percent of episodes from 2016 through 2018. Thus, for most RO participants, limiting or phasing in cancer types would mean that the RO Model requirements and billing guidance would apply to a subset of their RT services rather than to than to the majority of their RT services for a significant portion of the Model performance period (or if cancer types were further limited, for the entire Model performance period).

As explained earlier in this section of the final rule, we are modifying the list of included cancer types to exclude kidney cancer. We believe that including the 16 cancer types (Anal Cancer, Bladder Cancer, Bone Metastases, Brain Metastases, Breast Cancer, Cervical Cancer, CNS Tumors, Colorectal Cancer, Head and Neck Cancer, Liver Cancer, Lung Cancer, Lymphoma, Pancreatic Cancer, Prostate Cancer, Upper GI Cancer, and Uterine Cancer) that are commonly treated with RT and that can be accurately priced for prospective episode payments, is the best design for testing an episodic APM for RT services. The list of ICD-10 codes for the included cancer types under the RO Model, upon any subsequent revisions, can be located on the RO Model website.

After considering public comments, we are finalizing, without change, our proposed criteria for included cancer types and for removing cancer types at § 512.230(a) and (b) of our regulations. Additionally, we are finalizing without change at § 512.230(c) our 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 |

| Cancer Type | ICD-10 Codes |
|---|---|
| **Lymphoma** | C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x |
| **Pancreatic Cancer** | C25.xx |
| **Prostate Cancer** | C61.xx |
| **Upper GI Cancer** | C15.xx, C16.xx, C17.xx |
| **Uterine Cancer** | C54.xx, C55.xx |

b. Episode Length and Trigger

(1) Episode Length

We proposed to define the length of an episode under the RO Model as 90 days (84 FR 34498). Based on the analysis of Medicare claims data between January 1, 2014 and December 30, 2015, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. We proposed that 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. In other words, the relevant 90-day period would be considered an episode only if a Technical participant or Dual participant furnishes the TC to an RO beneficiary within 28 days of when a Professional participant or Dual participant furnishes the PC to such RO beneficiary. As we explained in the proposed rule, when those circumstances occur, the "start" of the episode would be the date of service that the initial treatment planning service was rendered. If, however, a Technical participant or Dual participant does not furnish the TC to an

RO beneficiary within the 28-day period, then no episode would have occurred and any payment will be made to the RO participant in accordance with our incomplete episode policy. (See 84 FR 34498 through 34499.) We refer readers to sections III.C.5.b and III.C.6 of the proposed rule and this final rule for an overview of our episode trigger and incomplete episode policies, respectively.

As discussed in the proposed rule (84 FR 3499), to better understand the standard length of a course of RT, we analyzed Medicare claims for beneficiaries who received any RT services between January 1, 2014 and December 30, 2015. Preliminary analysis showed that average Medicare spending for radiation treatment tends to drop significantly 9 to 11 weeks following the initial RT service for most diagnoses, including prostate, breast, lung, and head and neck cancers. Furthermore, based on this data, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. As we stated in the proposed rule, we made a summary-level, de-identified file titled "RT Expenditures by Time" available on the RO Model's website (https://innovation.cms.gov/initiatives/radiation-oncology-model/) that supports our findings in this preliminary analysis.

Based on our proposed rule analysis, for the purpose of establishing the national base rates for the PC and TC of each episode for each cancer type, episodes were triggered by the occurrence of a treatment planning service followed by a radiation treatment delivery service within 28 days of the treatment planning service (HCPCS codes 77261-77263). In addition, for the purpose of establishing the national base rates in section III.C.6.c, the episodes lasted for 89 days starting from the day after the initial treatment planning service in order to create a full 90-day episode. Based on these analyses, we proposed a 90-day episode duration.

(2) Episode Trigger

Because we only want to include episodes in which beneficiaries actually receive RT services, we 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 (as listed in the proposed rule at Table 2) is furnished by a Technical participant or a Dual participant within the following 28 days. The PC is attributed to the RT supplier of the initial radiation treatment planning service. The TC is attributed to the RT provider or RT supplier of the initial radiation treatment delivery service. As we explained in the proposed rule, an episode that is triggered will end 89 days after the date of the initial treatment planning service, creating a 90-day episode. If, however, 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, and no RO episode will have occurred, and the proposed incomplete episode policy would take effect.

In those instances where the TC of an episode is not furnished by a Dual participant (that is, when the same RO participant does not furnish both the PC and the TC of an episode), we proposed that the Professional participant would provide the Technical participant with a signed radiation prescription and the final treatment plan, all of which is usually done electronically. This will inform the Technical participant of the episode start date.

(3) Policy for Multiple Episodes and the Clean Period

Given our proposed rule findings that 99 percent of Medicare FFS beneficiaries complete treatment within 90 days of the initial treatment planning service, and to minimize any potential incentive for an RO participant to extend a treatment course beyond the 90-day episode in order to trigger a new episode, we proposed that another episode may not be triggered until at least 28 days after the previous episode has ended (84 FR 34499). This is because, while a missed week of treatment is not uncommon, a break from RT services for more than four weeks (or 28 days) generally signals the start of a new course of treatment.[31] As we explained in the proposed rule, we refer to the 28-day period after an episode has ended as the "clean period," and during this time an RO participant would bill for RT services furnished to an RO beneficiary as FFS. We proposed to codify the term "clean period" at § 512.205 of our regulations.

We proposed that if clinically appropriate, an RO participant may initiate another episode for the same beneficiary after the 28-day clean period has ended. During the clean period, an RO participant would be required to bill for RT services for the beneficiary in accordance with FFS billing rules. We proposed 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.

We solicited public comment on our proposal regarding episode length and trigger. The following is a summary of the public comments received on this proposal and our responses to those comments:

Comment: Some commenters noted their concern that the 90-day episode period would inappropriately incentivize providers and suppliers to reduce the number of fractions into the

[31] CMS was advised by radiation oncologists consulting on the design of the Model that four weeks signals the start of a new course of treatment.

shortest possible course of treatment. A commenter believed this would have negative effects on research, as encouraging providers and suppliers to opt for the shortest length of treatment possible would make it more difficult to study the optimal length of treatment for different types of patients. Another commenter suggested that this structure would disincentivize adoption of ground-breaking treatment paradigms. A few commenters requested that CMS consider the negative impact of the 90-day episode on services with higher upfront investment but longer term value. A couple of these commenters suggested that the 90-day episode period is unduly focused on short-term gains, failing to capture the medium- and long-term benefits and savings from treatment modalities like PBT. A few commenters also suggested that the financial disincentives created by the RO Model would lead to long-term adverse clinical consequences and additional spending. A commenter believed that short term savings would be outweighed by longer term costs.

Response: We appreciate commenters' concerns. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. We expect Medicare providers and suppliers to select the clinically appropriate treatment modality that will confer the greatest short-, medium-, or long-term benefit on the beneficiary. And, we believe our payment methodology, with its blend of national rates with participant-specific case mix and historical experience, will provide appropriate payment to incentivize high-value care, including the appropriate treatment modality and number of fractions. Thus, we do not believe that the Model will lead to long-term adverse clinical consequences or additional spending. We will be monitoring to ensure there are no unintended consequences.

Comment: A commenter requested clarification on whether an episode of care includes any course of treatment within 90 days or if an episode is limited to a specific diagnosis. Another

commenter requested clarification regarding billing practices for patients who, within a 90-day episode, are found to have new cancer sites with different HCPCS codes.

Response: We thank the commenter for their question. An RO episode includes all included RT services (See Table 2) furnished to an RO beneficiary with an included cancer type during the 90-day episode as codified at §§ 512.205 and 512.245. RT services furnished to an RO beneficiary for any additional diagnosis not specified on the list of included cancer types, the RT provider and/or RT supplier would bill FFS for those services.

Comment: Many commenters believed 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 couple of commenters believed that the 90-day episode structure would incentivize participants to delay care or shift patients to other treatment, waiting to capture payment for those services in the clean period or a subsequent episode. A commenter believed this might limit patient access to life-extending treatment protocols.

Response: We believe that the RO Model pricing methodology, with its reliance on historical experience and case mix adjustments, accounts for the range of patient scenarios and provides appropriate compensation to participants. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As finalized in section III.C.14, we will monitor for unintended consequences of the RO Model including but not limited to stinting on care.

Comment: Some commenters recommended that CMS reconsider its methodology in bundling multiple treatments into a single episode, factoring in the complexity of multiple eligible sites requiring treatment within a 90-day period. Some commenters specifically suggested that participants should be eligible for multiple bundles if they treat distinct disease

sites or diagnoses within a 90-day episode of care to accurately capture the costs of multiple treatments. A commenter suggested that FFS payment should be permitted for treatment of metastases within the 90-day episode as long as it is for a new site. A commenter recommended eliminating the 90-day episode to reimburse providers and suppliers for separate courses of radiation therapy within this period. Another commenter requested more information about what happens to a course of treatment for a specific diagnosis that lasts longer than 90 days.

Response: We believe that the RO Model pricing methodology, through the historical experience and case mix adjustments, will account for differences in RO participants' historical care patterns and the demographic characteristics of their patient populations and addresses the cost of treating multiple diagnoses or the cost of multiple treatments. It is important to note that, if treatment goes beyond the end of 90 days, after the RO participant bills the modifier indicating the end of an RO episode (EOE) the additional RT services furnished will be billed and paid FFS – this does not create an incomplete episode.

Comment: A couple commenters recommended that CMS tailor episode length to the likely pattern and timing of RT treatment for each cancer type.

Response: We believe that the RO Model pricing methodology will adequately reimburse participants for the patterns and timing of RT services during a uniform 90-day episode period. As previously stated, 99 percent of beneficiaries complete their RT course within 90 days. Although some cancer types might typically complete treatment in a period of time shorter than 90 days, our data shows that while significant expenditures occur through week 10 of an episode, additional expenditures occur throughout the remainder of the episode for all of the included cancer types. (See RT Expenditures by Time on the RO Model website.) As explained in section III.C.7, we have modified the billing requirements to allow the EOE claim to be submitted and

paid at the completion of a planned course of treatment, even when that course of treatment is shorter than 90 days. We believe that participants will be reimbursed for their services in an appropriate and timely manner under this structure.

Comment: A few commenters voiced concern about potential delays or breaks in therapy caused by adverse patient response or concurrent patient illness. A commenter believed that providers and suppliers could lose reimbursement for delivered services if a patient cannot tolerate treatment. A couple such commenters expressed that the breaks in treatment could extend the therapy beyond the 90-day end point, preventing timely EOE submission and resulting in an incomplete episode. This commenter recommended adjusting the EOE to the completion of the episode.

Response: Such breaks in therapy will not cause an incomplete episode. It is important to note that if treatment goes beyond the end of 90 days, the RO participant can bill the EOE and the additional RT services furnished will be billed and paid FFS.

Comment: A commenter noted that each clinical scenario is different and that physicians may have good reasons for ordering more treatment sessions with lower intensity. This commenter believed that CMS should evaluate the specifics of a clinical scenario that falls outside the expected parameters as part of the agency's data analysis.

Response: We appreciate this commenter's concerns. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. And, we believe that our cancer-specific bundles strike the right balance of capturing a range of clinical scenarios with little variability in pricing to prohibit setting a base rate. As described in section III.C.16, we will monitor for unintended consequences of the RO Model.

Comment: A commenter emphasized that the episode length could reduce the availability of palliative radiotherapy for pain control, as some evidence suggests that shorter courses of treatment lead to increased need for additional treatment and shortened pain control. Another commenter, believing that the episodes do not match standard medically accepted episodes of care, recommended that CMS create a separate category for palliative cases.

Response: Based on the analysis of Medicare claims data between January 1, 2014 and December 30, 2015, approximately 99 percent of beneficiaries receiving RT completed their course of radiation within 90 days of their initial treatment planning service. The Model does include Brain Metastasis and Bone Metastasis as included cancer types. For the other cancer types, our data shows that palliative treatment is included when RT services are being furnished to treat the primary cancer type and secondary malignancies and metastases. Thus, we will not be creating a separate category for palliative cases or altering the length of the episode.

Comment: A couple commenters expressed support of the 28-day window between the treatment planning code and the first treatment delivery service, finding this structure reasonable.

Response: We thank the commenters for their support.

Comment: A commenter requested clarification on how the planning and simulation of treatment are designated within an episode. In the event a patient receives multiple planning services prior to the commencement of treatment, this commenter wished to know which planning service would be considered the trigger and how multiple planning sessions are represented in the national base rates. A commenter expressed concern about claims processing for multiple planning services furnished within a 90-day episode for metastases identified during the episode. This commenter emphasized that the resources expended for subsequent planning sessions are equivalent to those expended in the initial planning session.

Response: The treatment planning service identified as the "first" treatment planning service is the trigger for an episode and its corresponding date of service marks the episode's start date. Subsequent planning sessions occurring within a previously defined episode are indeed included in the national base rates. Each treatment planning service furnished should be included on the no-pay claims described in section III.C.7 and codified at § 512.260(d). We will monitor utilization of services via these no-pay claims.

Comment: A few commenters expressed concern about the 28-day episode trigger window between the treatment planning code and the first treatment delivery service in particular scenarios. For example, a commenter stated that some cases of multi-radiation modalities, like EBRT followed by brachytherapy, require coordination with other specialties that might make it difficult to begin delivering treatment within a 28-day episode trigger window. Another commenter recommended that CMS remove the 28-day episode trigger window and instead trigger the first episode payment at the completion of treatment planning and commencement of treatment delivery without any required timeline.

Response: Our data show that treatment almost always occurs within this time period. And, if it does not, this would constitute an incomplete episode. We are finalizing that an episode will be triggered only if both of the following conditions are met: (1) there is an initial treatment planning service (HCPCS codes 77261-77263) furnished by a Professional participant or a Dual participant; and (2) at least one radiation treatment delivery service (See Table 2) is furnished by a Technical participant or a Dual participant within the following 28 days.

Comment: A commenter expressed concern about incomplete episodes resulting from planning services provided by an RO participant and treatment provided in an ASC outside of the Model, whether or not treatment is furnished within the 28-day episode trigger window.

A couple of commenters requested clarification on how PC and TC claims will be paid if treatment is not delivered within the 28-day episode trigger window. One such commenter advised that cash flow problems would result if providers and suppliers are required to wait until the reconciliation periods and true-up periods to receive payment for these incomplete episodes. For this reason, this commenter recommended that CMS pay all CPT/HCPCS codes that are billed outside this 28-day episode trigger window as FFS.

Response: We thank the commenters for their inquiry. RT services furnished in an ASC are not included in the RO Model. Thus, if the planning service was provided by a Professional participant (in an HOPD or a freestanding radiation therapy center) and the treatment delivery was furnished in an ASC, an episode could be triggered but rendered incomplete, thus the planning services should be billed FFS. If the TC is not rendered by a participant within 28 days, an episode will be considered incomplete and those services should be billed FFS. As noted in section III.C.7 of the proposed rule (84 FR 34512 through 34513) and this final rule, we expect to provide RO participants with additional instructions for billing, particularly as billing pertains to incomplete episodes, through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A couple of commenters supported FFS payments for treatments that exceed the 90-day episode period.

Response: We thank the commenters for their support. We will be finalizing as proposed in § 512.260 that an RO participant shall bill for any medically necessary RT services furnished to an RO beneficiary during a clean period pursuant to existing FFS billing processes in the OPPS and PFS.

Comment: A commenter supported the 28-day clean period between episodes for all but one included cancer type, metastatic bone disease. Because metastatic bone disease often requires ongoing treatment, this commenter suggested that RO participants have the ability to initiate subsequent episodes immediately after the prior episode ends, eliminating the clean period.

Response: We appreciate the suggestion, but we do not want to provide a financial incentive for RO participants to prolong or delay treatment for bone metastasis or any other clinical condition to initiate an additional episode.

Comment: A commenter recommended that the clean period be extended to 60 days to allow for treatment of secondary cancers.

Response: We appreciate the comment, but CMS was advised by radiation oncologists consulting on the design of the Model that four weeks typically signals the start of a new course of treatment. Therefore, we will not be extending the clean period in this final rule.

Comment: A commenter requested clarification on billing practices for patients who complete one 90-day episode and then return with a new diagnosis under their existing diagnosis code within the clean period.

Response: As stated in sections III.C.5.b(3) and III.C.7 of this final rule, any services provided during the 28-day clean period would be paid FFS.

After considering public comments received, we are finalizing at § 512.205 the definition of RO episode. Specifically, we are defining that an RO episode means the 90-day period that begins on the date of service that a Professional participant or a Dual participant furnishes an initial RT treatment planning service to an RO beneficiary, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary

within 28 days of such RT treatment planning service, with a modification to clarify that the initial RT treatment planning service to the RO beneficiary be furnished in a freestanding radiation therapy center or an HOPD. We are finalizing as proposed that the circumstance in which an episode does not occur because 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 qualifies as an incomplete episode. In addition, we are finalizing 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

We proposed at 84 FR 34499 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 and generally include a treatment consultation, treatment planning, technical preparation and special services (simulation), treatment delivery, and treatment management, which are also categorical terms used to generally describe RT services. As outlined in the proposed rule, the subcomponents of RT services have been described in the following manner:[32]

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.

[32] American Society for Radiation Oncology (ASTRO). Basics of RO Coding. https://www.astro.org/Basics-of-Coding.aspx.

Treatment planning: Treatment planning tasks include determining a patient's disease-bearing areas, identifying the type and method of radiation treatment delivery, specifying areas to be treated, and selecting radiation therapy treatment techniques. Treatment planning often includes simulation (the process of defining relevant normal and abnormal target anatomy and obtaining the images and data needed to develop the optimal radiation treatment process). Treatment planning may involve marking the area to be treated on the patient's skin, aligning the patient with localization lasers, and/or designing immobilization devices for precise patient positioning.

Technical preparation and special services: Technical preparation and special services include radiation dose planning, medical radiation physics, dosimetry, treatment devices, and special services. More specifically, these services also involve building treatment devices to refine treatment delivery and mathematically determining the dose and duration of radiation therapy. Radiation oncologists frequently work with dosimetrists and medical physicists to perform these services.

Radiation treatment delivery services: Radiation treatment is usually furnished via a form of external beam radiation therapy or brachytherapy, and includes multiple modalities. Although treatment generally occurs daily, the care team and patient determine the specific timing and amount of treatment. The treating physician must verify and document the accuracy of treatment delivery as related to the initial treatment planning and setup procedure.

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

As discussed in the proposed rule (84 FR 34500), our claims analysis revealed that beneficiaries received a varying number of consultations from different physicians prior to the treatment planning visit, which determines the prescribed course of radiation therapy, including modality and number of treatments to be delivered. We 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 we proposed to codify this at § 512.235. E/M services are furnished by a wide range of physician specialists (for example, primary care, general oncology, others) whereas the other radiation services are typically only furnished by radiation oncologists and their team. This is reflected in the HCPCS code set used to bill for these services. In our review of claims data for the proposed rule, many different types of specialists furnish E/M services. It is common for multiple entities to bill for treatment consultations (E/M services) for the same beneficiary, whereas typically only a single entity bills for RT services for a beneficiary when we limited the services considered to treatment planning, technical preparation and special services, treatment delivery, and treatment management. 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. When consultations and visits were included for an analysis of technical RT services during 2014-2016, 78 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. The difference in percentages is due to the fact that patients see a wide variety of doctors during the course of cancer treatment, which will often involve visits and consultations.

In the proposed rule we noted that we were not proposing to include E/M services as part of the episode payment. RO participants would continue to bill E/M services under Medicare FFS.

Given that physicians sometimes contract with others to supply and administer brachytherapy radioactive sources (or radioisotopes), we explained in the proposed rule that we considered omitting these services from the episode payment. After considering either including or excluding brachytherapy radioelements from the RO Model, we 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 we noted were proposed to be excluded from the Model.

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

We proposed that the RO Model payments would replace current FFS payments only for the included RT services furnished during an episode. For the included modalities, discussed in section III.C.5.d of the proposed rule (84 FR 34502 through 34503), we proposed that the RO Model episode include HCPCS codes related to radiation oncology treatment. Please see section III.C.7 for a discussion of our billing guidelines. We have compiled a list of HCPCS codes that represent treatment planning, technical preparation and special services, treatment delivery, and treatment management for the included modalities. As discussed in the proposed rule, RT services included on this list are referred to as "RO Model Bundled HCPCS" when they are

provided during an RO Model episode since payment for these services is bundled into the RO episode payment. Thus, we proposed to codify at § 512.270 that these RT services would not be paid separately during an episode. In the proposed rule, we indicated that we may add, remove, or revise any of the bundled HCPCS codes included in the RO Model. We proposed to notify participants of any changes to the HCPCS codes per the CMS annual Level 2 HCPCS code file. We proposed to maintain a list of the HCPCS codes included in the RO Model on the RO Model website.

We solicited public comment on our proposal. The following is a summary of the public comments received on this proposal and our responses:

Comment: A commenter recommended that CMS exclude consultation services from the Model, as these services are often provided to patients seeking second opinions. If CMS includes consultation services, this commenter suggested classifying these services as incomplete episodes when the patient does not pursue treatment post-consultation.

Response: Consultations, which are billed as E/M services, were not included in the RO Model's proposed pricing methodology and are not RT services, and they are not included in the final rule.

Comment: A couple of commenters expressed support for the exclusion of E/M services from the Model.

Response: We thank these commenters for their support.

Comment: A few commenters expressed concern over the bundling of IMRT planning code 77301 in that it no longer allows payment for advanced imaging used in data sets for dose planning and simulations when charged with IMRT treatments. The commenter believed this was inappropriate as it places a burden on providers and suppliers that cannot afford to upgrade

their CT, MR or PET equipment used in planning. The commenters expressed concern that these costs are not reflected appropriately in the national base rates.

Response: The episode payment amounts reflect payments made under the PFS and OPPS for RT services furnished during the baseline period. As such, when determining payment rates, we look at RT services in the baseline period that were allowed by Medicare (such as claims with HCPCS 77301 with payment amounts allowed), but we do not assign payment rates to other claims with other HCPCS codes from the baseline period that were denied (for example, in this example because they were in the range of HCPCS codes not allowed to be reported in addition to 77301 because they are part of the valuation of 77301). The RO Model is not intended to change Medicare policy on coverage.

Comment: A few commenters recommended excluding proton beam therapy (PBT) as a low-volume service. A couple commenters suggested specifically excluding neutron beam therapy, hyperthermia, and brachytherapy radioactive elements as low-volume services.

Some commenters requested clarification on how "low-volume" and "commonly used" will be defined in the Model. A couple of commenters suggested that the test for low-volume services should be conducted on a total and per cancer type basis.

Response: We used "low-volume" and "commonly used" in several different places in the proposed rule. We proposed to exclude certain RT services as low volume, including certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. All of these RT services are rarely furnished to Medicare beneficiaries. In contrast, we proposed to include the "most commonly used" RT modalities, including PBT, in the RO Model as they represent standard approaches to treatments that are cited in guidelines for the included cancer types. While we did not propose a definition for a commonly used RT

modality or RT service, we used those terms to describe what is standard practice for radiation oncology and the included cancer types. Though we appreciate the suggestion to look at low-volume RT services on a per cancer type basis, as described in the proposed rule, we plan to test the impact of the RO Model on RT as a whole, rather than specific RT services for specific cancer types. Further, we believe that including certain RT services for some cancer types but not others would be burdensome for RO participants, specifically regarding the tracking and management of which beneficiaries are in or out of the Model. We note that we are finalizing a low volume opt-out option for RO participants with fewer than 20 episodes in one or more of the CBSAs randomly selected for participation in the most recent calendar year with available claims data, as described in section III.C.3.c. Any PBT providers and suppliers who believe they qualify for such an exemption should refer to this section.

Comment: A couple of commenters requested clarification on the Model's treatment of radiopharmaceuticals. These commenters emphasized that, in the case of Radium, treatment often occurs monthly for six months, far longer than the 90-day episode. Many commenters requested the removal of C2616 for Yttrium 90 or Y90 as it is a radiopharmaceutical.

Response: We thank these commenters for this point. As indicated in the NPRM, radiopharmaceuticals are excluded from the RO Model, thus C2616 has been removed from the list of RO Model Bundled HCPCS.

Comment: Many commenters recommended that CMS exclude the radioactive sources from the Model. These commenters emphasized that individual patients often require unique brachytherapy sources, expressing concern that the Model would not appropriately compensate for differences in isotopes and radioactive intensity. A few believed that the Model would undermine access to the optimal isotope. A commenter believed that brachytherapy sources were

more appropriately considered medical devices rather than RT procedures. Some of these commenters recommended that CMS exclude specific brachytherapy sources, primarily the HCPCS A-codes, C-codes, and Q-codes from the Model. Many commenters emphasized that brachytherapy sources alone are frequently more expensive than the proposed bundled payments—particularly for high dose rate brachytherapy—in the proposed Model and that hospitals have little control over these costs. A couple commenters recommended excluding high dose rate brachytherapy from the Model.

Response: We thank the commenters for their suggestion. We package many expensive and more expensive services in value-based bundled payment; there is no reason to treat brachytherapy sources any differently than other necessary items and services such as linear accelerators. We believe that once the national base rates are adjusted for the RO participant's case mix and historical experience, they will see that final payments will be reflective of the inclusion of radioelements. As discussed in section III.C.14 and III.C.16 of this final rule, we will monitor for unintended consequences of the RO Model.

Comment: Several commenters stated that including medical physics services in the RO Model will lead to a loss of direct financial accountability for providing adequate technical supervision that is provided to each patient and could significantly reduce medical physics resources around the country. A commenter stated that medical physicists would move to an area not participating in the Model in order to maintain their salary.

Response: It is our understanding that medical physics is a state licensure requirement and is an integral to the delivery of RT services. We do not anticipate that the Model will have a detrimental impact on medical physics resources, as participants would continue to need these health care providers for many functions, including output calibrations and, where clinically

appropriate, hypo fractionation. As discussed in section III.C.14 and III.C.16 of this final rule, we will monitor for unintended consequences of the RO Model.

Comment: A commenter has requested that any changes made to the HCPCS code bundles be made through notice and comment rulemaking rather than through a list on the RO Model website.

Response: We believe that our proposal allows us to update the list in an expeditious manner if we detect an error to facilitate prompt and accurate payments. Thus, we are finalizing our policies as proposed, without modification, to add, remove, or revise any of the bundled HCPCS codes included in the RO Model; notify participants of any changes to the HCPCS codes per the CMS annual Level 2 HCPCS code file or quarterly update; and maintain a list of the HCPCS codes included in the RO Model on the RO Model website. If CMS intends to add any new HCPCS codes to the RO Model, we would go through rulemaking to add those new codes to the list of RO Model Bundled HCPCS.

Comment: Several commenters expressed concern that the proposed payment methodology was insufficient for codes 77387 and G6017, as these commenters believed that there is not currently sufficient payment under the PFS for these codes for surface guided radiation therapy (SGRT). These commenters believed that by including these two codes as RT services in the RO Model, payment under the Model would not accurately reflect the cost of all care in an episode. Specifically, a commenter noted that CMS has not assigned a relative value unit (RVU) for HCPCS 77387 or G6017 in the PFS. The commenter believed that inclusion of these two codes as RT services in the RO Model would extend the payment challenges associated with SGRT services into the Model. Another commenter stated that CMS has not

established PFS payment for the G6017 code, which has been in existence since 2015, and recommended CMS pay for SGRT separately from the Model.

Response: Although CPT® code 77387 was active in the PFS or OPPS in some year prior to the updated baseline period with spillover (2015-2019), it is not paid separately. As proposed, the Model was only to include codes paid separately. This code was mistakenly included on the list of include RT services but not in the pricing methodology. We would also like to clarify that the code G6017 is contractor-priced under the PFS. This means that CMS has not established nationally applicable RVUs for the service. Instead, individual Medicare Administrative Contractors (MACs) determine the payment rate for the service and apply that rate in their jurisdiction(s). Payment rates across MAC jurisdictions can vary. Due to the potential differences across jurisdictions, we calculated the average paid amounts for each year in the baseline period for contractor-priced RT services to determine their average paid amount to be included in the calculation of the national base rates. We will use the most recent calendar year with claims data available to determine the average paid amounts for these contractor-priced RT services that will be included in the calculation of the trend factors for the PC and TC of each cancer type. For instance, for the 2021 trend factor, we will calculate the average paid amounts for these contractor-priced RT services using their allowed charges listed on the 2019 claims.

Comment: A commenter stated that inserting a hydrogel spacer between the prostate and rectum has become a standard of care at many practices to reduce the toxicity of radiotherapy, by decreasing rectal dose exposure. Many practices have also implanted fiducial markers into the prostate to improve the accuracy of targeting. These items, particularly the hydrogel spacer, have a significant cost and added physician work component. The commenter suggested that payment include a provision to account for this added labor and cost.

Response: We believe the commenter is referring to HCPCS 55784. This is not an included RT service. Thus, the RO participant may continue to receive FFS payment upon furnishing this service.

Comment: Many commenters expressed concern about the lack of consideration for emerging or new technologies in the Model, and that the pricing methodology of the RO Model generally does not provide an incentive for participants to invest in new technologies and equipment. A commenter explained that the incentive is removed, because 2D, 3D, IMRT, and HDR treatment courses will be billed at the same rate, and the latest IGRT technologies will not be pursued. Another commenter noted that the RO Model does not include any approach to recognize new technology such as the MRI-LINAC.

Commenters defined emerging and new technologies differently. A commenter suggested defining new technology as any service that has been granted a new technology APC or pass-through payment. Another commenter suggested that devices be granted an innovative designation if a new technology and as a result qualify for additional reimbursement. This commenter suggested that the innovative designation would need approval by the FDA under a Premarket Approval Process and not be "substantially equivalent" to an existing device. Another commenter suggested that new technology could be signaled through a CPT® code transitions from a Category III code to a Category I code. This commenter also suggested that new technology could include the use of existing CPT®/HCPCS codes used in different combination or in more fractions than what has historically been used. A few commenters called attention to the need to reimburse HCPCS codes bundled in the RO Model that come to be used differently than historical patterns indicate, whether in frequency or in combination with other modalities, and this in itself was a new form of technology.

One commenter recommended adding a payment adjustment for new technology in the same way OCM has a novel therapies adjustment. Another commenter suggested that CMS consider modalities with the 510(k) clearances as innovations that should be paid separately outside of the RO Model.

A few commenters requested clarification as to whether new technologies would be paid FFS. A couple of commenters requested clarification concerning CPT® and HCPCS codes established after the publication of the Final Rule specifically, and if those code would be paid FFS.

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

Comment: Many commenters recommended excluding HCPCS codes that refer to either brachytherapy services commonly provided in a surgical setting or that refer to brachytherapy sources. These commenters emphasized that surgical codes for other modalities were excluded from the Model and questioned why surgical codes 57155, 57156, 55920, and 53846 were included for brachytherapy. These commenters emphasized that the surgical procedures often involve sub-specialized physicians, equipment, and other costs. By including the surgical component in the Model, these commenters worried that it would undermine patient access to care. As relatively low-volume services, these commenters believe excluding them from the

Model would not have a large impact on savings. A few commenters requested clarification on the inclusion of brachytherapy insertion codes.

Response: We have confirmed with clinical experts that these services are commonly furnished by radiation oncologists and thus will be included in the RO Model. We have not included brachytherapy surgical codes that are only provided by other types of physicians.

Comment: A few commenters agreed with the inclusion of RT services as proposed.

Response: We thank these commenters for their support. See Table 2 for the finalized list of included RT services.

**TABLE 2: LIST OF RO MODEL BUNDLED HCPCS**

| HCPCS | HCPCS Description | Category |
|---|---|---|
| 55920 | Placement Pelvic Needles/Catheters, Brachytherapy | Radiation Treatment Delivery (Brachytherapy Surgery) |
| 57155 | Placement Tandem and Opioids, Brachytherapy | Radiation Treatment Delivery (Brachytherapy Surgery) |
| 57156 | Placement Vaginal Cylinder, Brachytherapy | Radiation Treatment Delivery (Brachytherapy Surgery) |
| 58346 | Placement Heyman Capsules, Brachytherapy | Radiation Treatment Delivery (Brachytherapy Surgery) |
| 77014 | Computed tomography guidance for placement of | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77021 | Magnetic resonance guidance for needle placement | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77261 | Radiation therapy planning | Treatment Planning |
| 77262 | Radiation therapy planning | Treatment Planning |
| 77263 | Radiation therapy planning | Treatment Planning |
| 77280 | Set radiation therapy field | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77285 | Set radiation therapy field | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77290 | Set radiation therapy field | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77293 | Respirator motion mgmt simul | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77295 | 3-d radiotherapy plan | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77299 | Radiation therapy planning | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |

| HCPCS | HCPCS Description | Category |
|---|---|---|
| 77300 | Radiation therapy dose plan | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77301 | Radiotherapy dose plan imrt | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77306 | Telethx isodose plan simple | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77307 | Telethx isodose plan cplx | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77316 | Brachytx isodose plan simple | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77317 | Brachytx isodose intermed | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77318 | Brachytx isodose complex | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77321 | Special teletx port plan | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77331 | Special radiation dosimetry | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77332 | Radiation treatment aid(s) | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 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 |

| HCPCS | HCPCS Description | Category |
|---|---|---|
| 77435 | Sbrt management | Treatment Management |
| 77470 | Special radiation treatment | Treatment Management |
| 77499 | Radiation therapy management | Treatment Management |
| 77520 | Proton trmt simple w/o comp | Radiation Treatment Delivery |
| 77522 | Proton trmt simple w/comp | Radiation Treatment Delivery |
| 77523 | Proton trmt intermediate | Radiation Treatment Delivery |
| 77525 | Proton treatment complex | Radiation Treatment Delivery |
| 77761 | Apply intrcav radiat simple | Radiation Treatment Delivery |
| 77762 | Apply intrcav radiat interm | Radiation Treatment Delivery |
| 77763 | Apply intrcav radiat compl | Radiation Treatment Delivery |
| 77767 | Hdr rdncl skn surf brachytx | Radiation Treatment Delivery |
| 77768 | Hdr rdncl skn surf brachytx | Radiation Treatment Delivery |
| 77770 | Hdr rdncl ntrstl/icav brchtx | Radiation Treatment Delivery |
| 77771 | Hdr rdncl ntrstl/icav brchtx | Radiation Treatment Delivery |
| 77772 | Hdr rdncl ntrstl/icav brchtx | Radiation Treatment Delivery |
| 77778 | Apply interstit radiat compl | Radiation Treatment Delivery |
| 77789 | Apply surf ldr radionuclide | Radiation Treatment Delivery |
| 77790 | Radiation handling | Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services |
| 77799 | Radium/radioisotope therapy | Radiation Treatment Delivery |
| A9527 | Iodine i-125 sodium iodide | Radiation Treatment Delivery (Brachytherapy Materials) |
| 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) |
| C2642 | Brachytx, stranded, c-131 | Radiation Treatment Delivery (Brachytherapy Materials) |

| HCPCS | HCPCS Description | Category |
|---|---|---|
| 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) |

After considering public comments, we are modifying our proposed list of included RT services to the corresponding HCPCS codes in Table 2 of this final rule. We are not adding any HCPCS codes to those identified in the proposed rule, but are removing HCPCS codes 77387, 77424, 77425, C1715, C1728, C2616, and 77469 from the Model. We are codifying 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

We proposed at 84 FR 34502 through 34503 to include the following RT modalities in the 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. We proposed to include all of these modalities because they are the most commonly used to treat the 17 proposed cancer types and including these modalities would allow us to determine whether the RO Model is able to impact RT holistically rather than testing a limited subset of services.

As discussed in the proposed rule, because the OPPS and PFS are resource-based payment systems, higher payment rates are typically assigned to services that use more expensive equipment. Additionally, newer treatments have traditionally been assigned higher payment. Researchers have indicated that resource-based payments may encourage health care providers to purchase higher priced equipment and furnish higher-cost services, if they have a sufficient volume of patients to cover their fixed costs.[33] Higher payment rates for services involving certain treatment modalities may encourage use of those modalities over others.[34]

[33] Falit, B. P., Chernew, M. E., & Mantz, C. A. (2014). Design and implementation of bundled payment systems for cancer care and RT. International Journal of Radiation Oncology• Biology• Physics, 89(5), 950-953.
[30] Ibid.

In the proposed rule, we explained that Medicare expenditures for RT have increased substantially. From 2000 to 2010, for example, the volume of physician billing for radiation treatment increased 8.2 percent, while Medicare Part B spending on RT increased 216 percent.[35] Most of the increase in the 2000 to 2010 time period was due to the adoption and uptake of IMRT. From 2010 to 2016, spending and volume for PBT in FFS Medicare grew rapidly,[36] driven by a sharp increase in the number of proton beam centers and Medicare's relatively broad coverage of this treatment. While we cannot assess through claims data what caused this increase in PBT, we can monitor changes in the utilization of treatment modalities during the course of the Model. The previously stated increase in PBT volume may depend on a variety of factors.

As stated in the proposed rule, the RO Model's episode payment was designed, in part, to give RT providers and RT suppliers greater predictability in payment and greater opportunity to clinically manage the episode, rather than being driven by FFS payment incentives. The design of the payment model grouped together different modalities for specific cancer types, often with variable costs, into a single payment that reflects average treatment costs. As explained in the proposed rule, the Model would include a historical experience adjustment, which would account for an RO participant's historical care patterns, including an RO participant's historical use of more expensive modalities, and certain factors that are beyond a health care provider's control. We stated in the proposed rule that we believe that applying the same payment for the most commonly used RT modalities would allow physicians to pick the highest-value modalities.

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[35] Shen, X., Showalter, T. N., Mishra, M. V., Barth, S., Rao, V., Levin, D., & Parker, L. (2014). Radiation oncology services in the modern era: Evolving patterns of usage and payments in the office setting for Medicare patients from 2000 to 2010. Journal of Oncology Practice, 10(4), e201-e207.

[36] Spending in PBT rose from $47 million to $115 million, and the number of treatment sessions for PBT rose from 47,420 to 108,960, during that period.

We stated in the proposed rule that given the goals of the RO Model as well as the payment design, we believe that it is important to treat all modalities equally.

With respect to PBT, we noted in the proposed rule that there has been debate regarding the benefits of proton beam relative to other, less expensive modalities. The Institute for Clinical and Economic Review (ICER) evaluated the evidence of the overall net health benefit (which takes into account clinical effectiveness and potential harms) of proton beam therapy in comparison with its major treatment alternatives for various types of cancer.[37] ICER concluded that PBT has superior net health benefit for ocular tumors and incremental net health benefit for adult brain and spinal tumors and pediatric cancers. ICER judged that proton beam therapy is comparable with alternative treatments for prostate, lung, and liver cancer, although the strength of evidence was low for these conditions. In a June 2018 report to Congress, MedPAC discussed Medicare coverage policy and use of low-value care and examined services, including PBT, which lack evidence of comparative clinical effectiveness and are therefore potentially low value.[38] They concluded that there are many policy tools, including new payment models, that CMS could consider adopting to reduce the use of low-value services. Given the continued debate around the benefits of PBT, and understanding that the PBT is more costly, we discussed in the proposed rule that we believe that it would be appropriate to include in the RO Model's test, which is designed to evaluate, in part, site neutral payments for RT services. We solicited public comment on our proposal to include PBT in the RO Model.

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

[38] http://medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf

As discussed in the proposed rule, we considered excluding PBT from the included modalities in instances where an RO beneficiary is 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. We also solicited public comment on whether or not the RO Model should include RO beneficiaries participating in federally-funded, multi-institution, randomized control clinical trials for PBT. The following is a summary of the public comments received on these proposals and our responses:

Comment: Some commenters recommended including PBT in the final rule. A couple of commenters believed that including PBT in the episode payment would create an incentive to use lower-cost, comparable modalities. A commenter believed including PBT would allow the Model to test whether financial incentives are driving clinical decision-making. Another commenter believed the historical experience adjustment would compensate RO participants who use more expensive modalities. A couple of commenters believed that the evidence supporting PBT in certain common types of cancer, such as prostate and lung, is questionable.

Response: We thank the commenters for their support and note that we are 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. See § 512.240 for the finalized list of included modalities.

Comment: Many commenters believed that PBT is of high value and an effective, evidence-based treatment for many clinical indications. Some commenters suggested that CMS should not use questions about PBT's clinical value or high, upfront investment as the basis for inclusion in the RO Model. Some of these commenters believed that PBT was distinct from other

forms of RT and should not be treated as equivalent to other modalities by the Model. A couple of commenters also recommended exemptions for high-cost services like PBT when its use is supported by evidence.

Some of these commenters believed that the 2014 reports from the Institute for Clinical and Economic Review (ICER) and Medicare Patient Advisory Commission (MedPAC), which suggested PBT was of lower value than other modalities, were outdated. A few commenters specified that PBT is indicated for numerous forms of cancer, and can be particularly useful for patients who undergo re-irradiation.

Many these commenters stressed that patients often have better experiences with PBT than other forms of radiation, with improved survival, fewer side effects, fewer hospitalizations, and better quality of life.

Some commenters emphasized 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. A couple of commenters emphasized that PBT improves outcomes and reduces the total cost of care over 12 months. These commenters pointed to savings from lower health care consumption to treat side effects and lower rates of secondary malignancies due to more precise radiation delivery. A couple of commenters emphasized that PBT's precision makes it the safest way to hypofractionate treatment to sensitive parts of the body. A commenter emphasized that PBT is frequently used to hypofractionate regimens when proven to be effective, using prostate cancer as an example.

Response: We appreciate the commenters' concerns. The most recent ICER report focuses primarily on a pediatric population, whose outcomes may not be comparable to the Medicare population. The 2018 MedPAC report emphasized that the use of PBT has expanded in

recent years from pediatric and rare adult cancers to include more common types of cancer, such as prostate and lung cancer, despite a lack of evidence that PBT offers a clinical advantage over alternative treatments for these types of cancers. The 2019 Washington State Health Care Authority PBT re-review examined the comparative effectiveness of PBT over other forms of RT. For adult tumors, the report stated that the evidence was insufficient to evaluate the comparative effectiveness of PBT for bladder, bone, and pancreatic cancers; unclear for brain, spinal, and breast cancers; and comparable for head and neck, lung, and prostate cancers. The report did find that PBT may pose a benefit for liver and certain ocular cancers under specific conditions, but concluded that the strength of evidence for these benefits was low. As such, we are including PBT in the RO Model with the clinical trial exception, which we believe provides sufficient opportunity for more conclusive evidence to be generated around PBT in the Medicare population. We believe that continuing to gather such evidence in the excepted clinical trials will allow CMS to better address the commenters' beliefs about PBT's long term benefits. We will continue to review new evidence generated about PBT's effectiveness in the Medicare population as it becomes available.

Comment: Many commenters recommended that CMS exclude PBT from the RO Model. Many commenters emphasized that the reimbursement for PBT under the Model would be too low. These commenters emphasized the high operational cost of PBT, which commenters generally believed would not be covered by the current Model's proposed approach to setting episode payments. These commenters indicated that the Model would disproportionately reduce reimbursement for PBT as compared to other modalities. Some commenters believed that the RO Model would result in a nearly 50 percent reduction in payment for PBT, while reimbursement across all other modalities would decrease by 4 percent. A few commenters believed that low

reimbursement under the Model would further reduce PBT payments outside of the Model, as commercial insurers and Medicaid programs would follow suit.

Some commenters believed that the national base rate did not include a meaningful volume of proton therapy episodes, leading to payment rates that do not reflect the costs of providing PBT. A couple of these commenters emphasized that restricting the national base rate-setting methodology to only HOPD episodes excludes about 65 percent of PBT episodes. A commenter recommended that CMS reconsider the establishment of the national base rate based only on HOPD episodes due to its detrimental impact on proton beam therapy centers. Another commenter emphasized that PBT services do not follow the pattern for other RT services in HOPD and freestanding facilities: freestanding RT centers are paid less than their HOPD counterparts and PBT has a higher ratio of freestanding to HOPD providers than other modalities. This commenter also highlighted that a significant number of PBT centers have opened since 2015, meaning that the CMS data on which the base rates are founded does not represent the current state of PBT.

Many commenters believed the bundled price would either reduce investment in PBT therapies or cause existing PBT facilities to close. A couple of commenters stated their belief that many PBT facilities operate on thin margins and believed the Model would place them in tenuous financial positions. A commenter emphasized that such closures would result in the loss of jobs. A few of commenters emphasized the uneven geographic distribution of existing PBT facilities – a commenter stated that only 35 percent of the U.S. population has access to PBT today, and believed that this percentage would shrink under the Model. These commenters suggested that PBT center closures would force patients to travel significant distances to access PBT or forgo treatment.

Many commenters believed that the bundled price would reduce patient access to PBT. Some believed patient access would be reduced if PBT facilities closed due to financial hardship caused by the RO Model. Other commenters suggested that patient access would be reduced by providers and suppliers prescribing alternative modalities when PBT would be more appropriate. A couple commenters suggested that providers and suppliers might refer patients to PBT facilities in CBSAs selected for comparison. A commenter expressed that patients should have access to the treatment modality that affords them a chance to achieve the best possible outcome. Other commenters generally emphasized the value of PBT in delivering lower and more precise radiation doses. These commenters voiced their concern that, in incentivizing RO participants to utilize modalities other than PBT, patients would be exposed to more radiation and a greater risk of additional, costly cancers in the future. A couple of commenters stated that other countries will have greater access to PBT than the U.S. by 2024. These commenters generally believed that excluding PBT from the Model and continuing to reimburse it as FFS would prevent these reductions in patient access.

Some commenters believed that the impact of any PBT center closures would have an impact beyond the Medicare population. These commenters generally referenced the value of PBT to certain pediatric cancers, as well as head and neck cancer, brain tumors, and thoracic lymphoma, and feared that PBT center closures would jeopardize access for these patient groups. A couple of commenters believed the Model will deepen cancer disparities by targeting freestanding radiation therapy centers. One such commenter believed that if the Model forced freestanding PBT facilities to close, the impact would disproportionately impact low-income and minority groups. A commenter emphasized that the IPPS and OPPS provide stratifications of cost to avoid similar reductions in access to technology.

Some commenters expressed concern that including PBT in the Model would reduce the ability of providers and suppliers to generate evidence about PBT and stifle innovation in this field. A couple such commenters emphasized that slowing innovation could deprive Medicare of potentially significant long-term cost savings. A commenter recommended excluding PBT to allow the industry to further demonstrate the value of PBT. A few commenters emphasized that the cost of PBT has fallen over the years and believed that it would continue to fall if excluded from this rule.

Response: We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. We believe that the clinical trial exception will continue to enable providers and suppliers to generate evidence about PBT, allowing innovation in this field to continue. Further, our approach to the calculation of participant-specific episode payment amounts places great weight on an individual entity's historical experience. This approach accounts for an entity's high cost relative to the national average and includes a glide path over time. Furthermore, as described in section III.C.6.b, to address the concerns regarding the Model's national base rate, the base rates that were calculated for purposes of this final rule were shifted forward to 2016-2018, capturing more recent data from a greater number of PBT centers compared with the data used in the proposed rule. As described in section III.C.6.c, we believe that the use of HOPD episodes for calculating the national base rates provides a stronger empirical foundation. Blending together the national base rates, which are derived from HOPD episodes, with the RO participant's own historical experience (whether HOPD or freestanding radiation therapy center) will allow the RO participant's unique care patterns to be recognized in the participant-specific episode payment amounts.

We do not believe that the RO Model, which as finalized will be tested in approximately 30 percent of episodes nationally and which will include a gradual shift in payments toward the national average, will affect access to PBT. We plan to carefully monitor the RO Model for unintended consequences as finalized in section III.C.14 and III.C.16. If our monitoring reveals that the Model reduces patient access to PBT, we would consider making changes to the Model via future rulemaking. Further, our evaluation will consider longer-term impacts on health outcomes associated with the Model.

Comment: If included in the Model, many commenters had suggestions for how to structure PBT payments. A couple of these commenters recommended creating a separate bundled price for PBT that is a percentage of the current medically accepted case rate instead of the proposed APM bundled prices. A commenter suggested that CMS consider a step wise reduction in payments, which would account for the fact that adoption of this technology is still in the nascent stages. A couple other commenters recommended creating a separate Model for PBT. A few commenters recommended creating a separate base rate for PBT. Another commenter suggested that PBT should be reconsidered for inclusion at the end of the five-year pilot phase. Another commenter recommended exempting PBT facilities that have yet to be constructed. MedPAC expressed support for the inclusion of PBT in the RO Model because Medicare's payment rates for PBT are substantially higher than for other types of external beam radiation therapy. In addition, MedPAC noted that the use of PBT has expanded in recent years from pediatric and rare adult cancers to include more common types of cancer, such as prostate and lung cancer, despite a lack of evidence that it offers a clinical advantage over alternative treatments for these types of cancer. Therefore, including PBT in the episode payment would create an incentive to use lower-cost, comparable modalities.

Response: We thank the commenters for their feedback. We believe that our approach to blending the national base rates with the RO participant's historical experience, with the blend shifting more to the national base rates over time for those with historical payments above the national base rates, provides a stepwise reduction in payment over the Model, regardless of modality. We do not believe a separate model for PBT is necessary because we have created an exemption where PBT is not an included modality when 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. If we were to exclude all PBT from the RO Model or to create a separate base rate, it would undermine the RO Model test, which is testing an episode-based payment that does not vary based on where the services are provided or how many or which type of RT services are provided during the episode. Further, doing either of these recommended approaches could create an incentive for RO participants to provide PBT as a way to avoid being in the Model. In addition, we do not believe that an exemption is necessary for PBT facilities that have not yet been constructed since the geographic areas selected to participate in the Model and the national base rates will be publicly available; new PBT facilities in a selected geographic area will have their episode payment amounts adjusted for case mix once data are available. We are finalizing the inclusion of PBT in the RO Model's pricing methodology (see section III.C.6) to maintain our modality agnostic approach. See § 512.240 for the finalized list of included modalities.

Comment: A commenter believed that a randomly selected sample for the RO Model has a high likelihood of not selecting an adequate number of centers that provide PBT. The commenter believed this would reduce the ability to statistically validate the impact of proton therapy in the bundle. This commenter further believed that the geographic dispersion of centers

means that only a few centers could contribute the majority of episodes, leading to results inconsistent with the industry.

Response: As discussed in section III.C.16, the evaluation's focus will be on the impact of the Model as a whole rather than on comparing the impact of the Model on individual modalities, though subanalyses will be conducted where feasible.

Comment: Many commenters recommended that CMS exclude PBT as a low-volume modality. These commenters generally believed that PBT is not commonly used and that there is insufficient data supporting its inclusion in the Model. Some commenters emphasized that PBT only accounted for 0.7 percent of all episodes in 2017, while others specified that PBT episodes would represent more than 1 percent of total episodes for only six of the 17 cancer types and less than 0.5 percent of the episodes for the remaining 11. A commenter expressed concern that including a low-volume service like PBT would decrease the rigor of any evaluation, rendering results unreliable or misleading. A commenter suggested both limiting low-volume modalities like PBT to a smaller percentage of episodes and making participation voluntary.

Response: We appreciate these commenters' suggestions. Per many commenters as well as claims data, PBT is one of the standard approaches to providing radiotherapy for the included cancer types, and as such, it is appropriate and important to include PBT as a modality in the Model. Although PBT is currently used less frequently than the other included modalities, we believe that its exclusion would undermine our ability to test whether the Model incentivizes the use of high-value, appropriate care for RO beneficiaries. Notably, as discussed in section III.C.16, the evaluation's focus will be on the impact of the Model as a whole rather than on comparing the impact of the Model on individual modalities, though subanalyses will be conducted where feasible.

Comment: Some commenters supported the proposed exclusion of cases where an RO beneficiary is participating in a federally-funded, multi-institution, randomized control clinical trial for PBT. These commenters generally believed that the exclusion, as proposed, would permit the generation of further clinical evidence comparing PBT to other modalities, while allowing the Model to include some beneficiaries who receive PBT. MedPAC added that if CMS decides to exclude PBT from the Model when it is part of a research study, CMS should only do so if the study is a federally-funded, multi-institution, randomized control trial. This requirement would help ensure that studies of PBT produce robust information on how it compares with other modalities. In addition, limiting this exclusion would allow the Model to include at least some beneficiaries who receive PBT.

Many commenters recommended that CMS expand the proposed exclusion of cases where an RO beneficiary is participating in a federally-funded, multi-institution, randomized control trial. These commenters generally believed that the proposed exclusion might restrict opportunities that would benefit Medicare FFS beneficiaries.

One commenter believed that CMS should expand the proposed exclusion of cases because no existing clinical trials would meet the proposed criteria. Some commenters suggested that CMS use Medicare evidence development precedent—via a registry structured in compliance with CMS or AHRQ guidance or a clinical trial registered on clinicaltrials.gov—to structure this exemption. A commenter emphasized that this approach would be consistent with existing Local Coverage Decisions for some proton beam therapy providers and suppliers. Other commenters suggested that RT providers or RT suppliers with a history of evidence development should be exempt from the Model.

Some commenters, emphasizing the extensive evidence generated by recent PBT studies, recommended expanding the exclusion to cover all clinical trials, regardless of whether such trials are federally funded or randomized controlled trials. A couple of commenters emphasized that randomized clinical trials are challenging and not always practical in radiation oncology. These commenters also believed that registry data could generate clinical evidence. Other commenters believed that much ongoing research takes place in academic institutions without federal funding. These commenters generally believed that a broadened exemption would incentivize the collection of additional clinical data to determine PBT's clinical value, particularly in comparison to other modalities such as IMRT and brachytherapy.

An additional commenter suggested excluding beneficiaries who are enrolled in an IRB-approved clinical trial. A commenter recommended using this regulation to address the scope and caliber needed for a clinical trial to become exempt.

A couple of commenters recommended that the proposed clinical trial exclusion not be modified. A commenter recommended that the exclusion only cover participants in randomized clinical trials, suggesting that the payment could be readjusted if these studies demonstrate a defined clinical benefit.

A couple of commenters suggested that CMS decline to expand this exemption to include registry trials. A commenter emphasized that in sites such as breast, head and neck, esophagus, and prostate cancer, a registry trial adds only a single arm or retrospective data that does little to compare proton to photon therapy in these sites. Another commenter believed that an exemption for registry trials would lead every patient at every proton center to be put on a registry trial, adding only to an existing body of literature on single arm series of proton therapy. This commenter did not believe registry trials add sufficient evidence to change the standard of care.

One commenter emphasized that proton therapy for primary treatment of prostate cancer should be performed within the context of a prospective clinical trial or registry.

A few commenters recommended that CMS exempt all care—not just PBT—provided under a clinical trial protocol from the Model. A commenter specifically recommended that CMS exclude patients enrolled in clinical trials in which the focus is radiation oncology treatment or technology, emphasizing that the costs of these cases are unique and may influence adjustment factors or future Model data.

Response: We appreciate these comments and suggestions. We agree with commenters that the use of registry trials is insufficient, as the single-arm design of registry trials makes them unlikely to result in published studies evaluating the comparative effectiveness of PBT to other RT modalities. We agree that these registry trials are unlikely to generate the type of evidence needed to change the standard of care. We also note that data collected through registry trials is often not analyzed or published. We believe that the inclusion of federally-funded, multi-institution, randomized control clinical trial for PBT is important to include so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered. There are established procedures that exist in the Medicare claims systems for identifying and paying for services furnished during participation in clinical trials. A recent study concluded that prospective trials are warranted to validate studies related to the use of proton and photon beam therapies.[39]

[39] Baumann, B.C., Mitra, N., Harton, J.G., Xiao, Y., Wojciezynski, A.P., Gabriel, P.E., Zhong, H., Geng, H., Doucette, A., Wei, J., O'Dwyer, P.J., Bekelman, J.E., & Metz, J.M. (2019). Comparative effectiveness of proton vs proton therapy as part of concurrent chemoradiotherapy for locally advanced cancer. JAMA Oncology, doi:https://doi.org/10.1001/jamaoncol.2019.4889.

Comment: Some commenters supported the inclusion of brachytherapy in the Model, while many comments opposed its inclusion. For those that supported the inclusion of brachytherapy, they argued that its inclusion in the Model along with the other modalities would incentivize the provision of the most efficacious and cost-effective treatments and improve access to brachytherapy as a treatment option. A couple of commenters opposed brachytherapy's inclusion in the Model, worrying the Model might disincentivize its use, particularly among vulnerable cancer populations, such as women with cervical cancer. A couple of commenters recommended excluding brachytherapy on the premise that it is a low-volume modality.

Many commenters expressed concerns with the inclusion of brachytherapy as proposed. Some of these commenters emphasized brachytherapy's unique nature as it is a standalone treatment and is also used in combination with external beam radiotherapy (EBRT). These commenters 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, multiple RT providers or RT suppliers, multiple disease sites, or multiple treatment settings.

Some commenters focused on cases involving multiple modalities. These commenters emphasized that the brachytherapy "boost" when accompanying other modalities is an important, clinical guideline-driven treatment for certain patients. These multimodality cases are particularly common for treating cervical cancer, breast cancer, and prostate cancer, and they require more work than cases involving a single modality, as each modality requires unique treatment planning and delivery services. A commenter emphasized that patients are often sent to regional hub facilities for these boosts, reducing unnecessary duplication of expensive equipment and staff. A couple of these commenters expressed concern that should the Model not provide

adequate compensation for multiple modalities furnished within a single episode, particularly those involving brachytherapy, providers and suppliers might be incentivized to delay treatment or to depart from clinical guidelines. These commenters emphasized that these perverse incentives could reduce patient access to medically necessary care. Moreover, a couple of commenters believed that there were problems with the underlying data and pricing methodology. A commenter believed that errors in the claims data stemming from incorrect attribution of CPT®/HCPCS codes to certain modalities underrepresented the true cost of delivering a combination of modalities like EBRT and brachytherapy.

A few commenters emphasized that brachytherapy services are often provided by physicians other than radiation oncologists, such as gynecological oncologists, urologists, interventional radiologists, and surgical oncologists, and that these physicians could operate under the same or different RT provider or RT supplier when brachytherapy is provided in conjunction with another modality. Some commenters expressed concern that the current RO Model does not adequately account for the various combinations of physicians and treatment settings in which brachytherapy is furnished. A few commenters explained that CMS should not consider multiple modality cases delivered by two physicians as duplicate RT services, as these physicians are working in tandem on a treatment plan rather than duplicating one another's efforts.

A few commenters recommended that brachytherapy trigger a second RO Model bundle, with a separate PC and TC payment, when delivered within a single 90-day episode that also includes EBRT. Some commenters suggested that brachytherapy be reimbursed as FFS when delivered during an episode including EBRT. To implement this change, a commenter suggested adding a modifier to episodes in which both brachytherapy and EBRT are provided. This

modifier would trigger the second bundled or FFS payment and prevent the episode from going to reconciliation. These commenters believed that these solutions would adequately address the various combinations of modalities, RT providers and RT suppliers, and settings that might arise during brachytherapy treatment. A commenter further emphasized that this structure would alleviate possible negative incentives in the Model, ensure that patients continue to receive high-quality care, and have minimal impact on overall CMS expenditures.

Response: We thank commenters for their support of including brachytherapy as well as those commenters expressing their concerns and their suggestions.

An episode-based payment covers all included RT services furnished to an RO beneficiary during a 90-day episode. Bundled episode payment rates are premised on the notion of averages. The cases including a combination of EBRT and brachytherapy described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued, and, therefore, an adjustment for multiple modalities that include brachytherapy is not warranted at this time. Also, the case mix and historical experience adjustments help account for the costlier beneficiary populations in the participant-specific episode payment amounts. We will be monitoring for change in treatment patterns throughout the Model performance period and will consider modifications to the pricing methodology in future years of the Model should it be warranted.

We believe that including brachytherapy in the Model supports this modality as high value, and also that including it preserves the goal of the Model in establishing a true bundled approach to radiotherapy that is also site neutral and modality agnostic. And, we believe that the proposed and finalized pricing methodology and subsequent national base rates for each cancer type accounts for the cost of brachytherapy as a primary modality and if furnished in conjunction

with EBRT. We recognize the billing complexity when separate RT providers and RT suppliers furnish the brachytherapy and EBRT and will address this in billing guidance provided to RO participants. We will monitor for any unintended consequences of the Model on multi-modality treatment that includes both external beam and brachytherapy.

As for the concern that errors in the claims data (specifically those that commenters believe stem from incorrect attribution of CPT®/HCPCS codes to certain modalities) underrepresented the true cost of delivering a combination of modalities like EBRT and brachytherapy, we rely on the data submitted on claims by providers and suppliers to be accurate per Medicare rules and regulations. We are finalizing the provision to include brachytherapy in the RO Model.

Comment: A commenter specifically requested that the Model include electronic brachytherapy (EB).

Response: EB radiation is generated and delivered in a markedly different way than traditional brachytherapy, and its dosing and clinical implications are still being studied. Until EB is more commonly used, CMS will continue to pay FFS for this RT service.

Comment: A few commenters suggested excluding more modalities from the Model due to their infrequent use. A commenter recommended including only the most common modalities and excluding brachytherapy, SRS, SBRT, and PBT. A commenter recommended excluding IORT since it is used so rarely. A commenter was concerned that the proposed payment structure will promote the use of short course, less costly forms of treatment such as IORT in cases where traditional external beam radiation would have been preferred.

Response: We thank these commenters for these suggestions. We agree with the commenter that it would be appropriate to exclude IORT from the RO Model because it is not a

standard approach to treatment, and we believe that including IORT may incentivize misuse of this treatment. See § 512.240 for the finalized list of included modalities.

Comment: A commenter requested clarity on the codes used to define stereotactic radiosurgery and also expressed concern that the RO Episode File (2015-2017) has SRS attributed to episodes that are classified as brain metastasis or CNS. SRS as defined in the HCPCS should be a single treatment delivery and directed at an intracranial brain lesion. It is likely that CMS is incorrectly including SBRT into the SRS count, since SRS is typically used for brain metastases, and SBRT is typically used for early primary lung cancers or metastatic disease to various locations in the body. In addition to misattribution of the SRS episodes, this commenter stated that episodes of brachytherapy, SRS, and 1-10 3D EBRT occur in clinically unlikely episodes in the RO Episode File.

Response: We appreciate this question. We are confirming that SRS and SBRT are both included in the RO Episode File (2015-2017) under the classification of SRS. We understand the difference between and SRS and SBRT but erroneously labeled the column in the file as COUNT_SRS without explaining in the Data Dictionary posted on the RO Model website that COUNT_SRS includes both SRS and SBRT. This clerical error did not impact our calculations of the proposed base rates.

Comment: Some commenters expressed concern that the bundled payment structure might lead providers and suppliers to substitute older, less expensive modalities for newer, more expensive modalities. One of these commenters emphasized their concern for patient access to the most effective care from the RT provider or RT supplier, noting that the clinician is best suited to determine appropriate treatment for the patient. Another commenter emphasized that, while an individual RO participant might save costs by selecting the cheapest treatment during

the 90-day episode, longer-term Medicare costs could rise due to later complications or secondary tumors. A different commenter stated this Model incentivizes the use of the cheapest forms of radiation therapy, which also deliver the greatest amount of radiation to healthy tissue.

Response: We appreciate commenters' concerns. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As finalized in section III.C.14, we will monitor for unintended consequences of the RO Model including but not limited to stinting on care.

Comment: A commenter requested that CMS provide additional comparative effectiveness data between included and excluded modalities. This commenter expressed concern that more effective, and potentially more expensive modalities, were not included because they are not accessible to many Medicare beneficiaries. This commenter emphasized that racial and gender disparities in cancer outcomes may be due to disparities in treatment options, and requested that CMS justify how the inclusion of these modalities addresses disparities.

Response: We appreciate this commenter's concerns. We did not use comparative effectiveness data to determine whether modalities were included/excluded but rather focused on the most commonly utilized approaches to radiotherapy for the included cancer types. We believe that the RO Model pricing methodology, through the historical experience and case mix adjustments, will account for differences in RO participants' historical care patterns and the demographic characteristics of their patient populations. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. This includes prescribing the most appropriate modality. If a modality is not included in the RO Model, it will continue to be paid

FFS. As finalized in section III.C.14 and III.C.16, we will monitor for unintended consequences of the RO Model.

Comment: A couple of commenters expressed concern about the impact of the Model not only on Medicare beneficiaries, but also about the continued viability of offering PBT to patients. These commenters stated that unsustainable payment rates from Medicare would put centers' viability at risk, both operational centers as well as centers currently under development. They stated that Medicare is a material payor for the majority of members, representing the majority of their payor mix, and reducing their payment rates by up to 50 percent below cost will not be sustainable. They also stated that while the RO Model is focused on Medicare fee-for-service, it has implications for other payors, as many private payors often use the Medicare rates as a proxy, which could impact a center's broader payor mix. Further, these commenters stated that viability impacts not only Medicare beneficiaries but indirectly affects a broader set of patients including pediatric cancer patients who will lose access to a treatment that is now the standard of care.

Response: We appreciate these commenters' concerns. We disagree with the commenters on the expected magnitude of reduction in RO participants' payments for PBT compared to what they currently receive. As described in section III.C.6, the pricing methodology as finalized will blend together the national base rate with an RO participant's unique historical experience. If the RO participant is historically more costly than the national average, the blend in PY1 will be 90 percent of the RO participant's historical payments and 10 percent of the national base rate. This means that, prior to applying the discount factor and withholds that payments under the Model will be between 90 and 100 percent of the RO participant's historical payments. For historically inefficient RO participants, the blend shifts

over time to a 70/30 blend in PY5. This means that in PY5, prior to applying the discount factor and withholds that payments under the model will be more than 70 percent of the RO participant's historical payments. We believe that the pricing methodology tested under the Model represents an opportunity to provide high-value episode-based payments to RO participants for Medicare FFS beneficiaries; other payors determine their own payment approaches for RT services.

Comment: A commenter recommended applying savings proportionately to all modalities, particularly if CMS has a savings target under the Patient Access and Medicare Protection Act.

Response: While the RO Model is projected to be expenditure neutral or achieve Medicare savings, we did not have any specific predefined targets in mind, and we believe our pricing methodology has a graduated approach to setting participant-specific payments that is heavily weighted to the participant's historical experience.

After considering public comments, we are finalizing our 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

The proposed pricing methodology in the proposed rule described the data and process used to determine the amounts for participant-specific professional episode payments and participant-specific technical episode payments for each included cancer type (84 FR 34503). In the proposed rule, we proposed to define the term "participant-specific professional episode payment" as a payment made by CMS to a Professional participant or Dual participant for the

provision of the professional component of RT services furnished to an RO beneficiary during an episode, which is calculated as set forth in § 512.255. We further proposed to codify this term, "participant-specific professional episode payment," at § 512.205 of our regulations.

We proposed to define the term "participant-specific technical episode payment" as a payment made by CMS to a Technical participant or Dual participant for the provision of the technical component of RT services to an RO beneficiary during an episode, which we proposed to calculate as set forth in § 512.255 of the proposed rule. Further, we proposed to codify this term, "participant-specific technical episode payment," at § 512.205 of our regulations.

In the proposed rule, we proposed eight primary steps to the pricing methodology (84 FR 34503 through 34504). In the first step, we proposed to create a set of national base rates for the PC and TC of the included cancer types, yielding 34 different national base rates. Each of the national base rates represents the historical average cost for an episode of care for each of the included cancer types. We proposed that the calculation of these rates will 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 as described in section III.C.6.b of the proposed rule (84 FR 34504 through 34505) and this final rule. If an episode straddles calendar years, the episode and its claims are counted in the calendar year for which the initial treatment planning service is furnished. We proposed to exclude those episodes that do not meet the criteria described in section III.C.5 of the proposed rule and this final rule. From the remaining episodes (that is, not including the excluded episodes), we proposed to then calculate the amount CMS paid on average to providers and suppliers for the PC and TC for each of the included cancer types in the HOPD setting, creating the Model's national base rates. Unless a

broad rebasing is done after a later PY in the Model, these national base rates will be fixed throughout the Model performance period.

In the second step, we proposed to apply a trend factor to the 34 different national base rates to update those amounts to reflect current trends in payment for RT services and the volume of those services outside of the Model under the OPPS and PFS. We proposed to define the term "trend factor" to mean an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services. We proposed to codify the term "trend factor" at § 512.205 of our regulations. In this step, we 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. More specifically, as noted in the proposed rule, the calculations would update the national base rates using the most recently available claims data of those non-participating providers and suppliers and the volume at which they billed for RT services as well as their corresponding payment rates. Adjusting the national base rates with a trend factor will help ensure payments made under the Model appropriately reflect changes in treatment patterns and payment rates that have occurred under OPPS and PFS.

In the third step, we proposed to adjust the 34 now-trended national base rates to account for each Participant's historical experience and case mix history. The historical experience and case mix adjustments account for RO participants' historical care patterns and certain factors that are beyond an RO participant's control, which vary systematically among RO participants so as to warrant adjustment in payment. We proposed that there would be one professional and/or one technical case mix adjustment per RO participant depending on the type of component the RO participant furnished during the 2015-2017 period, just as there would be one professional and/or one technical historical experience adjustment per RO participant, depending on the type of

component the RO Participant furnished during the 2015-2017 period. We proposed to generate each RO participant's case mix adjustments using an ordinary least squares (OLS) regression model that predicts payment based on a set of beneficiary characteristics found to be strongly correlated to cost. In contrast, we proposed to generate each RO participant's historical experience adjustments based on Winsorized payment amounts for episodes attributed to the RO participant during the calendar years 2015-2017. The historical experience adjustments for each RO participant would be further weighted by an efficiency factor.[40] The blend measures if an RO participant's episodes (from the retrospectively constructed episodes from 2015-2017 claims data) have historically been more or less costly than the national base rates, and this determines the weight at which each RO participant's historical experience adjustments are applied to the trended national base rates.

In the fourth step, we proposed to further adjust payment by applying a discount factor. The discount factor is the set percentage by which CMS reduces payment of the PC and TC. The reduction on payment occurs after the trend factor and adjustments have been applied, but before standard CMS adjustments including the geographic practice cost index (GPCI), sequestration, and beneficiary coinsurance. The discount factor will reserve savings for Medicare and reduce beneficiary cost-sharing. We proposed to codify the term "discount factor" at § 512.205.

In the fifth step, we proposed to further 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. The incorrect payment withhold would reserve money for purposes of reconciling duplicate RT services and incomplete episodes

[40] Please note that in the final rule we are renaming the efficiency factor the "blend," as discussed in section III.C.6.e(2) of this final rule.

during the reconciliation process, as discussed in section III.C.11 of the proposed rule and this final rule. We proposed to define the term "duplicate RT service" to mean any included RT service (as identified at § 512.235 of the proposed rule) that is furnished to a single RO beneficiary by a RT provider or RT supplier or both that did not initiate the PC or TC of that RO beneficiary during the episode. We proposed to codify "duplicate RT service" at § 512.205 of the proposed rule. We proposed that an incomplete episode means the circumstances in which an episode does not occur 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 the initial RT treatment planning service to that RO beneficiary; (2) traditional Medicare stops being the primary payer at any point during the relevant 90-day period for the RO beneficiary; or (3) an RO beneficiary stops meeting the beneficiary population criteria under § 512.215(a) or triggers the beneficiary exclusion criteria under § 512.215(b) before the technical component of an episode initiates.

We also proposed to adjust for a quality withhold for the professional component of the episode. This withhold would allow the Model to include quality measure results as a factor when determining payment to participants under the terms of the APM, which is one of the criteria for an APM to qualify as an Advanced APM as specified in 42 CFR 414.1415(b)(1). We proposed to adjust for a patient experience withhold for the technical component of the episode starting in PY3 to account for patient experience in the Model. We would then apply all of these adjustments, as appropriate to each RO participant's trended national base rates.

In the sixth step, we proposed to apply geographic adjustments to payments. In the seventh and final eighth step, we proposed to apply beneficiary coinsurance and a 2 percent adjustment for sequestration to the trended national base rates that have been adjusted as

described in steps three through six, yielding participant-specific episode payment amounts for the provision of the PC and TC of each included cancer type in the Model. We proposed to calculate a total of 34 participant-specific professional and technical episode payment amounts for Dual participants, whereas we would only calculate 17 participant-specific professional episode payment amounts or 17 participant-specific technical episode payment amounts for Professional participants and Technical participants, since they furnish only the PC or TC, respectively.

Following this description of the data and process used to determine the amounts for participant-specific professional episode payments and participant-specific technical episode payments for each included cancer type, the proposed rule provided a pricing example for an episode of lung cancer (at 84 FR 34511). We provided this example to show how each pricing component (that is, national base rates, trend factors, case mix and historical experience adjustments, withholds, discount factors, geographic adjustment, beneficiary coinsurance, and sequestration) figures into these amounts. We also provided a summary-level, de-identified file titled the "RO Episode File (2015-2017)," on the RO Model's website to further facilitate understanding of the RO Model's pricing methodology. The following is a summary of the public comments received on this proposal, specifically those comments related not to particular pricing components, but rather comments related to the Model's pricing methodology in its general approach, potential impact, and structure as well as information provided to thoroughly review the methodology on these points and our response:

Comment: Many commenters requested additional information and data be provided in order to ascertain the degree of impact that the Model's pricing methodology will have on participant payment relative to what participants have historically been paid under FFS. Some

commenters argued that additional information is needed in order to justify the RO Model's pricing and policies in general. Several other commenters made requests for information related to specific pricing components. Several commenters stated that the case mix adjustment is not adequately defined and that more detail is needed concerning the regression models used to construct the case mix adjustments. A few commenters requested additional information regarding the historical experience adjustments, specifically the number and type of providers and suppliers that are classified as efficient versus inefficient.

Response: Based on a full review of comments and the detailed analyses contained within some of them, we believe that commenters have had sufficient detail to fully comment on the proposed RO Model. We prioritize, however, these comments and along with the finalized parameters of the Model, provide additional resources to include detailed illustrations, examples, and data, particularly concerning the case mix and historical experience adjustments. We refer readers to sections III.C.6.e.(1) and III.C.6.e.(2) of the case mix and historical adjustments, respectively, for that additional detail and to section III.C.6.j which closes the pricing methodology section. Here we list additional data we are able to provide at request of the commenters.

Comment: Many commenters expressed support for a prospective payment model in radiation oncology. A few commenters took issue with the prospective nature of the Model's payment rates, because they were not adjusted for factors occurring in the current performance year. A commenter suggested that the RO Model change to a retrospective payment model in that this would allow for payment rates to be adjusted for the patient population of the performance period for which payment was being allotted. A commenter opposed the Model generally, explaining that the RO Model is an experiment focusing on short-term effects and

costs, and ignores medium- and long-term complications and the resulting cost of care, such as costly side effects and secondary malignancies.

Response: We thank the commenters for sharing their support and concerns regarding a prospective payment model in radiation oncology. It is not the intent of the Model for payment based on 90-day episodes to incorporate the long-term health outcomes of a patient or associated costs, though the RO Model evaluation will analyze health outcomes that occur after RO episodes end to the extent feasible. The Model is designed to predict payment based on the historical characteristics of a participant's population based on the most recent claims data available. In particular, we refer readers to section III.C.6.e.(1) concerning the case mix adjustments. We update the case mix adjustment for each RO participant every year to account for the most recent set of episodes for which claims data is available. Also, it is important to note that in analyzing 2015-2017 episode data, we found that participants' case mix is relatively stable over time for most providers and suppliers.

We believe that this prospective episode-based payment structure for RT services is the best design for testing an episodic APM for RT services. The payment rates for RO episodes of care are unambiguous and known to RO participants prior to furnishing RT services. We are testing an approach where prospective episode-based payments will not be reconciled based on how many or which individual RT services are provided by the RO participant during the RO episode, with the exception of incomplete episodes and duplicate RT services. This allows us to test the impact of episode-based payments that do not have today's FFS incentives.

Comment: Many commenters expressed concern over the participant-specific professional episode payment and technical episode payment amounts related to what non-participants in the Model will receive under FFS. Commenters believed that the proposed

pricing methodology as constructed with the national base rates based on HOPD claims data alone along with the proposed adjustments, discounts, and withholds, RO participants will be unable to receive sufficient payment under the Model or reasonably achieve savings. A commenter estimated that RO participants would receive up to 50 percent less in payments under the Model than non-participants who continue to be compensated under FFS. Many commenters stated that the proposed pricing methodology does not adequately pay RO participants for labor and resources required to care for the most complex patients and that the Model underestimates the costs and administrative burden of adjusting to and complying with the Model. A few commenters explained that payment under the Model would represent significant cuts to what RT providers and RT suppliers have been historically paid, particularly because the TC is not associated with an APM Incentive Payment. A commenter expressed concern that there could be a great degree of variation in episode spending outside the control of HOPDs, particularly those with little experience with episode-based payments.

Several commenters recommended that CMS limit the downside risk for RO participants, because as proposed, the Model provides no safeguard for excessive financial downside risk. A few commenters recommended restructuring the Model altogether to permit two-sided risk that would allow providers and suppliers to enter into risk at a self-determined pace. A few commenters suggested that the RO Model take a "shared savings" approach with RO participants sharing risk for gains and losses. Another commenter suggested a graduated glide path to risk for the RO Model, similar to the approach adopted in the Medicare Shared Savings Program (Shared Savings Program) Pathways to Success final rule. Another commenter suggested that payment be set by optimal actual costs of well-managed sites of service that furnish radiation with a margin to allow for innovation and upgrades. A commenter requested clarification as to

whether RO participants could reinsure or get stop-loss insurance to mitigate risk, since RO participants are at risk for all costs over the bundled payment amounts.

Response: We thank these commenters on their feedback and suggestions related to Model payments relative to those received under FFS. We disagree that episode payment amounts would be reduced by 50 percent as compared to non-participants. We designed the pricing methodology so that participant-specific professional and technical episode payment amounts are largely based on what each participant has been paid historically under FFS and trended forward based on latest payment rates under FFS. Moreover, we adjust for those beneficiary characteristics that have a large impact on cost in the case mix adjustment.

We note, however, that RO participants that have fewer than 60 episodes in the baseline period do not have sufficient historical volume to calculate a reliable historical experience adjustment. Since these RO participants will not qualify to receive a historical experience adjustment and may see greater increases or reductions as compared to what they were historically paid under FFS as a result of not receiving the adjustment, we believe that it is appropriate to adopt a stop-loss limit of 20 percent for RO participants that have fewer than 60 episodes in the baseline period and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule (see section III.C.6.e(4) of this final rule). We are adding a definition at § 512.205 for "stop-loss limit," which means the set percentage at which loss is limited under the Model used to calculate the stop-loss reconciliation amount. We are also adding at § 512.205 a definition for "stop-loss reconciliation amount" which means the amount owed to RO participants that have fewer than 60 episodes during 2016-2018 and were furnishing included RT services in the CBSAs selected for participation at the

time of the effective date of this final rule for the loss incurred under the Model as described in § 512.285(f).

Thus, we disagree with the premise that the proposed pricing methodology does not adequately pay RO participants for labor and resources required to care for the most complex patients. In particular, we refer readers to section III.C.6.e.(2) of this final rule for more information regarding the blend used to determine how much participant-specific historical payments and national base rates figure into payment. The blend provides a glide path toward the national average for each cancer type. Moreover, this is not a total cost of care model in that each RO episode covers only RT services. We limited the Model in this way, because we believe that these RT services are in control of the RT provider and RT supplier. For these reasons, reconfiguring the RO Model to incorporate either a "shared savings" element or gradual risk at a pace determined by RO participants is not necessary.

To ease any burden of adjusting to and complying with the Model, we are finalizing policies that reduce the discount factor by 0.25 percent for both the PC and TC, so that the discount rates are 3.75 percent and 4.75 percent for the PC and TC, respectively (see sections III.C.6.a and III.C.6.f). See section § 512.205 for the modification to the proposed discount factors. Also, we are finalizing policies that reduce the incorrect payment withhold to 1 percent. See section III.C.6.g(1) for the modification to the proposed incorrect payment withhold. These reductions, as detailed in the pricing methodology component sections to which they apply, should further minimize any cost differential that a participant may experience under the Model as opposed to what the participant historically received in payment under FFS.

Comment: Many commenters suggested that the payment structure be adjusted to account for patients receiving treatment for multiple tumor sites. A commenter stated that a

diagnosis of primary lung cancer and prophylactic whole brain treatment would not both be covered by the national base rate for lung cancer. A commenter suggested monitoring the frequency and cost of care associated with multiple treatment sites in order to determine if the pricing methodology should be modified in future years on this point.

Response: We thank these commenters for their feedback regarding patients receiving treatment for multiple tumor sites. An episode-based payment covers all included RT services furnished to an RO beneficiary during a 90-day RO episode as codified at § 512.205 and § 512.245. Episodes are constructed using all Medicare FFS claims for radiation therapy services included in the Model. All RT services included on a paid claim line during the 90-day episode were multiplied by the OPPS or PFS national payment rate for that service and were included in the payment amounts for the PC and TC of that episode regardless of whether the service is aimed at treating the attributed primary disease site or not. As such, the national base rates incorporate payments for treatment of multiple tumor sites to the extent that more than one site was the focus of RT services during episodes of care in the historical period. Bundled episode payment rates are premised on the notion of averages. These cases described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued, and, therefore, an adjustment for multiple tumor sites is not warranted at this time. Yet, we will be monitoring for change in treatment patterns related to patients being treated for multiple tumor sites throughout the Model performance period and will consider modifications to the pricing methodology in future years of the Model should it be warranted. Any changes to the pricing methodology will be made via notice and comment rulemaking.

Comment: Several commenters noted that the national base rates for prostate cancer and for gynecological cancers are not reflective of the increased costs of combined modality care, but rather these rates are driven by large volumes of patients who receive external beam radiation only. As a consequence, these commenters argued that RO participants would not be sufficiently compensated for these beneficiaries.

Response: As noted in the previous comment, an episode-based payment covers all included RT services furnished to an RO beneficiary during a 90-day episode as codified at § 512.205 and § 512.245. All RT services included on a paid claim line during the 90-day episode are multiplied by the OPPS or PFS national payment rate for that service and are included in the payment amounts for the PC and TC of that episode regardless of the type of modality used to treat the beneficiary. As such, the national base rates incorporate payments for treatment from multiple modalities to the extent that more than one modality was furnished during episodes of care in the historical period. These cases described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued, and, therefore, an adjustment for multiple modalities is not warranted at this time. Yet, we will be monitoring for change in treatment patterns related to patients being treated with multiple modalities throughout the Model performance period and will consider modifications to the pricing methodology in future years of the Model should it be warranted. Any changes to the pricing methodology will be made via notice and comment rulemaking.

Comment: A few commenters 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. Several commenters expressed concern that no adjustment would be made if multiple courses of treatment were furnished within that 90-day period.

Response: An RO episode includes all included RT services (See Table 2) furnished to an RO beneficiary with an included cancer type during the 90-day episode as codified at § 512.205 and § 512.245. These cases described by the commenters are part of the set of historical episodes included in the averages that determine the national base rates and contribute to how payment amounts are valued and, therefore, an adjustment for multiple courses of treatment is not warranted at this time.

Comment: Many commenters suggested that the payment structure be adjusted to account for patients receiving treatment for secondary malignancies.

Response: An RO episode includes all included RT services (See Table 2) 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 (for example, there may be claims for RT services included in the pricing for that episode that indicate more than one cancer type according to the ICD-10 diagnosis codes listed on the various claims), those RT services and their costs are all included in the calculation of the payment rate for that episode.

We would like to clarify how cancer type is assigned to an episode for calculation of the national base rates. It is important to note that episodes are first assigned a cancer type when the episode is created, whether the cancer type is included in the Model or not, and then if that cancer type is not included in the Model, that episode is excluded subsequently from Model pricing. For instance, episodes first assigned with a secondary malignancy for cancer type during the episode construction phase are then excluded when pricing calculations are conducted. Our process for assigning a cancer type to an episode is as follows:

First, ICD-10 diagnosis codes during an episode were identified from:

(1) E&M services with an included cancer diagnosis code from Medicare PFS claim lines with a date of service during the 30 days before the episode start date, on the episode start date, or during the 29 days after the episode start date.

(2) Treatment planning and delivery services (See Table 2) with an included cancer diagnosis code from Medicare PFS claim lines, or treatment delivery services from Medicare OPPS claim lines with an included cancer diagnosis code on the claim header, with a date of service on the episode start date or during the 29 days after the episode start date. Note that the cancer diagnosis code from OPPS claims must be the principal diagnosis to count toward cancer type assignment; and that treatment delivery services that concern image guidance do not count toward cancer type assignment as we determined that image guidance was not an important indicator of cancer type.

Then, these ICD-10 diagnosis codes are summarized and counted across the claim lines to determine the episode's cancer type assignment according to the algorithm described in (a) through (c):

(a) If two or more claim lines fall within brain metastases or bone metastases or secondary malignancies (per the mapping of ICD-10 diagnosis code to cancer type described in Table 1 of Identified Cancer Types and Corresponding ICD-10 Codes), we set the episode cancer type to the type (either brain metastases or bone metastases) with the highest count. If the count is tied, we assign the episode in the following order of precedence: brain metastases; bone metastases; other secondary malignancies.

(b) If there are fewer than two claim lines for brain metastases, bone metastases and other secondary malignancies, we assign the episode the cancer type with the highest claim line count among all other cancer types. We exclude the episode if the cancer type with the highest claims line count among other cancer types is not an included cancer type.

(c) If there are no claim lines with a cancer diagnosis meeting the previously discussed criteria, then no cancer type is assigned to that episode and therefore, that episode is excluded from the national base rate calculations.

Comment: A commenter recommended that a payment adjustment be made for the increased use of Magnetic Resonance simulation that was not present during the baseline period of 2015-2017 in order to monitor patient safety and treatment efficacy.

Response: We will be monitoring for changes in treatment patterns throughout the Model's performance period with particular attention to the increased use of MR simulation. We will consider proposing modifications to the pricing methodology in future years of the Model should it be warranted.

Comment: Many commenters expressed concern that the pricing methodology fails to account for complex clinical scenarios and treatment costs. Many commenters recommended that only standard medically accepted case rates should be used to determine payment.

Response: At this time, we have only claims data available to design and operationalize the RO Model. The claims data do not include clinical data. We are finalizing our proposal to collect clinical data from RO participants so that we can assess the potential utility of additional clinical data for monitoring and calculating episode payment amounts (see section III.C.8.e of this final rule). Further, we believe that the case mix adjustment appropriately accounts for the

complexity of an RO participant's patient population, and the historical experience adjustment captures additional unmeasured factors that may make one RO participant's patient population more complex, and thus more costly, than another's. We also believe that the national base rates would be lower if we were to use a standard treatment course to set payments, since there are situations in which greater volume is used than would be prescribed by a standard course of treatment.

Comment: A commenter suggested assigning an episode of care initiator, who would be responsible for total spending for the PC and TC, similar to the BPCI Advanced Model.

Response: Similar to the BPCI Advanced Model, the RO participants initiate (or trigger) RO episodes of care with an initial service, which is the treatment planning service in the RO Model. In both the RO Model and BPCI Advanced Model, the model participant is responsible for Medicare fee-for-service (FFS) expenditures for all items and services included in an episode of care starting with the episode trigger. However, in the RO Model, we have limited financial risk to RT services whereas the BPCI Advanced Model participants are responsible for the total amount of Medicare spending for non-excluded items and services in the episode of care. As described in section III.C.5.c, we believe that it is appropriate to limit risk in the RO Model just to RT services, which are managed by the radiation oncologist.

Comment: A commenter expressed support for the proposed policies related to the definition of incomplete episodes. A few commenters requested that CMS provide an example calculation for how an incomplete episode would be paid. Another commenter requested clarification on the situation of a beneficiary switching RT providers and/or RT suppliers and how each would be paid if both RT providers and/or RT suppliers were participants in the Model.

Response: We thank these commenters for their support and requests. As noted in the proposed rule and in this final rule, we expect to provide RO participants with additional instructions for billing, particularly as billing pertains to incomplete episodes and duplicate RT services, through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website. For a subset of incomplete episodes in which (1) the TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished the RO participant is owed only what it would have received under FFS for the RT services furnished to that RO beneficiary, CMS will reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. When an RO beneficiary switches RT provider or RT supplier, he or she is no longer under the care of the RO participant that initiated the PC and/or TC of the RO episode.

In the case that traditional Medicare ceases to be the primary payer for an RO beneficiary after the TC of the RO episode has been initiated but before all included RT services in the RO episode have been furnished, then each RO participant will be paid only the first installment of the episode payment. The RO participant will not be paid the EOE PC or TC for these RO episodes as CMS cannot process claims for a beneficiary with dates of service on or after the date that traditional Medicare is no longer the primary payer. If the SOE for the PC is paid and the RO beneficiary ceases to have traditional Medicare FFS, for example by switching to a Medicare Advantage plan, before the TC is initiated, then during reconciliation, CMS will calculate what the RO participant would have received under FFS for the RT services included in

the PC furnished to that beneficiary prior to the beneficiary switching from traditional Medicare to another payer.

We account for duplicate RT services differently. In the proposed rule, a duplicate RT service means any included RT service that is furnished to a single RO beneficiary by a RT provider or RT supplier or both that did not initiate the PC or TC for that RO beneficiary during the RO episode. We are finalizing this proposed definition of duplicate RT service with modification. Duplicate RT service means any included RT service identified at § 512.235 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. Such services are furnished in addition to the RT services furnished by the RO participant that initiated the PC or TC and continues to furnish care to the RO beneficiary during the RO episode. This modification also clarifies that RT services furnished by a RT provider or supplier excluded from participation in the Model (for example, an ambulatory surgery center, see section III.C.3.c for exclusion criteria) are not considered a duplicate RT service. If the EOE PC and TC payments have been made to the RO participant that initiated the PC or TC of that RO episode, and claims are submitted on behalf of that same beneficiary for RT services furnished by another RT provider or RT supplier during that RO episode, then during reconciliation, payments for those duplicate RT services will be reconciled against the incorrect payment withhold for the RO participant that received full payment for the RO episode. The other RT provider or RT supplier that furnished RT services to that beneficiary, whether an RO participant or not, will be paid FFS for those RT services.

For any RO episode that involves one or more duplicate RT services, the payment for the RO participant that initiated the PC or TC will be reconciled by reducing the RO participant's

episode payment by the FFS amount of the duplicate RT services furnished by the RT provider or RT supplier that did not initiate the PC or TC. The FFS amount to be subtracted from the RO participant's bundled payment, however, cannot exceed the amount that the RO participant would receive under FFS for the RT services they furnished during the RO episode. We note that a duplicate RT service is distinct from the situation where an RO beneficiary switches to a different RT provider or RT supplier. As explained above, when an RO beneficiary switches to a new RT provider or RT supplier, and is no longer under the care of the RO participant that initiated the PC and/or TC, the RO episode is an incomplete episode. The RO participant is owed what it would have received under FFS for the RT services furnished to that RO beneficiary, and CMS will use no-pay claims to reconcile the episode payment with what the FFS payments would have been for the RT services. For further details, see section III.C.11(b) of this final rule.

In sum, all claims for RT services for an RO beneficiary with dates of service during the 90-day RO episode will be reviewed during annual reconciliation, to determine if that RO episode qualifies as complete as stipulated in section III.C.11 and codified at § 512.285 and if duplicate RT services occurred as defined in section III.C.6a and codified at § 512.205. As a consequence of this process, CMS will determine how all of these claims impact the annual reconciliation amount on an episode-by-episode basis. The sum of payments for duplicate RT services and the sum of payments for RT services during the incomplete episode represent the impact of those duplicate RT services and incomplete episodes across all RO episodes attributed to the RO participant for the PY considered in that annual reconciliation. See section III.C.11 for further details on this process. Table 14 in that section is an example of the annual reconciliation

calculation. For more information on billing under the RO Model, see section III.C.7; for more information on reconciliation during the RO Model, see section III.C.11.

In our proposed eight primary steps to the pricing methodology, we are making 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. We proposed to apply the OPPS Pricer as it is automatically applied under OPPS outside of the Model at 84 FR 34510 of the proposed rule, and see section III.C.6.h. of this final rule. We also proposed to use RO Model-specific RVU shares to apply PFS RVU components (Work, PE, and MP) to the new RO Model payment amounts in the same way they are used to adjust payments for PFS services in section III.C.6.h. In order to use RO Model-specific RVU shares to apply PFS RVU components to the new RO Model payment amounts in the same way they are used to adjust payments for PFS services, the geographic adjustment must be applied to the trended national base rates prior to the case mix and historical experience adjustments and prior to the discount factor and withholds. We note that, although modifying the sequence of the pricing methodology in this way slightly changes the amount of dollars attributed to the discount factor and to each withhold, the participant-specific professional episode payment amounts and the participant-specific technical episode payment amounts do not change as a result of this modification. We list all modifications to the pricing methodology at the end of the pricing methodology section, section III.C.6 of this final rule.

b. Construction of Episodes Using Medicare FFS Claims and Calculation of Episode Payment

For the purpose of calculating the national base rates, case mixes, and historical experience adjustments, we 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 as discussed in section III.C.3.d of the proposed rule and this final rule. We proposed to exclude those episodes that do not meet the criteria discussed in section III.C.5 of this final rule. Each episode and its corresponding payment amounts, one for the PC and one for the TC, would represent the sum totals of calculated payment amounts for the professional services and the technical services of the radiation treatment furnished over a defined 90-day period as discussed in section III.C.5.b of this final rule. We proposed to calculate the payment amounts for the PC and TC of each episode as the product of: (a) the OPPS or PFS national payment rates for each of the RT services included in the Model multiplied by (b) the volume of each professional or technical RT service included on a paid claim line during each episode. We proposed to neither Winsorize nor cap payment amounts nor adjust for outliers in this step.

So that all payment amounts are in 2017 dollars, we 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. We proposed to apply this same process for episodes starting in 2016. To weigh the most recent observations more heavily than those that occurred in earlier years, we would weight episodes that initiated in 2015 at 20 percent, episodes that initiated in 2016 at 30 percent, and episodes that initiated in 2017 at 50 percent.

We proposed that conversion of 2015 and 2016 payment amounts to 2017 dollars would be done differently, depending on which step of the pricing methodology was being calculated. For instance, episode payments for episodes used to calculate national base rates and case mix regression models would only be furnished in the HOPD setting, and consequently, for purposes

of calculating the national base rates and case mix regression models, the conversion of episode payment amounts to 2017 dollars would be based on average payments of episodes from only the HOPD setting. On the other hand, episode payments for episodes used to calculate the historical experience adjustments would be furnished in both the HOPD and freestanding radiation therapy center settings (that is, all episodes nationally), and consequently, for purposes of calculating the historical experience adjustments, the conversion of episode payment amounts to 2017 dollars would be based on average payments of all episodes nationally from both the HOPD and freestanding radiation therapy center settings.

Comment: A few commenters disagreed with weighting the most recent episodes more heavily than those that occurred in earlier years, specifically weighting episodes that initiated in 2015 at 20 percent, episodes that initiated in 2016 at 30 percent, and episodes that initiated in 2017 at 50 percent. A couple of commenters stated that the 2017 rates were the lowest rates of all three years in the baseline, yet accounts for 50 percent of the national base rates. A commenter stated that the average reduction in rates from 2015 to 2017 was 11 percent for all included modalities except Conformal External Beam (CEB), which saw an 8 percent increase. Another commenter stated that the lower 2017 rates would increase the net loss that participants are likely to experience under the Model.

Response: We proposed to weight the most recent year in the baseline more heavily because this gives more weight to the most recent episode data available, including the most recent treatment patterns, not because they are the "lowest" rates. Furthermore, since we are moving the dates of service for the construction of episodes up a year from CYs 2015-2017 to CYs 2016-2018, episodes initiated in 2017 will be weighted at 30 percent not 50 percent. We are finalizing this provision with modification to construct episodes based on dates of service for

Medicare FFS claims paid during the CYs 2016-2018 as well as claims that are included under an episode where the initial treatment planning service occurred during the CYs 2016-2018 as discussed in section C.III.6 of the proposed rule and this final rule. To weigh the most recent observations more heavily than those that occurred in earlier years as proposed, we 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

We 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 included cancer types. We further proposed to codify this term at § 512.205 of our regulations.

The proposed rule would exclude the following episodes 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 our criteria for inclusion in the Model, as discussed in section III.C.5.a of the proposed rule (84 FR 34497 through 34498) and this final rule;
- 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);

• Episodes in which a Medicare beneficiary does not meet the eligibility criteria discussed in section III.C.4 of this final rule.

We proposed to exclude episodes without positive (>$0) total payment amounts for professional services or technical services, since we would only use episodes where the RT services were not denied and Medicare made payment for those RT services. We proposed to exclude episodes that are not assigned a cancer type and episodes assigned a cancer type not on the list of Included Cancer Types, since the RO Model evaluates the furnishing of RT services to beneficiaries who have been diagnosed with one of the included cancer types. The remaining proposals listed in section III.C.6.c of the proposed rule excluded episodes that are not in accordance with section III.C.5 of the proposed rule.

(1) National Base Rate Calculation Methodology

When calculating the national base rates, we proposed to only use episodes that meet the following criteria: (1) episodes initiated in 2015-2017; (2) episodes attributed to an HOPD; and (3) during an episode, the majority of technical services were provided in an HOPD (that is, more technical services were provided in an HOPD than in a freestanding radiation therapy center). We explained in the proposed rule that OPPS payments have been more stable over time and have a stronger empirical foundation than those under the PFS. The OPPS coding and payments for radiation oncology have varied less year over year than those in the PFS for the applicable time period. In addition, generally speaking, the OPPS payment amounts are derived from information from hospital cost reports, which are based on a stronger empirical foundation than the PFS payment amounts for services involving capital equipment.

CMS proposed to publish the national base rates and provide each RO participant its participant-specific professional episode payment amounts and/or its participant-specific

technical episode payment amounts for each cancer type no later than 30 days before the start of the PY in which payments in such amounts will be made.

Our proposed national base rates for the Model performance period based on the criteria set forth for cancer type inclusion were summarized in Table 3 of the proposed rule.

Comment: Many commenters disagreed with the proposal for calculating the national base rates based on average payment of episodes from only the HOPD setting. These commenters stated that utilizing only HOPD episodes does not reflect the actual payment experience for freestanding radiation therapy centers, and that it is inappropriate to base a site neutral test on HOPD episodes alone. Some commenters questioned CMS' rationale for excluding freestanding radiation therapy center data from the calculation of the national base rates. The commenters claim that CMS' rationale (that is, that HOPDs furnished a lower volume of services and used less costly modalities within such episodes than did freestanding radiation therapy centers even though HOPDs provided more episodes nationally from 2015 through 2017) is not sufficient to warrant the exclusion of freestanding radiation therapy centers from the calculation of the national base rates. Another commenter stated that the analysis conducted by CMS provides no basis to suggest that higher utilization, particularly of IMRT in freestanding radiation therapy centers, is not medically necessary. Another commenter stated that particularly with respect to treatment of prostate cancer, the number of fractions for a course of treatment have held constant for nearly a decade, regardless of site of service. A few commenters questioned the veracity of the claim that the vast majority of increased utilization is occurring in the freestanding radiation therapy centers and requested that CMS share the details of its calculation that freestanding radiation therapy centers received 11 percent higher reimbursement per episode than HOPDs. MedPAC argued that using HOPD rates would increase payments to

freestanding radiation therapy centers and reduce savings for Medicare. Finally, a few commenters took issues with the premise that OPPS rates have been more stable than the PFS rates, since PFS payments for radiation therapy codes have been frozen since 2015. Using one or more of the previously discussed arguments, many commenters recommended calculating the national base rates using a blend of PFS and OPPS rates rather than basing the rates on OPPS rates alone. These commenters argued that this blend would better account for different care patterns across the different sites of service. Additionally, several commenters recommended CMS use more recent data than 2015-2017, if available.

Response: We refer readers to the November 2017 Report to Congress that discusses FFS incentives and the site-of-service payment differential between HOPDs and freestanding radiation therapy centers in detail. It is true that the PFS rates have been fixed since 2015 and added stability temporarily, but these rates were fixed at the behest of professional organizations in radiation oncology in large part because of their concerns that those rates were unstable and under review as being potentially misvalued. The OPPS rates are constructed from hospital cost data. This cost data provides empirical support for the OPPS rates. The PFS rates do not have the same empirical cost data backing, as we explained in the proposed rule and in the November 2017 Report to Congress. We would also like to clarify 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 in episodes where beneficiaries sought treatment from both HOPDs and freestanding radiation therapy centers.

We disagree that a blend of PFS and OPPS rates would better account for different care patterns across the different settings of HOPDs and freestanding radiation therapy centers. We

believe the argument that the number of fractions has held constant for nearly a decade for a course of treatment for prostate cancer, regardless of site of service, supports the Model's move toward site neutrality, in that the settings are comparable, and no matter which site of service is used as the basis for payment, it should make no difference to treatment outcomes. We have found no evidence supporting different utilization rates based on setting. For clarity, we have found no evidence to suggest that, on average, higher utilization rates are warranted for RT services furnished in freestanding radiation therapy centers than for RT services furnished in the HOPD setting. We proposed to adopt both case mix and historical experience adjustments to account for the different care patterns of each RO participant specifically, not the different care patterns of HOPDs and freestanding radiation therapy centers in general. Furthermore, as patterns of care change over time, we will apply a trend factor to the 32 different national base rates to account for current trends in payment for RT services and the volume of those services outside of the Model in both HOPDs and freestanding radiation therapy centers. For clarity, we will use the volume and payment for RT services experienced in both settings to determine the trend factor.

As for hypofractionation, the RO Model is not intended to make hypofractionation the standard of care in radiation oncology unless it is clinically appropriate to do so. We refer readers to section III.B.3, aligning payments to quality and value, rather than volume, where the issue of hypofractionation is discussed in detail.

We agree with the comment that using HOPD rates would increase payments to freestanding radiation therapy centers, but only if we are considering payment on a per service basis, not when services are bundled under an episode of care and paid for accordingly, as will be done under the RO Model.

Finally, we agree with the commenters about using more recent baseline data, and therefore, we are 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.

Comment: Several commenters raised concerns regarding the OPPS comprehensive APC (C-APC) methodology. CMS applies this policy to certain RT services under the OPPS and commenters explained that radiation oncology is better suited for component coding to account for several steps in the process of care. The commenters also noted that the OPPS C-APC methodology does not account for the several steps in the process of care and fails to capture appropriately coded claims. A few commenters stated that the amount a hospital charges for a service does not have a direct or consistent relationship to what the service actually costs, and hospitals often use monthly or repetitive service claims. The commenters suggested that CMS monitor the impact of the OPPS methodology on payment rates under the RO Model and consider using the OPPS APC without the C-APC methodology for the technical component of the national base rate for cervical cancer, in particular.

Response: We thank the commenters for expressing their concerns regarding the OPPS C-APC policy that is used to pay for certain HOPD-furnished RT services. We also appreciate their recommendations regarding monitoring the impact of these policies on the episode payment amounts under the Model. We refer readers to section III.C.5.a, where we discuss the inclusion of cervical cancer as it relates to the C-APC methodology.

The purpose of the RO Model is to test a site-neutral and modality-agnostic approach to payment for RT services. We determined it was necessary to include certain RT services (for example, Stereotactic Radio Surgery) which are subject to the packaging policy under the OPPS in the RO Model to help ensure site neutrality and a modality-agnostic approach. For clarity, we

would have likely had to exclude certain commonly provided RT services if we wanted to avoid those codes that are subject to the OPPS C-APC policy. In addition, the RO Model will calculate a single episode payment rate for all of the included RT services for a 90-day period. As a result, the impact of any one code on the overall episode payment amount is minimal. We will monitor the impact of the C-APCs on the episode payment rates.

Comment: Many commenters expressed concerns regarding the calculation of the national base rates in that they believe the rates inappropriately include palliative care cases and distort the true cost of cancer care. A few commenters expressed concern about the lung cancer national base rates, in particular, and stated that 47 percent of the cases were palliative in nature. These commenters argued that the intent of treatment should determine pricing in these cases. CMS should determine whether these cases are palliative or curative in nature, and from this, develop separate rates within this cancer type.

Many commenters suggested that removing palliative cases would more accurately account for the cost of delivering standard of care in radiation oncology, but commenters differed on which cases would constitute care that is palliative in nature. A commenter suggested removing conformal radiation therapy treatment with ten or fewer fractions and then creating a separate "Cancer symptom palliation, not otherwise specified" episode, asserting that pulling these cases out would more accurately account for the cost of care. A few commenters suggested removing all episodes of 1-10 fractions with 2D or 3D management and removing non-SBRT episodes. Another commenter noted that even treatment courses of 11-20 fractions have high probability of being palliative episodes.

Response: In assigning cancer types, we created the Model to be as sensitive as possible in identifying palliative cases, including bone and brain metastasis cases. We believe the

methodology we use to assign cancer types, which preferences assignment of bone and brain metastasis cases, appropriately captures those clinical circumstances where a beneficiary was treated not for cancer at the original site but for metastasis to the bone or brain, respectively. Other palliative cases described by the commenters are part of the set of historical episodes for other cancer types and are included in their national base rates. We refer readers to the comment responses in the overview of the pricing methodology in section III.C.6.a, where we detail how cancer type is assigned to an episode. Removing episodes determined to be palliative based solely on a low number of treatments would remove cases where a curative treatment included a low number of fractions. We cannot definitively determine if a treatment was palliative in nature based on count of fractions, and we do not intend to tie episode payment to fraction count, which would keep in place the FFS-incentive structure the RO Model intends to change. We will be monitoring to ensure that episodes of bone and brain metastasis are appropriately billed under the Model. We will not remove cases that are perceived to be palliative in nature based on the number of fractions furnished during the episode.

Comment: Many commenters called into question the integrity of data used to generate the national base rates. Many commenters stated that the national base rate calculations inappropriately include incomplete episodes of care. A commenter stated that 14 percent of HOPD cases look like incomplete episodes, because they had technical charges that were less than $5,000. A commenter estimated that if these incomplete episodes of care were to be excluded, this would increase the national base rates by approximately 16 percent.

Another commenter expressed concern about the payment differential between the average freestanding radiation therapy center rate and the average HOPD rate with regard to prostate cancer. The commenter attributed the payment differential, whereby the freestanding

radiation therapy center rate was 7.5 percent higher than the average HOPD rate, to the additional $4,000 per episode for brachytherapy.

A commenter stated that a few providers and suppliers account for a large percentage of the total amount of episodes and that these providers and suppliers could have a disproportionate impact on the setting of the national base rates, homogenizing the data used to set those rates, and therefore, the method of calculating the national base rates should be reconsidered. Several commenters stated that non-standard treatment episodes are included in the calculation of the national base rates, and as a consequence, artificially depress actual cost. In a similar vein, a commenter added that artificially low payments caused by coding errors and billing infrequency in the HOPD setting may cause CMS to qualify otherwise efficient practices as inefficient participants. As an example, the commenter explained that many episodes had more than 10 brachytherapy treatment delivery services, while other episodes had brachytherapy counts 1-10 or 11-20 and also 11-20 or 21-30 IMRT/CEB counts. This signals an inconsistency in the way codes were used in COUNT_BRACHY. The commenter requested that the code set used for each code count be provided in the data dictionary that accompanies the episode file on the RO Model website.

Several commenters suggested CMS establish tiered base rates rather than a single base rate per cancer type. A commenter suggested developing different base rates based on resource levels and clinical complexity analogous to OPPS ambulatory payment classification levels. Similarly, a few commenters recommended the national base rates be stratified based on the clinical characteristics of beneficiaries as this significantly affects the number and type of treatment received, not just by the broad category of cancer they have. A commenter suggested that cancer stage and intensity of treatment be considered in payment. A commenter suggested

that CMS use fewer than 34 different national base rates, because so many different rates would cause confusion for RO participants that treat multiple types of cancers.

Response: We thank these commenters for expressing these concerns and for their suggestions. We disagree that incomplete episodes were inappropriately included in the national base rates. We used the same criteria to identify episodes in the baseline as we will use in the Model. Only episodes that meet certain criteria, codified at § 512.250**,** would be included in the national base rate calculation and in the calculation of the trend factor, case mix and historical experience adjustments. We are finalizing episode exclusion criteria with a few clarifications. We are clarifying that we exclude episodes in the baseline which are not attributed to an RT provider or RT supplier, an exceedingly rare case (less than 15 episodes out of more than 518,000 episodes in the baseline period) where the only RT delivery services in the episode are classified as professional services (because there are a few brachytherapy surgery services that are categorized as professional services). We are also clarifying that episodes are excluded if either the PC or TC is attributed to an RT provider or RT supplier with a U.S. Territory service location or to a PPS-exempt entity. However, services within an episode provided in a US Territory or provided by a PPS-exempt entity are included in the episode pricing. Thus, for the constructed episodes used to determine the baseline, we will include the costs of any services provided by such an RT provider or RT supplier, as long as the RT provider or RT supplier does not provide the majority of either the professional or technical services, in which case the PC or TC would be attributed to the entity and the episode would be excluded. We are also clarifying that episodes are excluded if they include any RT service furnished by a CAH. Further, we are clarifying that we exclude all Maryland and Vermont claims before episodes are constructed and attributed to an RT provider or RT supplier. For this reason, there are not episodes in which

either the PC or TC is attributed to an RT provider or RT supplier with a Maryland or Vermont service location. We similarly exclude inpatient and ASC claims from episode construction and attribution.

Episodes are not excluded based on any clinical standards of care or based on the size of HOPD that furnished the episode. We also do not use the size of RT providers or RT suppliers, that is, the number of episodes that a given RT provider or RT supplier furnishes, as a measure of exclusion. We disagree that the national base rate calculation should account for size of the RT provider or RT supplier, as we do not believe that large RT providers and RT suppliers make up a disproportionate share of the episodes in the calculation of the national base rates. As long as HOPD episodes meet inclusion criteria as stated in section III.C.6.c, they will be included in the calculation of the national base rates, regardless of the size of the RT provider or RT supplier where the episode was furnished. It is important to note that the cost of RT services vary by modality and cancer type, and although payment differentials may exist across episodes due to the use of multiple modalities as a commenter stated, we believe that using a blend to determine payment (that is, a blending of participant-specific historical payments with national base rates to determine payment) allows us to balance the national context (as represented by the spectrum of HOPDs nationally) with participant experience.

Furthermore, we have only claims data available to design and operationalize the RO Model. These claims data do not include clinical data, which is why we are finalizing our proposal to collect clinical data from RO participants to assess the potential utility of additional data for monitoring and calculating episode payment amounts (see section III.C.8.e). We do not have the clinical or resource level data to design tiered base rates as several commenters suggested. Further, we believe that the case mix adjustment appropriately accounts for the

complexity of an RO participant's patient population, and the historical experience adjustment captures additional unmeasured factors that may make one RO participant's patient population more complex, and thus more costly, than another's. Similarly, no resource databases are available that have the kind of data necessary to determine national base rates for a generalizable sample of Medicare FFS beneficiaries. We believe the best way to calculate prospective payment rates is to look to what we have historically paid for those episodes based on treatment patterns in claims and historical payment rates, and then trend these amounts forward. We believe that treatment patterns as reflected in the episode file represent the variation in care patterns currently delivered nationally. We can only account for codes that have been submitted in claims. We cannot account for coding or submission errors made on the part of RT providers or RT suppliers, unless they have been corrected appropriately in claims. Furthermore, using fewer than 32 different national base rates would not appropriately compensate RO participants for the cancer type they are treating and the component they are furnishing, whether professional or technical. Based on a full review of comments and the detailed analyses contained within some of them, we believe that commenters have had sufficient detail to fully comment on the proposed RO Model.

Comment: Many commenters also expressed concern about the way in which primary and secondary malignancies are coded, suggesting that improper coding could skew the national base rates. These commenters suggested that the presence of low cost episodes in the episode file posted on the RO Model website are likely misattributed to a primary disease site and should have been attributed to a palliative care site and should not have been included in the calculation of the base rate of the attributed primary disease site.

Response: The pricing methodology does not attempt to assign cancer types using clinical logic of primary and secondary cancers, but rather follows a plurality rule based on E&M services, treatment planning services, and treatment delivery services. We rely on the data submitted on claims by providers and suppliers to be accurate per Medicare rules and regulations. We refer readers to the comment responses in the overview of pricing methodology in section III.C.6.a, where we detail how cancer type is assigned to each episode. We believe this approach appropriately captures episodes for the treatment of metastases by prioritizing assignment to those cancer types.

Comment: Several commenters stated that data integrity is challenged by the ICD-9 and ICD-10 diagnosis coding. Many commenters requested more detail on how diagnosis codes are assigned. A few commenters stated that the episode file on the RO Model website had each episode classified by disease site but not by ICD-9 or ICD-10 and requested that ICD-9 and ICD-10 codes be made available in the episode file for review along with a guide on how these codes are mapped to the corresponding disease site. A few commenters noted concern about the transition from ICD-9 to ICD-10 coding systems and called into question providers' and suppliers' coding accuracy when using the new ICD-10 code set alongside the 1-year grace period that was granted for using the ICD-9 code set. A commenters requested specifically that the algorithm for metastatic brain and breast ICD codes be made public.

Response: We rely on the data submitted on claims by providers and suppliers to be accurate per Medicare rules and regulations. The mapping of ICD-10 diagnosis codes to cancer type is described in Table 1. We believe sufficient information was provided in the episode file available on RO Model website to allow comment. We are 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 modification reduces the risk of coding errors that could result from the transition from ICD-9 to ICD-10 codes.

Comment: Many commenters disagreed with the proposal to include proton beam therapy in the calculation of the national base rates. MedPAC, however, expressed support of CMS' proposal to include PBT in the Model. MedPAC explained that Medicare's payment rates for PBT are substantially higher than for other types of external beam radiation therapy. Additionally, the use of PBT has expanded in recent years from pediatric and rare adult cancers to include more common types of cancer, such as prostate and lung cancer, despite a lack of evidence that it offers a clinical advantage over alternative treatments for these types of cancer. Some commenters believe that including PBT in the episode payment would create an incentive to use lower-cost, comparable modalities.

Many commenters stated that the national base rates do not include a meaningful volume of PBT episodes in the calculation and, therefore, the payment rates are not reflective of the cost of providing PBT, and, if finalized, would lead to significant cuts. Several commenters called attention to the national base rate for head and neck cancer in that PBT does not statistically contribute to that rate, only accounting for 0.8 percent of all modalities used, 18 of which were boost treatments. Therefore, a large cohort of patients incurs costs below the cost of the standard episode of care for head and neck cancer. Many commenters recommended that PBT-specific national base rates be developed to reflect the high value resources and patient complexity that is unique to patients that require PBT.

Response: We thank these commenters for expressing their concerns and for their suggestions. RO Model payments are designed to be disease specific and agnostic to treatment and modality type. We believe that using a blend to determine payment (that is, a blending of

participant-specific historical payments with national base rates to determine payment), whereby a large share of the payment calculation is determined by historical payments will appropriately account for the difference in payment for PBT. We refer readers to section III.C.5.d for discussion of PBT.

Comment: A couple of commenters noted that the episode file contained episodes where the professional pay and technical pay categories had a $0 value and requested clarity on how this data would be included in the analysis.

Response: Some payment variables on the episode file that was made available under the NPRM had missing values by design. For example, the RADONC_PRO_PAY, RADONC_TECH_PAY, RADONC_PRO_PAY_WINSORIZED_OPD, and RADONC_TECH_PAY_WINSORIZED_OPD variables have values set to "missing" for episodes in the free-standing facility setting because they are not used for payment-related purposes under the Model. The variables RADONC_PRO_PAY_WINSORIZED_ALL and RADONC_TECH_PAY_WINSORIZED_ALL are fully populated because they are used in creating historical experience adjustments. These values are all greater than $0.

Comment: 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 for each cancer type no later than 30 days before the start of the PY in which payments in such amounts would be made, explaining that 30-day notice is insufficient. A few commenters proposed 60-day notice and a commenter proposed 90-day notice similar to the notice given to participants of the CJR Model.

Response: Because the RO payment amounts incorporate the PFS and OPPS payment rates in the trend factor, the participant-specific professional and technical episode payment

amounts are dependent upon publication of the PFS and OPPS final payment rules for the upcoming calendar year. These payment regulations are statutorily required to be 60 days in advance of the start of a calendar year. CMS then subsequently performs calculations to determine the RO Model trend factor and then creates the participant-specific professional and technical episode payment amounts. We may notify RO participants of these adjustments prior to the 30-day notice deadline to the extent possible. As noted in the proposed rule, even though the Model will establish a common payment amount for the same RT services regardless of where they are furnished, payment will still be processed through the current claims systems, with geographic adjustments as discussed in section III.C.7 of the proposed and this final rule, for OPPS and PFS.

We are noting one technical change. CMS 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.

First, we are only able to provide estimates for geographic adjustment based on the payment area(s) in which an RO participant furnishes included RT services. The exact geographic adjustment will vary based on the location billed by the RO participant, so the actual payments calculated by CMS' payment contractors may be different from preliminary estimates. Second, any differences of rounding at one step versus another during payment processing between a preliminary estimate and what actually occurs during claims processing could create some small discrepancies. Third, any estimate of the participant-specific professional episode payment amounts would not include any payment adjustments due under MIPS. Fourth, the

participant-specific technical payment amounts would not include possible additional payments that Medicare would make in the event that the beneficiary coinsurance is capped at the inpatient deductible limit under OPPS. These issues taken together will leave a discrepancy (and the size of the discrepancy will vary among RO participants) between what CMS could estimate the participant-specific professional and technical episode payment amounts to be before the PY begins and what RO participants actually receive. Therefore, CMS will provide each RO participant its case mix and historical experience adjustments for both the professional and technical components, rather than their participant-specific professional and technical episode payment amounts, at least thirty (30) days prior to the start of the PY to which those adjustments apply.

After considering public comments on the proposed national base rates, we are finalizing as proposed the determination of national base rate as codified at § 512.250. We are finalizing our proposal with one technical change. We are 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. We are also finalizing 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. Our 32 national base rates for the Model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3 (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[41] | 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 |
| *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. Proposal to Apply Trend Factors to National Base Rates

[41] The final HCPCS codes specific to the RO Model would be published in an upcoming quarterly update of the CY2020 Level 2 HCPCS code file.

We proposed to next apply a trend factor to the 34 different national base rates in Table 3 of the proposed rule. For each PY, we 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. The 34 separate trend factors would be updated and applied to the national base rates prior to the start of each PY (for which they would apply) so as to account for trends in payment rates and volume for RT services outside of the Model under OPPS and PFS.

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

To calculate the numerator, we proposed to multiply: (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished for the most recent calendar year with complete data[42] by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming performance year.

To calculate the denominator, we proposed to multiply: (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in 2017 (the most recent year used to calculate the national base rates) by (b) the corresponding FFS payment rate in 2017. The volume of HCPCS codes determining

[42] For 2020 (PY1), the most recent year with complete episode data would be 2017; for 2021 (PY2), the most recent year with complete episode data would be 2018.

the numerator and denominator would be derived from non-participant episodes that would be otherwise eligible for Model pricing. For example, for PY1, we would calculate the trend factor as:

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)

We proposed to 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 a PC and a TC trended national base rate for each included cancer type. The trended national base rates for 2020 would be made available on the RO Model's website once CMS issues the CY 2020 OPPS and PFS final rules that establish payment rates for the year.

To the extent that CMS introduces new HCPCS codes that CMS determines should be included in the Model, we proposed to cross-walk the volume based on the existing set of codes to any new set of codes as we do in the PFS rate-setting process.[43]

We proposed to use this trend factor methodology as part of the RO Model's pricing methodology.

The following is a summary of the public comments received on the proposal to apply trend factors to national base rates and our responses to those comments:

Comment: A few commenters expressed support for the proposal to update the trend factor using the most recent, complete calendar year of data available. Several commenters, however, opposed the application of the trend factor as proposed for various reasons. Several commenters stated that the trend factor will reflect macro changes to reimbursement and

[43] The process of cross-walking the volume from a previous set of codes to the new set of codes in rate-setting for the PFS was most recently explained in the CY 2013 PFS Final Rule, 77 FR 68891, 68996-68997.

utilization, not practice-specific technology acquisition and, therefore, the trend factor will not provide an adequate safeguard for innovation before technology has a significant foothold in the marketplace. Many commenters stated that the trend factor is not nuanced enough and will disadvantage providers and suppliers who care for higher risk patients. Many commenters expressed concern with the delay between any increase in episode cost occurring outside of the Model among non-participants and the time it would take to be reflected in the trend factor. A commenter opposed the trend factor as proposed if it would result in lower base rates.

Many commenters suggested modifications to the proposed trend factor. Several commenters suggested that CMS trend payment amounts based on changes in the cost of technologies and the mix of treatments that evidence indicates is appropriate. In a similar vein, several commenters suggested that in addition to the trend factor, CMS adopt a rate review mechanism whereby RO participants could make the case for participant-specific rate modifications based on added service lines. Similarly, a few commenters suggested carve out payments for new service lines. For the RO participants that introduced a new radiation oncology service line in a given period of time, for example, they would be eligible for a carve-out payment for part of the Model's performance period.

One commenter suggested using only OPPS data to determine the trend factors for the TC of the national base rates. Another commenter suggested including RO participant data in the calculation of the trend factor. Another commenter suggested recalculating the trend factor denominator based on a more recent year rather than 2017.

Several commenters requested clarification as to how the trend factor is calculated. A few commenters requested clarity specifically as to which fee schedules CMS will use to calculate the trend factors.

Response: We will calculate unique trend factors for the PC and TC separately for each cancer type, since the number and types of RT services within episodes vary across the PC and TC of each cancer type, and there is sufficient national data to develop separate trend factors for the PC and TC of each cancer type just as there were for development of the national base rates. For the PC of each included cancer type and the TC of each included cancer type, we will calculate as proposed a ratio of: (a) volume-weighted FFS payment rates for RT services included in that component for that cancer type in the upcoming PY (that is, numerator) to (b) volume-weighted FFS payment rates for RT services included in that component for that cancer type in the most recent baseline year (that is, the denominator), which will be FFS rates from 2018 rather than 2017 as was proposed.

We would like to clarify how RT services that are contractor-priced under MPFS are incorporated into Model pricing. Instead of relying on the CMS-determined resource-based relative value units (RVUs) to establish the payment rate under the MPFS, Medicare Administrative Contractors (MACs) determine the payment rate for contractor-priced services. This rate is used by the MAC in their respective jurisdiction. Payment rates across MAC jurisdictions can vary. Due to the potential differences across jurisdictions, we will calculate the average paid amounts for each year in the baseline period for each of these RT services to determine their average paid amount that will be used in the calculation of the national base rates. We will use the most recent calendar year with claims data available to determine the average paid amounts for these contractor-priced RT services that will be used in the calculation of the trend factors for the PC and TC of each cancer type. For instance, for the 2021 trend factor, we will calculate the average paid amounts for these contractor-priced RT services using the allowed charges listed on 2018 claims. For the 2022 trend factor, we will

calculate the average paid amounts for these contractor-priced RT services using the allowed charges listed on the 2019 claims, and so forth.

We will calculate the numerator as proposed and multiply: (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished for the most recent calendar year with complete data by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming PY. It is important to note that for PY1 (2021), the most recent year with complete episode data will be 2018, not 2017, as proposed. This mirrors the final policy to change the baseline from 2015-2017 to 2016-2018 with respect to the calculation of the national base rates. We would like to clarify that volume-weighted FFS payment rate means a weighted average of all of the included RT services' FFS payment rates, where the frequency of each RT service determines its relative contribution to the calculation.

We will calculate the denominator as proposed and multiply: (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 in 2018 (and not 2017 as proposed), since this is the most recent year used to calculate the national base rates by (b) the corresponding FFS payment rate in 2018 (and not 2017 as proposed). The volume of HCPCS codes, which determines the numerator and denominator of the trend factors, will be derived as proposed from non-participant episodes that would be otherwise eligible for Model pricing. For example, for PY1, we 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)

It is important to note that the trend factors will be based on service volumes from episodes attributed to both HOPDs and freestanding radiation therapy centers, and both PFS and OPPS fee schedules will be used to create the annual trend factors. The use of trend factors based on updated PFS and OPPS rates ensures that spending under the RO Model does not diverge too far from spending under the FFS that non-participants will receive for the underlying bundle of services had they been in the Model. The trend factors will only generate significant swings if there are large swings in payment rates for RT services that are frequently used during episodes, which is unlikely to be the case. If there are big swings upward, that is, OPPS or PFS rates or service volumes increase, then RO participants would receive the corresponding increases. Conversely, if there were big swings downward, spending under the RO Model would become unsustainably high comparable to the FFS alternative if we did not apply a negative trend factor, so RO participants would receive the corresponding decreases.

As for considerations of innovation and added service lines, the trend factor will reflect updates to input prices as reflected in updated PFS and OPPS rates. Prospective payments in general, including episode-based payment rates of the RO Model, are not designed to reflect specific investment decisions of individual providers and suppliers, such as practice-specific technology acquisition. Furthermore, we do not want to incorporate RO participants' episodes (RO episodes) in the trend factor calculation, because we do not want to penalize RO participants for any efficiencies gained during the Model. A rate-review mechanism is not practical at this time. We will monitor the adequacy of payments over time, including the trend factor and consider re-baselining in the later PY if analysis indicates it is necessary.

We are finalizing policies in this section as proposed 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. We note that 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. As described in the proposed rule, the denominator does not change over the Model's performance period unless we propose to rebaseline, which we would propose through future rulemaking.

e. Adjustment for Case Mix and Historical Experience

In the proposed rule, we proposed that after applying the trend factor in section III.C.6.d of the proposed rule (84 FR 34506 through 34507), we would adjust the 34 trended national base rates to account for each RO participant's historical experience and case mix history.

(1) Case Mix Adjustments

As explained in the proposed rule, the cost of care can vary according to many factors that are beyond a health care provider's control, and the presence of certain factors, otherwise referred to here as case mix variables, may vary systematically among providers and suppliers and warrant adjustment in payment. For this reason, we proposed to apply an RO participant-specific case mix adjustment for the PC and the TC that would be applied to the trended national base rates.

In developing the proposed rule, we consulted clinical experts in radiation oncology concerning potential case mix variables believed to be predictive of cost. We then tested and

evaluated these 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, we 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. The national beneficiary profile 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. We would first Winsorize, or cap, the episode payments in the national beneficiary profile at the 99$^{th}$ and 1$^{st}$ percentiles, with the percentiles being identified separately by cancer type. We proposed to use 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 would measure how much of the variation in episode payments can be attributed to variation in the case mix variables.

The regression models generate coefficients, which are values that describe how change in episode payment corresponds to the unit change of the case mix variables. From the coefficients, we proposed to determine an 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. As proposed, 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. This process would be carried out separately for the PC and the TC.

We proposed to then determine an RO participant's expected payments or the payments expected when a participant's case mix (other than cancer type) is not considered in the calculation. To do this, we would use the average Winsorized episode payment made for each cancer type in the national beneficiary profile. These average Winsorized episode payments by cancer type would be applied to all episodes attributed to the RO participant to determine the expected payments. These expected payments would be summed across all episodes attributed to an RO participant to determine a single expected payment for the PC or the TC. The difference between an RO participant's predicted payment and an 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. In the proposed rule, we explained that mathematically this would be expressed this as follows:

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

The proposed rule noted 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 an RO participant's case mix adjustments take into account more recent changes in the case mix of their beneficiary population. For example, we proposed to use data from 2015-2017 for PY1, data from 2016-2018 for PY2, data from 2017-2019 for PY3, etc.

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

To determine historical experience adjustments for an RO participant we proposed to use episodes attributed to the RO participant that initiated during 2015-2017. We proposed to

calculate a historical experience adjustment for the PC (that is, a professional historical experience adjustment) and the TC (that is, a technical historical experience adjustment) based on attributed episodes. For purposes of determining historical experience adjustments, we proposed to use episodes as discussed in section III.C.6.b of this final rule (that is, all episodes nationally), except we proposed to Winsorize, or cap, episode payments attributed to the RO participant at the 99$^{th}$ and 1$^{st}$ percentiles. These Winsorization thresholds would be the same Winsorization thresholds used in the case mix adjustment calculation. We would then sum these payments separately for the PC and TC. As with the case mix adjustments, the historical experience adjustments will not vary by cancer type.

As discussed in the proposed rule, the historical experience adjustment for the PC would be calculated as the difference between: the sum of (a) Winsorized payments for episodes attributed to the RO participant during 2015-2017 and (b) the summed predicted payments from the case mix adjustment calculation, which will then be divided by (c) the summed expected payments used in the case mix adjustment calculations. We proposed to repeat these same calculations for the historical experience adjustment for the TC. In the proposed rule, we explained that mathematically, for episodes attributed to the RO participant, this would be expressed as:

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

Based on our calculation, if an RO participant's Winsorized episode payments (determined from the retrospectively constructed episodes from 2015-2017 claims data) are equal to or less than the predicted payments used to determine the case mix adjustments, then it would have historical experience adjustments with a value equal to or less than 0.0, and be

categorized as historically efficient compared to 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. Conversely, if an RO participant's episode payments are greater than the predicted payments used to determine the case mix adjustments, then it would have historical experience adjustments with a value greater than 0.0 and be categorized as historically inefficient compared to 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. The historical experience adjustments would be weighted differently and therefore, applied to payment (that is the trended national base rates after the participant-specific case mix adjustments have been applied) differently, depending on these categories. To do this, we proposed to use an efficiency factor. Efficiency factor means the weight that an RO participant's historical experience adjustments are given over the course of the Model's performance period, depending on whether the RO participant's historical experience adjustments fall into the historically efficient or historically inefficient category.

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 over the Model's performance period. More specifically, for RO participants with a PC or TC historical experience adjustment with a value greater than 0.0, we proposed that 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 Model's performance

period. The following is a summary of the public comments received on the proposed case mix adjustment and historical experience adjustments, and our responses to those comments.

Comment: Several commenters expressed support for the proposal to have case mix and historical experience adjustments. These commenters stated that these adjustments would account for RO participants' varied historical uses of more or less expensive modalities and treatment decisions that may be impacted by patient demographics.

Response: We thank these commenters for their support of these adjustments.

Comment: A couple of commenters expressed concern that the Model does not address equipment replacement or upgrades. A few commenters suggested that CMS adopt a rate review mechanism for new service lines and upgrades. Another commenter used the example of providers and suppliers who add PBT centers and therefore lack evidence of historical pricing in their claims data – in such cases, this commenter recommends exempting these new service line modalities for three years until the modality and higher payment is accurately accounted for in the practice's historical claims data.

Response: We appreciate the commenters' recommendations. In section III.C.6.d of this final rule, we respond to comments related to added service lines. We note that prospective payments in general, including episode-based payment rates of the RO Model, are not designed to reflect specific investment decisions of individual providers and suppliers, such as practice-specific technology acquisition. We did not propose to re-baseline participants during the model to avoid a possible reduction in payment due to participants becoming more efficient during the model, but we would consider balancing this consideration against the issue of new service lines as the model is implemented. We will monitor for this occurrence and if necessary propose a method to support this in future rulemaking.

Comment: Several commenters recommended that CMS design the case mix and historical experience adjustments to be cancer-specific rather than participant-specific as it is currently proposed.

Response: There are not enough episodes to design a separate case mix adjustment approach for each cancer type, so we have chosen to create a single case mix adjustment approach across all cancer types. The case mix model incorporates cancer type and so the RO participant-specific case mix adjustment for the PC and the TC reflects the case mix of the participant's population including variation in the cancer types treated. The same is true for the approach taken for the historical experience adjustment.

Comment: A commenter suggested that aside from the case mix and historical experience adjustments, CMS should adjust payments to account for the higher cost of delivering RT services in rural communities than in urban settings.

Response: Generally, CBSAs do not include the extreme rural regions. In cases where RO participants are furnishing RT services in rural communities, the historical experience adjustment will account for those RO participants' historical care patterns and their relative cost.

Comment: Many commenters expressed concern over the case mix adjustments. A few commenters suggested that rather than deriving the case mix adjustments from a rolling three-year average, CMS should implement a static baseline, while other commenters suggested that the coefficients of the case mix adjustment formula should change annually. A commenter suggested that a health care provider's case mix adjustment should reflect the beneficiaries they treated in the current performance year rather than a beneficiary cohort for a few years earlier. A few commenters stated that the time lag between the years on which the adjustment data is based and its application to payment was especially problematic for the use of mortality rate as a case

mix variable. These commenters explained that death during an episode and the timing of when a patient died has the largest impact on a health care provider's case mix adjustment. A commenter estimated that if a beneficiary dies in the first 30 days of an episode, the TC payment for that episode would be nearly $6,000 less than if the patient had survived. A commenter argued that the case mix adjustment disregards the differences between the case mix of freestanding radiation therapy centers and HOPDs.

Many commenters suggested that the case mix adjustment be based on beneficiary characteristics that affect the appropriate type and amount of evidence-based treatment that is reflected in clinical data. These commenters suggested a variety of clinical factors should be accounted for in the case mix adjustment. Commenters stated such factors as disease stage, line of treatment, comorbidities, treatment intent, and change in patient acuity over the course of the episode. A couple of commenters recommended that social determinants of health be incorporated into the calculation of the case mix adjustment. A commenter requested that CMS derive each beneficiary's HCC score or NCI comorbidity index, test that variable in the regression models, and disclose the results. Another commenter suggested differing payments based on a participant's patient risk levels.

Several commenters requested clarity on the ordinary least squares regression model that derives the case mix adjustments. Several commenters asked why cancer type is included in the case mix adjustment. A few commenters requested that CMS clarify the weight of each variable used to calculate the case mix adjustment. A few commenters requested examples regarding the calculation of predicted payments and expected payments that determine the case mix and historical adjustments. A commenter specifically requested how chemotherapy and major

procedures are defined under the RO Model and suggested that the definitions align with the OCM to promote alignment between the two models.

Response: We thank these commenters for expressing their concerns and suggestions regarding the case mix adjustment. The case mix adjustment is designed to adjust payment rates for demographic characteristics, presence of chemotherapy, presence of major procedures, and death rates. We call these the case mix variables. With respect to chemotherapy, we define chemotherapy using the same definitions and coding lists as OCM. With respect to major procedures, the list of major procedure codes for radiation oncology goes beyond the list of cancer-related surgeries used in OCM's risk adjustment to include a comprehensive set of major procedures not necessarily related to cancer. As noted in the proposed rule, we adopted this approach after consulting with clinical experts in radiation oncology. These experts advised that utilization and expenditures are influenced by the presence of any major procedure, and not just cancer-related procedures. Cancer type is included 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.

As noted in response to comments concerning the national base rates, we have only claims data available to design and operationalize the RO Model. The claims data do not include clinical data. We are finalizing our proposal to collect clinical data from RO participants so that we can assess the potential utility of additional clinical data for monitoring and calculating episode payment amounts (see section III.C.8.e).

The case mix approach we adopt in the Model has the goal of reflecting the net impact of the case mix variables after controlling for cancer type, which is already accounted for in the national base rates. We believe that the case mix adjustment will provide a consistent adjustment

approach to the case mix of episodes furnished by RO participants in both the HOPD and freestanding radiation therapy center settings. It is true that we have designed the pricing methodology around HOPD episode utilization and expenditure patterns, and that the case mix adjustment is designed to measure the occurrence of the case mix variables among the beneficiary population that each RO participant has treated historically in the most recent 3-year set of data with complete episodes available (that is, among beneficiaries whose episodes have been attributed to the RO participant during 2016-2018 in PY1 and 2017-2019 in PY2, etc.) relative to the occurrence of these variables in the national beneficiary profile. The RO Model, a prospective episode-based payment model, requires a time lag between the years on which the adjustment data is based and the year it is applied to payment, precisely because it is prospective in nature. Since the national base rate calculations are premised on HOPD episodes nationally, so too is the case mix model and the case mix coefficients built upon these episodes, so differences in characteristics between that HOPD-based national beneficiary population and the beneficiary population the RO participant has historically treated is appropriately captured. Recall that the national beneficiary profile is developed from the same episodes used to determine the Model's national base rates, that is the updated 2016-2018 episodes attributed to all HOPDs nationally. The 2016-2018 episodes attributed to all HOPDs nationally are the reference point used for comparison to measure how much an RO participant's case mix should affect their respective episode payment amounts, precisely because the national base rates are derived from those same episodes.

We will develop a regression model as proposed that predicts Winsorized episode payment amounts based on cancer type and demographic characteristics, presence of chemotherapy, presence of major procedures, and death rates, and we will also finalize our

approach to calculating the case mix adjustment as the difference between predicted and expected payment, which is then divided by expected payment. To provide more clarification and simplify the process for calculating the expected payment for each RO participant, rather than using average Winsorized episode payments for each cancer type as proposed, we will develop a second regression model that calculates expected payment amounts based on cancer type alone. This will align the use of regression models in the numerator and denominator of the case mix calculation. For a given RO participant, the difference between predicted episode payment amounts from the first regression model and expected payment amounts from the second regression model, which is then divided by the expected payment amounts, represents the net impact of demographics, presence of chemotherapy, presence of major procedures, and death rates on episode payment amounts for that RO participant.

The case mix adjustment will be updated for each RO participant annually, based on a three-year rolling period of episodes attributed to the RO participant that will be input into the case mix regression model. We cannot use the case mix of episodes during the current PY, because this would prevent us from making a prospective payment. As for the suggestion that rather than deriving the case mix adjustments from a rolling three-year average, CMS should implement a static baseline, we note that we use the same set of episodes to create the case mix coefficients as we did to generate the national base rates, so that the case mix adjustment properly connects to the starting point of the national base rates. We will include examples on the RO Model website that demonstrate how the case mix and historical experience adjustments are calculated.

Comment: Many commenters expressed concern over the historical experience adjustments. A commenter recommended that the historical experience adjustment be removed

entirely as the national base rates are disproportionately determined by the Winsorized historical payment, preventing the adoption of a truly site neutral policy for radiation oncology. A few commenters also recommended removing the historical experience adjustment, and adjusting the national base rates instead through a blend of a participant's historical experience with the national historical experience and corresponding regional historical experience.

One commenter requested that CMS provide the number and type of providers and suppliers that are identified as historically efficient and historically inefficient and how the adjusted episode rates compare to the amount providers and suppliers would receive absent the Model.

Response: Our analyses show that variation across regions of the country is low, so we believe that a regional historical experience adjustment is not necessary. We identify what proportion of CCNs and TINs are historically efficient and what proportion are historically inefficient based on the updated 2016-2018 episode data, as shown in Table 4. We do 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. We are finalizing the case mix and historical experience adjustments as proposed with modification to a component part of their calculation, the expected payments as previously discussed in this section, and with modification to derive calculations based on episodes from the same period, 2016-2018, used to derive the national base rates, as appropriate.

**TABLE 4. PERCENT OF RO PARTICIPANTS (PGPS, HOPDS, AND FREESTANDING RADIATION THERAPY CENTERS RANDOMIZED INTO THE MODEL) THAT ARE HISTORICALLY EFFICIENT, HISTORICALLY 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% |

* RO participants with fewer than 60 attributed episodes in the baseline period are assigned historical experience adjustments of 0.0.

Comment: A few commenters supported the proposed efficiency factor, stating that this will help practices as they transition into the Model. Many commenters recommended that the efficiency factor be removed for efficient practices. Several commenters including MedPAC stated that the historical experience adjustment as applied under the efficiency factor would reward historically inefficient providers and suppliers and penalize historically efficient providers and suppliers, paying them more and less than the base rate, respectively. A commenter added that the efficiency factor does not protect efficient participants from experiencing payment cuts under the Model. Several commenters disagreed with the efficiency factor proposal on the grounds that it would financially penalize participants that appropriately treat beneficiaries who require more expensive or more frequent treatments.

A few commenters suggested that CMS should determine annually whether a participant is efficient or not based on more recent data, so that participants that become efficient over the course of the Model are rewarded with an efficiency factor fixed at 0.90 over the Model performance period.

Response: We thank these commenters for expressing both their support and their concerns as well as suggestions for the proposed efficiency factor. We believe 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. We calculate episode-based payments under the RO Model based on the average spend for each episode in all HOPDs nationally. If RO

participants spent less historically (on average) than the average 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 the discount and withholds being applied; for some of these participants, the payment amounts will be an increase under the Model even with the discount and withholds being applied. If we remove the efficiency factor for efficient providers and suppliers, this would prevent the Model from maintaining costs or achieving savings. For instance, see Table 5 for an example of an efficient RO participant in this section of this final rule.

**TABLE 5: RO PARTICIPANT WITH HISTORICAL EXPERIENCE ADJUSTMENT EQUAL TO OR BELOW 0.0 (EFFICIENT)**

| | |
|---|---|
| National Base Rate | $15,000 |
| RO Participant 1 Average | $14,000 |
| 90/10 (PY1-PY5) | $14,100 |

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, but the difference would be gradual over time to allow the RO participant to gradually adjust to the new model payments. An RO participant that is categorized as historically inefficient, but becomes more efficient over time, is rewarded under this Model design, specifically as the blend is designed. These RO participants are privy to the sliding-scale blend factor where payment each PY is

determined more and more by the national base rates. If a historically inefficient RO participant becomes more efficient than the national average, payment would be higher than what they would receive under FFS because the payment would be based on the blend of the RO participant's historical payments and the national base rate, both of which would be higher than what they would receive under FFS during the model for less costly care. See Table 6 for examples of inefficient RO participants in this section of this final rule.

**TABLE 6: RO PARTICIPANTS WITH HISTORICAL EXPERIENCE ADJUSTMENT ABOVE 0.0 (INEFFICIENT)**

| | |
|---|---|
| National Base Rate | $15,000 |
| RO Participant 2 Average | $30,000 |
| | |
| 90/10 (PY1) | $28,500 |
| 85/15 (PY2) | $27,750 |
| 80/20 (PY3) | $27,000 |
| 75/25 (PY3) | $26,250 |
| 70/30 (PY5) | $25,500 |

| | |
|---|---|
| National Base Rate | $15,000 |
| RO Participant 3 Average | $20,000 |
| | |
| 90/10 (PY1) | $19,500 |
| 85/15 (PY2) | $19,250 |
| 80/20 (PY3) | $19,000 |
| 75/25 (PY3) | $18,750 |
| 70/30 (PY5) | $18,500 |

We believe that historical payment is the proper basis for comparison, and to this effect, historically efficient RO participants will experience an increase in payment. In contrast, historically inefficient RO participants will experience an incremental decrease in payment over the Model's performance period as the national base rates come to account for incrementally more of the payment outcomes. The RO Model is not designed to create equal rates for all RO

participants as the only way to do this without significantly decreasing some RO participants' payments compared to their historical would be to pay all RO participants at the highest levels of any in the historical period. If we were to do so, the RO Model would result in much higher spending during its performance period than would occur absent the Model. Rather, the RO Model is designed to create participant-specific professional and technical episode payment amounts that draw RO participants as a group toward an average payment over time. In order to soften the transition from a FFS payment system to an episode-based one for RO participants, we designed a pricing methodology that hews closely to historical payment amounts. Finally, we believe the case mix and historical experience adjustments account for beneficiaries who require more expensive or more frequent treatments.

After considering the comments received, we will finalize 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. We modified the way in which we 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, we will use a second regression model that calculates expected payment amounts based on cancer type alone.

After considering the comments received, we will finalize the historical experience adjustment as proposed, and we will finalize the efficiency factor, henceforth called the "blend," with modification. We refer readers to our regulation 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) Proposal to Apply the Adjustments

To apply the case mix adjustment, the historical experience adjustment, and the efficiency factor (now referred to as the blend) as discussed in section III.C.6.e of the proposed rule (84 FR 34507 through 34509) and this final rule to the trended national base rates detailed in Step 2, for the PC we proposed to 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. In the proposed rule, we expressed this mathematically 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. We proposed to repeat these calculations for the corresponding case mix adjustment, historical experience adjustment, and blend for the TC, yielding a total of 34 RO participant-specific episode payments for Dual participants and a total of 17 RO participant-specific episode payments for Professional participants and Technical participants (now 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 with the removal of kidney cancer).

We proposed to use these case mix adjustments, historical experience adjustments, and efficiency factors to calculate the adjustments under the RO Model's pricing methodology. We received no comments on this proposal and, therefore, are finalizing this provision with only the modification that reflects the removal of kidney cancer. We are finalizing 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) Proposal for HOPD or Freestanding Radiation Therapy Center with Fewer than Sixty Episodes during 2015-2017 Period

In the proposed rule (84 FR 34508), we proposed that if an HOPD or freestanding radiation therapy center (identified by a CCN or TIN) furnished RT services during the Model performance period within a CBSA selected for participation and was required to participate in the Model because it meets eligibility requirements, but had 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. In PY2, if an RO participant with fewer than 60 episodes attributed to it during the 2015-2017 period continued to have fewer than 60 episodes attributed to it during the 2016-2018 period, then we proposed that the RO participant's participant-specific professional episode payment and technical episode payment amounts would continue to equal the trended national base rates in PY2. However, if the RO participant had 60 or more attributed episodes during the

2016-2018 period, then we proposed that the RO participant's participant-specific professional episode payment and technical episode payment amounts for PY2 would equal the trended national base rates with the case mix adjustment added. In PY3-PY5, we proposed to reevaluate those same RO participants as we did in PY2 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 2017-2019). RO participants that continue to have fewer than 60 attributed episodes in the rolling three year period used in the case mix adjustment for that performance year would continue to have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates, whereas those that have 60 or more attributed episodes would have participant-specific professional episode payment and technical episode payment amounts that equal the trended national base rates with the case mix adjustment added. The following is a summary of the public comments we received on the proposal related to RO participants with fewer than 60 episodes during the 2015-2017 period, and our responses to those comments.

Comment: A few commenters expressed support for the proposal that if an RO participant had fewer than 60 episodes during the 2015-2017 period, then that RO participant's participant-specific professional episode payment and technical episode payment amounts would equal the trended national base rates. These commenters supported this gradual approach to establishing payment rates for low volume participants that are typically small or new practices that are likely to gradually ramp up services over the life of the Model.

Several commenters recommended CMS exclude providers and suppliers with fewer than 60 episodes during the 2015-2017 period, rather than just making adjustments to their episode payments. Another commenter noted that for participants without historical experience, the

reduction in payment, particularly for those delivering PBT, would be immediate and could be as high as 50 percent. Several commenters proposed that a stop-loss policy be added to protect those participants at risk for significant loss. A few of those commenters suggested that CMS pay participants amounts that correspond to the no-pay HCPCS codes in the amount participants would have been paid absent the RO Model if it exceeds episode payments by a certain percentage and referenced CMS APMs such as the BPCI Advanced Model, the CJR Model, Medicare Shared Savings Program (MSSP), and OCM, which all cap downside risk.

Response: We thank these commenters for their support and suggestions. We refer readers to the low volume opt-out option in section III.C.3.c, which applies to those providers and suppliers that furnish fewer than 20 episodes during the most recent calendar year with claims data in the CBSAs randomly selected for participation. We agree with commenters that if an RO participant has fewer than 60 episodes during the 2016-2018 period (rather than 2015-2017 period), then the RO participant will not have a historical experience adjustment unless we find the need to rebaseline, which would require future rulemaking. Furthermore, if an RO participant has fewer than 60 episodes during the 2016-2018 period, then the RO participant will not receive a case mix adjustment for PY1. Therefore, we are finalizing our 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 that had fewer than 60 episodes in both the 2016-2018 period, then the RO participant will have a case mix adjustment for PY2 and the remaining PYs of the Model. In PY3-PY5, we 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). Please see Table 10 that summarizes data sources and time periods used to determine the values of key pricing components.

We also agree with commenters regarding their concerns for RO participants without historical experiences and the payment reduction that would result in the absence of a historical experience. In response to comments, we are including a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule.

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.

We are finalizing this stop-loss policy at § 512.255(b)(7).

(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

We proposed that a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2024, meets the Model's proposed eligibility requirements discussed in section III.C.3 of the proposed rule and this final rule. If the new TIN or CCN begins to furnish RT services within a CBSA selected for participation, then it must participate in the Model. We proposed this policy in order to prevent HOPDs and

freestanding radiation therapy centers from engaging in mergers, acquisitions, or other new clinical or business relationships so as to avoid participating in the Model.

We proposed for the RO Model to require advanced notification so that the appropriate adjustments are made to the new or existing RO participant's participant-specific professional episode payment and participant-specific technical episode payment amounts. This requirement for the RO Model is the same requirement as at § 512.180(c) of the proposed rule, except that under the RO Model, RO participants must also provide a notification regarding a new clinical relationship that may or may not 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. For our policy regarding change in legal name and change in control provisions, we refer readers to discussion at 84 FR 34489 of the proposed rule and in section II.L this final rule and our regulations at § 512.180(b) and (c).

We received no comments on this proposal. We are finalizing our proposal at § 512.255(b)(5), with modification to align with the finalized 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. Applying a Discount Factor

After applying participant-specific adjustments under section III.C.6.e of the proposed rule to the trended national base rates, we proposed, at 84 FR 34509, to next deduct a percentage discount from those amounts for each performance year. The discount factor would not vary by cancer type. We proposed that the discount factor for the PC be 4 percent and the discount factor

for the TC be 5 percent. We proposed to use the 4 and 5 percent discounts based on discounts in other models tested under section 1115A and private payer models. We believed these figures for the discount factor, 4 and 5 percent for the PC and TC, respectively, struck an appropriate balance in creating savings for Medicare while not creating substantial financial burden on RO participants with respect to reduction in payment.

We proposed to apply these discount factors to the RO participant-adjusted and trended payment amounts for each of the RO Model's performance years. The following is a summary of the public comments received on this proposal to apply a discount factor and our responses to those comments:

Comment: Many commenters suggested reducing the discount factors 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. These commenters cited the BPCI Advanced Model, the CJR Model, and the proposed Episode Payment Model along with the downside track of the OCM, all of which had lower discount factors than what is currently proposed for the RO Model.

Many commenters expressed particular concern about the discount factor related to the TC. A few suggested that RO participants should receive a 5 percent incentive payment based on both the PC and TC as part of their APM Incentive Payment. Alternatively, if there is no opportunity to include the TC payments in calculating the 5 percent APM Incentive Payment, then the commenters recommended that there should be no discount factor for the TC. These commenters explained that RO participants rely on technical payments to invest in technologies, which can increase the value of care and decrease the long-term toxicity of RT services.

Several commenters stated that the discount factors create an un-level playing field between RO participants and non-participants. A commenter questioned the validity of using

private payer models as a guide to setting discount factor amounts in a Medicare model, given the meaningful differences in rate structures. A few commenters requested that a rationale be given as to why the discount factor for the TC is higher than that of the PC.

Response: We thank these commenters for expressing their concerns and for their suggestions. We designed the RO Model to test whether prospective episode payments in lieu of traditional FFS payments for RT services would reduce Medicare expenditures while preserving or enhancing quality. We believe 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 payment to RO participants as initially proposed. The level of discounts is based on actuarial projections for how the Model as a whole will impact Medicare payments; the level of discounts is not based on the percentage rate of the APM Incentive Payments. We believe that RO participants will benefit from their participation in this alternative payment model, and we disagree that the Model will create an un-level playing field between RO participants and non-participants. Also, given that the 2 percent quality withhold applies to the PC whereas the TC will have a 1 percent patient experience withhold beginning in PY3 (see section III.C.6.g), we believe that the PC should have a lower discount factor than the TC.

We are finalizing this provision with modification in section III.C.6.f 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. The discount factor for the TC will be 4.75 percent. Additionally, we are modifying 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 and model-specific adjustments have been applied but before

beneficiary cost-sharing and standard CMS adjustments, including the geographic practice cost index (GPCI) and sequestration, have been applied.

g. Applying Withholds

We 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 payment issues and to create incentives for furnishing high quality, patient-centered care. We outlined our proposals for three withhold policies in section III.C.6.g of the proposed rule and in this section of this final rule.

(1) Incorrect Payment Withhold

We 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 as discussed in section III.C.6.a of the proposed rule; and (2) incomplete episodes as discussed in section III.C.6.a of the proposed rule.

We proposed a withhold for these two circumstances in order to decrease the likelihood of CMS needing to recoup payment, which could cause administrative burden on CMS and potentially disrupt an RO participant's cash flow. We believe that a 2 percent incorrect payment withhold would set aside sufficient funds to capture an RO participant's duplicate RT services and incomplete episodes during the reconciliation process. In the proposed rule, we stated that we anticipate that duplicate RT services requiring reconciliation will be uncommon, and that few overpayments for such services will therefore be subject to our reconciliation process. Claims data from January 1, 2014 through December 31, 2016 show less than 6 percent of episodes had more than one unique TIN or CCN billing for either professional RT services or technical RT services within a single episode. Similarly, our analysis showed that it is uncommon that a RT

provider or RT supplier does not furnish a technical component RT service to a beneficiary within 28 days of when a radiation oncologist furnishes an RT treatment planning service to such RO beneficiary.

We proposed to use the annual reconciliation process described in section III.C.11 of this final rule to determine whether an RO participant is eligible to receive back the full 2 percent withhold amount, a portion of it, or must repay funds to CMS. We proposed to define the term "repayment amount" to mean the amount owed by an RO participant to CMS, as reflected on a reconciliation report. We proposed to codify the term "repayment amount" at § 512.205 of our regulations. In addition, we proposed to define the term "reconciliation report" to mean the annual report issued by CMS to an RO participant for each performance year, which specifies the RO participant's reconciliation payment amount or repayment amount. Further, we proposed to codify the term "reconciliation report" at § 512.205.

(2) Quality Withhold

We proposed to also 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. This would allow the Model to include quality measure results as a factor when determining payment to participants under the terms of the APM, which is one of the Advanced APM criteria as codified in 42 CFR 414.1415(b)(1). 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). We proposed to define the term "AQS" to mean the numeric score calculated for each RO participant based on its performance on, and reporting of, quality measures and clinical data, as described in section III.C.8.f of the proposed rule, which is used to determine an RO participant's quality reconciliation payment

amount. We proposed to codify this definition at § 512.205 of our regulations. We proposed that the annual reconciliation process described in section III.C.11 of the proposed rule would determine how much of the 2 percent withhold a Professional participant or Dual participant would receive back.

(3) Patient Experience Withhold

We proposed to apply a 1 percent withhold 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 Model. Under this proposal, 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 for Radiation Therapy (CAHPS® Cancer Care survey) as discussed in section III.C.8.b of the proposed rule.

Like the incorrect payment and quality withholds, the initial reconciliation process discussed in section III.C.11 of the proposed rule would determine how much of the 1 percent patient experience withhold a participant will receive back.

We proposed the incorrect payment withhold, the quality withhold, and the patient experience withhold be included in the RO Model's pricing methodology. The following is a summary of the public comments we received on this proposal and our responses to those comments:

Comment: Many commenters expressed concerns with the incorrect payment withhold, the quality withhold, and the patient experience withhold and the financial burden that these withholds could pose for RO participants. A few commenters requested that CMS explain the

rationale for the withholds over other means of accounting for patient experience and quality in the Model. A few commenters stated that the withholds are punitive in nature as they occur prior to the delivery of services. A commenter noted that the funds withheld, which are eventually paid to the participant through the reconciliation process, are not subject to coinsurance collection from beneficiaries or from beneficiaries' supplemental insurance. A commenter stated that withholds applied to the TC in particular will make it difficult to keep up with debt service.

Several commenters expressed concern over the incorrect payment withhold in particular. A few commenters suggested eliminating the incorrect payment withhold. A commenter called attention to the CMS claim that it is uncommon that a RT provider or RT supplier does not furnish a technical component RT service to a beneficiary within 28 days of when the radiation oncologist furnishes an RT treatment planning service to such RO beneficiary, and that, therefore, the additional cash flow burden the incorrect episode withhold would place on RO participants is not warranted. A commenter suggested recouping funds from participants for duplicate services and incomplete episodes in the subsequent performance year rather than implementing a withhold structure to prospectively account for those funds. The commenter argued that this would reduce RO participants' financial exposure.

One commenter specifically addressed the patient experience withhold. This commenter disagreed with the 1 percent patient experience withhold starting in PY3, stating that patient experience surveys that are mailed out have varying response rates, do not adequately capture performance, and as such the 1 percent patient experience withhold is unreasonable. This commenter argued that the patient experience surveys should only serve as supplemental data collection.

Response: We thank these commenters for expressing their concerns and for their suggestions. Although we expect incomplete episodes and duplicate payments to be uncommon, we believe that the burden of recoupment (if we were to not do a withhold) would outweigh the burden of withholding funds until annual reconciliation for those RO episodes that require reconciliation.

Yet, given stakeholders' concerns regarding the cash flow burden that the withholds may cause and given that funds withheld are not subject to coinsurance collection from beneficiaries or from beneficiaries' supplemental insurance, we are finalizing a reduced incorrect payment withhold of 1 percent rather than 2 percent. The reduction of this withhold will also ease the burden of keeping up with debt service as a commenter noted. We believe that the upfront quality withhold will provide the incentive for RO participants to provide high-quality care. Further, we believe that the predetermined withholds help support the Model goal of providing RO participants with prospective, predictable payments. As for effectiveness of the patient experience surveys, we refer commenters to section III.C.8, where quality measures are discussed in detail. We note that we would propose specific benchmarks for the patient experience measures in future rule-making.

After considering public comments, we are finalizing our proposals on incorrect payment withhold, quality withhold, and patient experience withhold, with modifications. We are finalizing 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 we will reduce the incorrect payment withhold to 1 percent beginning in PY1. Based on the concerns raised by commenters, we intend to reevaluate this amount and need for the incorrect payment withhold in PY3. Additionally, we have 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

As noted in the proposed rule, geographic adjustments are standard Medicare adjustments that occur in the claims system. Even though the Model will establish a common payment amount for the same RT services regardless of where they are furnished, payment will still be processed through the current claims systems, with adjustments as discussed in section III.C.7 of the proposed and this final rule, for OPPS and PFS. We proposed that geographic adjustments would be calculated within those shared systems 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). We proposed to adjust the trended national base rates that have been adjusted for each RO participant's case mix, historical experience and after which the discount factor 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.

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. We stated in the proposed rule that 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, PE and MP. To calculate a locality-

adjusted payment rate for the RO participants paid under PFS, we proposed to 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. First, the trended national base rates for the PC and TC would be divided by the PFS conversion factor (CF) for the upcoming year to create an RO Model-specific RVU value for the PC and TC payment amounts. Next, since the PFS geographic adjustments are applied separately to the three RVU components (Work, PE, and MP), these RO Model-specific RVUs would be split into RO Model-specific Work, PE, and MP RVUs. The 2015-2017 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD would be used to calculate the implied RVU shares, or the proportional weights of each of the three components (Work, PE, and MP) that make up the value of the RO Model-specific RVUs. Existing radiation oncology HCPCS codes that are included in the bundled RO Model codes but paid only through the OPPS would not be included in the calculation. The RVU shares would be calculated as the volume-weighted Work, PE, and MP shares of each included existing HCPCS code's total RVUs in the PFS. The PCs and TCs for the RO episodes would have different RO Model-specific RVU shares, but these shares would not vary by cancer type. Table 4 of the proposed rule (at 84 FR 34510) provided the proposed relative weight of each for the PCs and TCs of the RO Model-specific RVUs share.

We indicated in the proposed rule that we would include these RO Model-specific RVUs in the same process that calculates geographically adjusted payment amounts for other HCPCS codes under the PFS with Work, PE, and MP and their respective RVU value applied to each RO Model HCPCS code.

We proposed to apply the OPPS Pricer as is automatically applied under OPPS outside of the Model. We proposed to use RO Model-specific RVU shares to apply PFS RVU components (Work, PE, and MP) to the new RO Model payment amounts in the same way they are used to adjust payments for PFS services. See RVU shares in Table 7.

The following is a summary of the public comments we received on the proposal to adjust for geography, and our responses to those comments:

Comment: A few 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. A couple of commenters stated that the adjustment for geography was unnecessary or inappropriate. A commenter explained that the geographic adjustment was inappropriate, because the national market determines competition and purchase price in the field of radiation oncology. Another commenter agreed that the adjustment was unnecessary, but explained that it was unnecessary not because of the national market argument, but because the national base rates are set using 2015-2017 claims data to which the GPCI had already been applied.

Response: We thank these commenters for these suggestions. We would like to clarify that we construct and calculate the payment amounts for the PC and TC of each episode as the product of: (a) the OPPS or PFS national payment rates for each of the RT services included in the Model multiplied by (b) the volume of each professional or technical RT service included on a paid claim line during each episode. Episode payments under the Model are standardized in the sense that their basis is service volume and national fee schedule prices. Moreover, the calculations that determine the trend factors as well as the case mix and historical experience

adjustments are based on these standardized payments that are without geographic adjustment. As previously stated, this method of geographic adjustment is the standard way we pay through PFS and OPPS, and we want to recognize differences in payment based on geographic area. We have no way of determining whether the national market determines competition or purchase price in the field of radiation oncology, as a commenter suggested. Importantly, we want to design episode payments in such a way that they could be implemented on a broader scale, if the Model is successful.

After considering public comments, we are finalizing our proposal on the geographic adjustment with modification to clarify that although the RO Model-specific RVU values are derived from the national base rates which we are finalizing to be based on 2016-2018 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD, we 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 determining the RO Model-specific RVU values.

**TABLE 7: RVU SHARES**

| **RVU Shares** | | | | | |
|---|---|---|---|---|---|
| **Professional Component** | | | **Technical Component** | | |
| **WORK** | **PE** | **MP** | **WORK** | **PE** | **MP** |
| 0.66 | 0.3 | 0.04 | 0 | 0.99 | 0.01 |

i. Applying Coinsurance

We proposed to calculate the coinsurance amount for an RO beneficiary after applying, as appropriate, the case mix and historical experience adjustments, withholds, discount factors, and geographic adjustments to the trended national base rates for the cancer type billed by the RO participant for the RO beneficiary's treatment. 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). We proposed that this policy remain the same under the RO Model. RO beneficiaries will 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.

In the proposed rule (84 FR 34510 through 34511), we stated that maintaining the 20 percent coinsurance payment would help preserve the integrity of the Model test and the goals guiding its policies. Adopting an alternative coinsurance policy that would maintain the coinsurance that would apply in the absence in the Model, where volume and modality type would dictate coinsurance amounts, would change the overall payment that RO participants would receive. This would skew Model results as it would preserve the incentive to use more fractions and certain modality types so that a higher payment amount could be achieved.

In the proposed rule, we noted 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. However, because the PC and TC would be subject to withholds and discounts described in the previous section, we stated in the proposed rule that we believed that, on average, the total coinsurance paid by RO beneficiaries would be lower than what they would have paid under Medicare FFS for all of the services included in an RO episode. In other words, the withholds and discount factors would, on average, be expected to reduce the total amount RO beneficiaries or secondary insurers will owe RO participants.

In the proposed rule, we also explained 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 consequently be higher than it would otherwise be for a single RT service visit. For RO beneficiaries who do not have a secondary insurer, we stated in the proposed rule that we would encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments via a payment plan (provided the RO participants would inform patients of the installment plan's availability only during the course of the actual billing process).

In addition, for the TC, we proposed to continue to apply the limit on beneficiary liability for copayment for a procedure (as described in in section 1833(t)(8)(C)(i) of the Act) to the applicable trended national base rates after the case mix and historical experience adjustments, discount factor, applicable withholds, and geographic adjustment have been applied.

We solicited public comment on our proposal to apply the standard coinsurance of 20 percent to the trended national base rates for the cancer type billed by the RO participant for the RO beneficiary's treatment after the case mix and historical experience adjustments, withholds, discount factors, and geographic adjustments have been applied.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Many commenters requested clarification as to the role of secondary payers, MediGap, and Medicaid and whether secondary payers would be held accountable if the RO episode is not allowed and payment is recouped. A commenter requested clarification as to whether CMS would provide information to insurance entities that receive crossover or secondary claims under the Model. A commenter recommended that CMS follow current

Coordination of Benefits rules and transmit no-pay claims for RT services under the RO Model as "paid" to supplemental insurers for secondary payment under FFS.

Response: We appreciate the commenters concerns. CMS liaisons to the secondary payers will provide RO Model-specific information to those payers including how the RO Model-specific HCPCS shall be processed. Current Coordination of Benefits rules shall continue to apply. As noted in the proposed rule, we expect 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.

Comment: A few commenters expressed concern that the Model's policy of imposing a 20 percent coinsurance payment on the episode payment amount will be confusing to beneficiaries. Some commenters requested specific guidance on creating a payment plan for beneficiaries and expressed concern that participants will not have the billing staff to implement payment plans for beneficiaries. A few commenters disagreed with CMS' proposal to encourage RO participants to implement payment plans for beneficiaries but to restrict RO participants' ability to inform patients of the payment plan's availability to the time of the actual billing process. Those commenters argue that this delay, waiting until the course of the actual billing process, conflicts with CMS' price transparency proposal that patients know their financial responsibilities prior to receiving services. A few commenters added that CMS should not dictate when this discussion occurs. A commenter requested clarification as to whether uncollected beneficiary coinsurance under the RO Model remains subject to additional payment under the Medicare bad debt provision.

Response: It is important to note that RO participants should expect to receive beneficiary coinsurance in the same manner as they do for FFS. All the standard rules and regulations under FFS pertaining to beneficiary coinsurance apply under the RO Model, including the Medicare bad debt provision. We do not believe that beneficiaries would be confused by 20 percent of episode payment as 20 percent is the standard coinsurance policy under Medicare. Although we encourage RO participants to implement payment plans for RO beneficiaries, neither the proposed rule nor the final rule requires RO participants to implement payment plans. At this time, we are not providing specific guidance on creating payment plans because we believe that RO participants who choose to implement a payment plan for beneficiaries should have the flexibility to create one that meets their needs. We agree with the commenter that patients should be informed of the availability of the payment plan before they receive services under the RO Model. However, the availability of payment plans may not be used as a marketing tool to influence beneficiary choice of health care provider. Accordingly, we are finalizing at § 512.255(b)(12) a provision that (1) permits RO participants to collect beneficiary coinsurance payments for services furnished under the RO Model in multiple installments via a payment plan, (2) prohibits RO participants from using the availability of payment plans as a marketing tool to influence beneficiary choice of health care provider, and (3) provides that an RO participant offering such a payment plan may inform the beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter.

Comment: Several commenters expressed concerns that beneficiaries who receive fewer 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. A

commenter noted that although many patients have supplemental insurance that will shield them from higher cost-sharing amounts, some beneficiaries may be financially harmed by this approach. A few commenters suggested CMS set beneficiary cost-sharing at the lesser of (a) what the beneficiary would have paid in cost-sharing under Medicare FFS payment amounts for the specific services the patient received, or (b) 20 percent of the bundled payment amount. Several commenters suggested that CMS should base beneficiary coinsurance on no-pay FFS claims for services provided during an RO episode. A commenter suggested removing the requirement of beneficiary coinsurance of 20 percent on each of the episode's payment amounts in a specific instance, such as when a beneficiary ends treatment after receiving a single radiation treatment.

Response: We thank these commenters for expressing their concerns and for their suggestions. Although a beneficiary's coinsurance obligation under most RO episodes may not be the same as it would be under Medicare FFS, we believe that, on average, the total coinsurance paid by RO beneficiaries would be lower than what they would have paid under Medicare FFS for all of the services included in an RO episode. The average payment amounts from which the 20 percent of coinsurance is determined is reduced by both the discount factor and the withholds. There may be cases where the beneficiary coinsurance is slightly higher than what the RO beneficiary would have owed under FFS. Yet, for a bundled payment approach that moves away from FFS volume-based incentives to payment based on the average cost of care, this is unavoidable. This would present a payment issue in that either CMS or the RO participant may need to absorb any potential reduction in episode payment. Furthermore, we did not propose to base beneficiary coinsurance on no-pay FFS claims because, if we did so, then a significant portion of the payments that an RO participant received under the Model would be

premised on FFS payment and be subject to the usual FFS volume-based incentives. To avoid compromising the integrity of the Model test in this way, we are not waiving the 20 percent beneficiary coinsurance requirement based on the beneficiary receiving a limited number of RT services, such as one RT service.

However, we are not finalizing our coinsurance proposal with respect to a subset of incomplete episodes, specifically those in which: (1) the TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished.

Thus, the beneficiaries who receive RT services in this subset of incomplete episodes would pay the coinsurance amount of 20 percent of the FFS amounts for those services. We note that RO participants that set up coinsurance payment plans may be able to charge and adjust coinsurance more timely and accurately for incomplete episodes; but in some circumstances the true amount owed by the beneficiary may not be determined until the reconciliation process has occurred.

In instances where an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service, the RO beneficiary would pay 20 percent of the first installment of the RO episode. However, if the RO participant bills the Model-specific HCPCS code and EOE modifier with a

date of service that is prior to the date that the RO beneficiary ceases to have traditional FFS Medicare, then the beneficiary coinsurance payment equals 20 percent of the full episode payment amount for the PC or TC, as applicable. Because these policies would only apply to a relatively small number of RO episodes, we do not believe that it would be unduly burdensome for RO participants to administer or affect the integrity of the Model test and the goals guiding its policies.

We are finalizing, in part, our proposal related to coinsurance. Specifically, we are codifying 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, we are not finalizing our 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 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 Payment for an Episode Involving Lung Cancer in PY1

Table 8 and Table 9 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. Table 8 and Table 9 are updated

versions of Table 5 and Table 6 of the proposed rule, respectively, that reflect policies described in section III.C.5. of this final rule. Table 5 and Table 6 are displayed in the proposed rule at 84 FR 34511 and 34512. Tables 8 and 9 also reflect the following technical changes: (1) the change in sequence related to the geographic adjustment discussed in section III.C.6.h. of this final rule; (2) a change in the way the withhold calculation is displayed in the proposed rule example; (3) a change in the way discount factor and withholds are displayed in the proposed rule example; and (4) a change in the way the total episode payment amount is split between the SOE payment and EOE payment. As a result of these technical changes, Tables 8 and 9 properly reflect the way in which the claims systems process payment. First, the geographic adjustment comes in the proper sequence, prior to the case mix and historical experience adjustments, discount factor and withholds. Second, the withhold calculation properly accounts for 1 percent for the incorrect payment withhold and 2 percent for the quality withhold for the professional component. The corresponding proposed rule table, Table 5, incorrectly had the withholds multiplied together, resulting in slightly lower withheld amounts. Third, the discount factor and withholds now display the percentage of reduction as finalized, rather than the inverse of those percentages as was shown in the proposed rule at Tables 5 and 6.

Finally, Tables 8 and 9 properly reflect the way in which the claims systems split total payment between SOE and EOE payments. The claims systems begin with half the trended national base rate amount that corresponds with the RO Model-specific HCPCS code listed on the claim submitted by the RO participant for the cancer type and component (professional or technical) billed. The claims systems then apply the appropriate adjustments, discount factor, and withholds to that amount. Tables 8 and 9 reflect this by splitting payment at the offset (see

Tables 8 and 9, row (d)) rather than at the end, as the proposed rule example has displayed (see rows (s) and (t) in Table 5 at 84 FR 34511 and Table 6 at 84 FR 3512).

Please note that Table 8, which displays the participant-specific professional episode payment example does not include any withhold amount that the RO participant would be eligible to receive back or repayment if more money was needed beyond the withhold amount from the RO participant. It also does not include any MIPS adjustment that applies to the RO participant.

**TABLE 8: EXAMPLE: PARTICIPANT-SPECIFIC PROFESSIONAL EPISODE PAYMENT FOR LUNG CANCER PY1**
**ALL NUMBERS ARE ILLUSTRATIVE ONLY**

| | 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 9 details the participant-specific technical episode payment paid by CMS to a single TIN or single CCN for the furnishing of RT technical services to an RO beneficiary for an RO episode of lung cancer. The participant-specific technical episode payment in this example does not include any rural sole community hospital adjustment that the RO participant would be eligible to receive. Also, please note that for the participant-specific technical payment amount, the beneficiary coinsurance cannot exceed the inpatient deductible limit under OPPS.

**TABLE 9: EXAMPLE: PARTICIPANT-SPECIFIC TECHNICAL EPISODE PAYMENT FOR LUNG CANCER IN PY1**

| | Technical Component | |
|---|---|---|
| | **Amount** | **Formula** |
| National Base Rate (a) | $11,451.00 | |
| Trend Factor (b) | 1.04 | |
| Subtotal (c ) | $11,909.04 | c = a * b |
| SPLIT for SOE/EOE payments (d) | $5,954.52 | d =c/2 |
| Geographic Adjustment (e) | 1.02 | |
| Subtotal1 (f) | $6,073.61 | f = d * e |
| Case Mix Adjustment (g) | 0.02 | For example (102-100) / 100 |
| Historical Experience Adjuster (h) | 0.11 | For example (116-102) / 100 |
| PY1 Blend (i) | 0.90 | |
| Adjustments combined (j) | 1.12 | j = g + (h * i) + 1 |
| Subtotal (k) | $6,796.37 | k = j * f |
| Discount Factor (l) | 0.0475 | |
| Subtotal (m) | $6,473.54 | m = (1 - l) * k |
| Withhold #1 (Incorrect Payment) (n) | 0.01 | |
| Withhold #2 (Patient Experience) - not applied until PY3 (o) | | |
| Total Withhold (p) | 0.01 | p = n + o |
| Half of Total Episode Payment to RO Participant without sequestration (q) | $6,408.81 | q = (1 - p) * m |
| Beneficiary Coinsurance for SOE payment Determined (r) | $1,281.76 | r = q * 0.20 |
| SOE Participant Payment | $5,127.05 | s = q * 0.80 |
| Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment] | $5,024.50 | t = s * 0.98 |
| **Episode Payment 1: SOE (u)*** | **$5,024.50** | **u = t** |
| **Episode Payment 2: EOE (v)*** | **$5,024.50** | **v = t** |
| **Total Episode Payment to RO Participant (w)** | **$12,612.53** | **w = u+v+2r** |

^ All numbers are rounded to two decimal places.

After considering public comments on our proposed pricing methodology, as previously summarized, we are finalizing the pricing methodology as proposed with the following modifications. We are also providing Table 10, which summarizes the data sources and time periods used to determine the values of key pricing components as a result of these modifications.

(1) Change the name of the "efficiency factor" of the historical experience adjustment to "blend."

(2) Reduce the discount rate of the PC and TC from 4 and 5 percent to 3.75 and 4.75 percent, respectively.

(3) Reduce the incorrect payment withhold from 2 percent to 1 percent.

(4) Apply 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 this final rule.

We are also making the following modifications, which are not being codified in regulation text, to our pricing methodology policy:

(1) Change 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) Change 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) Update 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 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.

(4) Update the years used to determine the case mix values, beginning with 2016-2018 for PY1, 2017-2019 for PY2, and so on.

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

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

Please note that we will review utilization data in non-RO participants' 2020 episodes to assess the impact of the PHE on RT treatment patterns and whether an alternative method is needed to determine the trend factor for PY3 to prevent the PY3 trend factor from being artificially low or high due to the PHE. If we find an alternative method is necessary, we will propose this in future rulemaking.

**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 |
| Low Volume Opt-Out Eligibility (<20 episodes) | Participant-specific | 2019 | 2020 | 2021 | 2022 | 2023 |

7. Professional and Technical Billing and Payment

Similar to the way many procedure codes have professional and technical components as identified in the CMS National PFS Relative Value File, we proposed that all RO Model episodes would be split into two components, the PC and the TC, to allow for use of current claims systems for PFS and OPPS to be used to adjudicate RO Model claims. As stated in the proposed rule, we believe that the best design for a prospective episode payment system for RT services would be to pay the full participant-specific professional and technical episode payment amounts in two installments. We believe that two payments reduce the amount of money that may need to be recouped due to incomplete episodes and the likelihood that the limit on beneficiary liability for copayment for a procedure provided in an HOPD (as described in section 1833(t)(8)(C)(i) of the Act) is met.

Accordingly, we proposed that we would 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.

To reduce burden on RO participants, we proposed that we would make the prospective episode payments for RT services covered under the RO Model using the existing Medicare payment systems by making RO Model-specific revisions to the current Medicare FFS claims processing systems. We proposed that we would make changes to the current Medicare payment systems using the standard Medicare Fee for Service operations policy related Change Requests (CRs).

As proposed, our design for testing a prospective episode payment model (that is, the RO Model) for RT services would require making prospective episode payments for all RT services included in an episode, as discussed in section III.C.5 of this final rule, instead of using Medicare FFS payments for services provided during an episode. We proposed that local coverage determinations (LCDs), which provide information about the conditions under which a service is reasonable and necessary, would still apply to all RT services provided in an episode.

In the proposed rule, we stated that 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. We proposed that we 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. As stated in the proposed rule, payment for the PC would be made through the PFS and would only be paid to physician group practices (as identified by their respective TINs).

Under our proposed billing policy, a Professional participant or Dual participant that furnishes the PC of the episode would be required to bill one of the new RO Model-specific HCPCS codes and an SOE modifier. As stated in the proposed rule, this would indicate within the claims systems that an episode has started. Upon submission of a claim with an RO Model-specific HCPCS code and an SOE modifier, we would pay the first half of the payment for the PC of the episode to the Professional participant or Dual participant. A Professional participant or Dual participant would be required to bill the same RO Model-specific HCPCS code that initiated the episode with a modifier indicating the 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 codes and EOE modifier, we proposed that we would pay the second half of the payment for the PC of the episode to the Professional participant or Dual participant.

Under our proposed billing policy, a Technical participant or a Dual participant that furnishes the TC of an episode would be required to bill a new RO Model-specific HCPCS code with a SOE modifier. We proposed that we 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 an RO Model-specific HCPCS code with a SOE modifier. We proposed that we would pay the second half of the payment for the TC of the episode after the end of the episode. We proposed that the Technical participant or Dual participant would be required to bill the same RO Model-specific HCPCS code with an EOE modifier that initiated the episode. As stated in the proposed rule, this would indicate that the episode has ended.

Similar to the way PCs are billed, we proposed that we would develop new HCPCS codes (and any modifiers) for the TC of each of the included cancer types. We proposed that 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. We proposed that the two payments for the TC of the episode would cover the provision of equipment, supplies, personnel, and costs related to the radiation treatment during the episode.

We proposed that the TC of the episode would begin on or after the date that the PC of the episode is initiated and that it would last until the PC of the episode concludes. Accordingly, the portion of the episode during which the TC is furnished may be up to 90 days long, but could be shorter due to the time between when the treatment planning service is furnished to the RO beneficiary and when RT treatment begins. We proposed this because the treatment planning service and the actual RT treatment do not always occur on the same day.

We proposed that RO participants would be required to submit encounter data (no-pay) claims that would include all RT services identified on the RO Model Bundled HCPCS list (See Table 2) as those services are furnished and that would otherwise be billed under the Medicare FFS systems. We proposed that we would monitor trends in utilization of RT services during the RO Model. We proposed that these claims would not be paid because the bundled payments cover RT services provided during the episode. We proposed that the encounter data would be used for evaluation and model monitoring, specifically trending utilization of RT services, and other CMS research.

We proposed that if an RO participant provides clinically appropriate RT services during the 28 days after an episode ends, then that RO participant would be required to bill Medicare FFS for those RT services. We proposed that a new episode would not be initiated during the 28 days after an episode ends. As we explain in section III.C.5.b(3) of this final rule, we refer to this 28-day period as the "clean period."

In the event that an RO beneficiary changes RT provider or RT supplier after the SOE claim has been paid, we proposed that CMS would subtract the first episode payment paid to the RO participant from the FFS payments owed to the RO participant for services furnished to the beneficiary before the transition occurred and listed on the no-pay claims. We proposed that this adjustment would occur during the annual reconciliation process described in section III.C.11 of this final rule. We proposed that the subsequent provider or supplier (whether or not they are an RO participant) would bill FFS for furnished RT services.

Similarly, in the event that a beneficiary dies, 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), during the annual reconciliation process we proposed

that CMS would subtract the first episode payment paid to the Professional participant or Dual participant from the FFS payments owed to that RO participant for services furnished to the beneficiary and listed on the no-pay claims before the transition occurred.

In the event that traditional Medicare stops being the primary payer after the SOE claims for the PC and TC were paid, we proposed that 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. If a beneficiary dies or selects the Medicare hospice benefit (MHB) after both the PC and the TC of the episode have been initiated, we proposed that 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.

In the proposed rule we acknowledged that there may be instances where new providers and suppliers begin furnishing RT services in a CBSA selected for participation in the RO Model. We proposed that these new providers and suppliers would be RO participants and noted that they would have to be identified as such in the claims systems. When a claim is submitted with an RO Model-specific HCPCS code for a site of service that is located within one of the CBSAs randomly selected for participation, as identified by the service location's ZIP Code, but the CCN or TIN is not yet identified as an RO participant in the claims systems, we proposed that the claim would be paid using the rate assigned to that RO Model-specific HCPCS code without the adjustments. Once we are aware of these new providers and suppliers, we proposed that they would be identified in the claims system and would be paid using Model-specific HCPCS code with or without the adjustments, depending on whether the TIN or CCN new to the Model is a result of a merger, acquisition, or other new clinical or business relationship and

whether there is sufficient data to calculate those adjustments as described in the pricing methodology section III.C.6 of this final rule.

We proposed that lists of RO Model-specific HCPCS codes would be made available on the RO Model website prior to the Model performance period. In addition, we noted in the proposed rule that we expect 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.

The following is a summary of the public comments received on these proposals and our response:

Comment: Several commenters expressed concern that billing systems are not ready for a prospective payment model as they are designed to bill after the services are furnished and not before, and that this could pose significant financial risk. Commenters stated that the RO Model as proposed introduces new billing and collection processes to include new HCPCS and modifiers, billing at the start of and at the end of services, and the submission of no-pay claims detailing the actual services provided. Commenters further stated that the complexity of learning new codes and tracking episode dates creates administrative burden for RO participants. Commenters noted that many health care providers and health systems do not complete their billing internally, and instead rely on external third party vendors so RO participants will require time to determine how to best partner with these vendors to ensure appropriate billing.

Many commenters expressed concern around the lack of details regarding billing requirements for the proposed RO Model. Multiple commenters requested that we clarify in our billing instructions that we will require providers and suppliers billing individual patient encounters to use HIPAA-mandated transaction code sets (that is, CPT® and HCPCS Level II

codes) for Professional/Dual participant services on 1500/837P claims and hospital outpatient participant services on UB04/837I. Commenters stated that it was particularly important that charges meet the requirements of the Provider Reimbursement Manual Part 1 section 2202.4, which mandate that charges be related consistently to the cost of the services and uniformly applied to all patients, whether Medicare, Medicaid, or commercial patients. Commenters stated that the RO Model cannot alter these requirements because doing so could undermine the validity of the hospital cost reporting process. Commenters requested that we address the following items for the new prospective HCPCS codes and the no-pay claims: (1) the type of claim form; (2) necessary claim lines; (3) items that should be excluded from the claim; and (4) ability to move the zero-pay HCPCS codes to the non-billable column on the claim. Commenters asked for clarification on encounter claim data submission under the Model. A commenter noted operational concerns with the zero charge encounter bills the RO Model requires participants to submit. The commenter stated that automated internal accounting software generates both claims and internal cost accounting reports and that setting charges to zero dollars would wreak havoc on internal cost tracking and would create significant administrative burden. The commenter requested that CMS permit the original HCPCS charges to be listed in the non-covered charges' claim column while zero dollars would be submitted in the covered charges field.

Response: We appreciate the commenters concern. We believe that we have created a billing process that will be easily implemented within current systems because it is based on how FFS claims are submitted today. To facilitate understanding and implementation, we encourage RO participants to access forthcoming instructions for billing the RO Model-specific HCPCS codes and related modifiers and condition code provided by CMS through the Medicare

Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter requested that CMS not withhold payments due to incomplete episodes during the test period, as this could ultimately create significant cash flow issues. Instead, the commenter suggested that CMS could utilize the new HCPCS codes and modifiers intended as no-pay, initial and ending payments as place holders to assess the various scenarios for at least 3 years. This 3-year testing period would at a minimum identify the scenarios and allow time for CMS to assess, realize impact, and provide data to the public for public comment.

Response: We thank the commenter for the suggestion. In the final rule at § 512.255(h), we have reduced the incorrect payment withhold from the proposed 2 percent to 1 percent, which is proportional to the occurrence of incomplete episodes per our claims data. The amount of the incorrect withhold that the RO participant earns back is determined during the annual reconciliation process described in section III.C.11.

Comment: Many commenters expressed concern around 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. Commenters were concerned that without this knowledge, unnecessary incomplete episodes might result. However, these commenters were also concerned that the burden of coordination of episode start dates between professional and Technical participants could greatly increase the administrative burden of the Model.

One commenter stated that unique logic would have to be established for each patient to track how many days the Technical participant's billing team would need to zero out claims

since RT start dates within the 90-day period will vary. Other commenters noted that when entities billing TC and PC services are clinically, financially, and legally separate, the likelihood of their ability to coordinate care declines. Noting that Health Information Exchanges are not yet broadly available and that sharing of information is not the same as coordinating care, a commenter requested a delay in implementation to allow participants to establish the formal or informal relationships likely necessary to succeed in the proposed Model. Another commenter recommended that CMS include in the Model a methodology by which it would notify Technical participants of the start of an episode. A commenter noted that CMS stated that the technical billing component will be driven off a signed radiation prescription. As there is a professional as well as technical component of the simulation session, the commenter stated that CMS should use the professional simulation session claim to trigger for the technical SOE.

Response: We appreciate the commenters' concerns. We believe it to be an established standard of care that RT delivery services cannot be administered to a patient without a signed radiation prescription and the final treatment plan. Thus, we proposed that the Professional participant will provide the Technical participant with a signed and dated radiation prescription and treatment plan, all of which is usually done electronically. This will inform the Technical participant of when the RO episode began, allowing them to determine the date of the end of the RO episode. The submission and payment of TC claims is not dependent on the submission of PC claims. If the TC claim with the SOE modifier is received first, the claims system will estimate the first day of the episode. A similar process will occur for EOE claims. When claims for only one component are submitted (either PC or TC), an RO episode would not have occurred because an RO episode begins when both the PC is initiated and the TC is initiated within 28 days. In these circumstances, the component that is submitted will be addressed

during the reconciliation process finalized in section III.C.11, and the payments will be reconciled so that the RO participant receives the FFS amount based on the no-pay claims instead of the participant-specific episode payment. We encourage RO participants to access forthcoming instructions provided by CMS for billing the RO Model-specific HCPCS codes and related modifiers and condition code provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: Commenters requested clarification on how billing was to be done when either the technical component of the services and/or the professional component of the services extends beyond the 90-day episode triggered by the planning services.

Response: To clarify, as stated in the proposed rule, all RT services provided within the 28-day clean period (that is, days 91-118) following a 90-day RO episode will be billed FFS. In these situations, the RT provider or RT supplier will bill individual HCPCS or CPT® codes for each RT service furnished as they would outside of the RO Model. If RT services are still being provided after 118 days, the RO participant will submit a SOE claim for a new RO episode. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: Multiple commenters expressed concerns about the timing of our proposed payments. A commenter stated that the time estimates CMS has made available show that almost two thirds of all episodes are completed within 50 days while other commenters noted most services are completed within a month of initiating treatment. Commenters noted that under our proposal, most providers and suppliers would have to wait more than a month to be able to bill for care that has already been provided. Commenters expressed concerns that

delayed payments will impact their cash flows, creating hardships in their ability to pay bills, to order medical supplies and to provide the necessary staffing coverage. Commenters also expressed concern that patient access might become an issue due to these cash flow delays and that beneficiaries might have to drive further to get care when staffing is compromised because of delayed payments. A commenter suggested that full payment at the beginning of the episode, rather than payment in two installments, would improve cash flow and reduce administrative burden by not requiring an EOE claim. Other commenters requested that providers and suppliers be able to receive the 2nd payment sooner than 90 days, ideally when the services complete. A commenter requested that CMS consider adding a modifier to signal a course of radiation is completed and that CMS should make the 2nd half of the payment at the time that completion claim is submitted rather than waiting for the end of the 90-day period. In addition, that commenter also stated that adding a modifier to the start and end of a course of treatment would signal if a new course, not related to previous course, started during the 90-day time frame.

Response: We thank the commenters for expressing their concerns and for their suggestions. Based on these comments, we are modifying our policy 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. We believe 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. To ensure that a Professional participant or a Dual participant does not bill an EOE claim for an incomplete episode, they should not submit an EOE claim before 28 days after the initial treatment planning service has been furnished to minimize the need to reconcile the EOE payments against the incorrect

payment withhold. 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. We will monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns and subsequent billing patterns. This modification does not require a change to the regulatory text at § 512.260.

Comment: 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) who is selected to be in the Model via an included ZIP Code, but who furnishes their RT services at an exempt facility (ASC, PCH, CAH), is to bill for those encounters. The commenters questioned how a non-participant RT provider or RT supplier would be protected from having a large volume of incomplete episodes. A commenter noted that during the August 22, 2019 Open Door Forum Listening Session on the Radiation Oncology Model, CMS staff stated they would create a modifier for Professional participants to use to indicate that RT services were furnished by a non-participant. Commenters requested that CMS consider an alternative to a new modifier that does not require any changes in how professionals bill their radiation oncologist services. A commenter suggested that CMS use the location of services in item number 32 and the NPI in item 32a on the 837P/1500 claim form, which is mandated on the 837P/1500 claim form, to exclude the services from the RO Model. Commenters also suggested that instead of creating another modifier, CMS could direct Professional participants who deliver services at exempt facilities to bill the usual radiation oncology HCPCS codes, and to not initiate an episode by excluding the RO Model-specific HCPCS code. Commenters further requested that if CMS believes it must require the use of a

new modifier to signify services in an exempt facility, we should allow the modifier to be reported with the usual RT planning, simulation, and management CPT® and HCPCS codes rather than asking for the RO Model-specific HCPCS code to be reported.

Response: CMS worked closely with the Provider Billing Group in the Center for Medicare, the Medicare Administrative Contractors, and the Shared System Maintainers to establish the least burdensome way to submit claims for instances that do not follow the standard course of an episode. We 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. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter requested clarification on billing when one physician provides EBRT and a different physician, either co-located in the same facility or in a different facility, provides brachytherapy services. The commenter wanted clarification on when the brachytherapy physician would be considered part of the RO Model and when the brachytherapy physician would be paid FFS. A commenter requested that CMS provide clarification regarding how the agency will handle a second claim for a case that has already received an episodic payment associated with a second physician who bills the brachytherapy insertion codes. The commenter stated that accommodations should be made to pay the insertion codes at the FFS rate when a second physician is involved to prevent cash flow issues that could result if the second claim were held up as part of the RO Model reconciliation process.

Response: When RT services are furnished by an RO participant and a non-participant or when the PC is furnished by more than one Professional participant or Dual participant, or when the TC is provided by more than one Technical participant or Dual participant, these scenarios would be considered duplicate services. The RO beneficiary would remain under the care of the RO participant that initiated the PC and/or TC, and in many circumstances, the duplicate RT service would be a different modality than what is furnished by the RO participant. The RO participant(s) that bills the SOE and EOE claims would receive the bundled payment and the RT provider and/or RT supplier furnishing one or more duplicate RT services would bill claims using the designated modifier or condition code to indicate that they should be paid FFS. Thus, cash flow would not be affected by this. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: Some commenters expressed concerned about specific considerations related to the proposed 90-day episodic billing time frame. Commenters agreed with our assumption that RT services would generally be completed within the 90-day episodic period and a new RO episode would not begin until at least 28 days have elapsed, but commenters noted that there are times when extenuating circumstances like an inpatient admission or preplanned patient travel that can cause the outpatient RT services to begin after the 28-day window. From an operational standpoint, commenters were concerned that if the treatment does not begin within the 28-day period, but the physician plans to treat the patient with RT services, that there may be no "trigger" to begin an episode of care. Commenters requested that we clarify how Medicare Administrative Contractors will manage PC and TC claims after the 28-day window between the

treatment planning code and the treatment delivery code has passed without triggering an episode. Commenters also requested that we provide answers to the following questions: Would all subsequent PC and TC claims be paid as FFS? Would the TC claims (either with the RO Model-specific HCPCS code or FFS HCPCS code) and the second PC episode payment claims be denied and then reconciled as per the incomplete episode policy in the proposal? Would all TC claims after the 28-day window be paid under FFS and the initial episode PC payment be the only amount reconciled? The commenter urged CMS to pay all CPT®/HCPCS codes that are billed outside of the 28-day window (that is an incomplete episode) as FFS.

Response: We appreciate the commenters' concerns. Medicare claims data analyzed during the design of the RO Model, show that in 84 percent of episodes RT is delivered within 14 days of the planning service and within 28 days for the remaining 16 percent. There will be billing instructions that address how to submit claims for those instances that do not follow the standard course of an episode. In these situations, the RT provider or RT supplier will bill individual HCPCS or CPT® codes for each RT service furnished as they would outside of the RO Model. These scenarios would be considered incomplete episodes. We encourage RO participants to access forthcoming instructions for billing RT services during the Model performance period provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter expressed appreciation that CMS has taken into consideration situations in which a patient passes or is transferred to hospice care during an RO episode, noting that in these situations, CMS proposed to provide full payment and not to consider these two scenarios as incomplete episodes.

Response: We thank the commenter for the support and note that we are finalizing the policy to provide full payment for RO episodes in which a patient passes or is transferred to hospice care during an RO episode.

Comment: A commenter requested that we change the proposed policy in cases where the patient moves from traditional Medicare FFS as their primary payer to a Medicare Advantage plan during an episode. As proposed, the commenter noted that CMS would pay 50 percent of both the PC and TC to participants, regardless of whether the RT was complete. The commenter stated that they believe this payment policy would not fairly reimburse RO participants for services rendered, and recommended that we drop these episodes and revert retrospectively to FFS payments for the services that were billed to Medicare Part A and B, in the same manner that we proposed to do for other categories of incomplete episodes.

Response: We thank the commenter for their concern and suggestion. Our analysis indicates that for episodes where a beneficiary moves from traditional Medicare as their primary payer to a Medicare Advantage plan during the RO episode, the average cost is less than 50 percent of those episodes when compared to episodes where a beneficiary had Medicare as their primary payer for the full 90-day episode. Thus, we believe that paying the SOE PC and TC only in these cases is appropriate. Our data also shows that switching payers during an episode rarely occurs. When an RO beneficiary ceases to have traditional Medicare as his or her primary payer during an RO episode, the RO participant will not be paid the EOE PC or TC because CMS cannot process claims for a beneficiary with dates of service on or after the date that traditional Medicare is no longer the primary payer. We believe that finalizing our proposal with the modification allowing the EOE claim to be submitted and paid at the completion of the planned course of treatment, instead of waiting for 90 days, will mitigate this concern. If the RO

beneficiary has traditional Medicare as of the date of service on the EOE claim, the RO participant will be paid both installments of the episode payment.

Comment: Several commenters expressed concern about our proposed policy that local coverage determinations would still apply to all RT services provided in an episode. A commenter noted that at this time, there are few LCDs in publication and that most radiation oncology specific LCDs have been retired, with the exception of those for proton therapy and a few other LCDs for IMRT, SRS and SBRT. The commenter further noted that currently there are no active LCDs for standard external beam, 3D conformal, brachytherapy or radiopharmaceutical therapy, and that multiple MACs have never published radiation oncology LCDs. The commenter stated that the IOM publications by CMS provide few instructions specific to radiation oncology techniques, required documentation, and coverage requirements, which leads to inconsistency across the specialty. The commenter asked if there is a reason there are not more LCDs or possible National Coverage Determinations (NCDs) if there is an expectation that radiation oncology facilities are to follow a common set of guidelines and expectations for coverage. Another commenter stated that LCDs are a form of prior authorization and requested that CMS abandon the use of LCDs to determine coverage for those services delivered to Medicare beneficiaries as part of the RO Model. The commenter stated that the establishment of episode-based payments effectively decouples payment from modality of treatment and that LCDs or other methods of prior authorization should not apply for the RO Model.

Response: LCDs are decisions made by a Medicare Administrative Contractor (MAC) whether to cover a particular item or service in a MAC's jurisdiction (region) in accordance with section 1862(a)(1)(A) of the Social Security Act. The MAC's decision is based on whether the

service or item is considered reasonable and necessary. The MACs will not have the ability to apply LCDs to RO Model claims because only the RO Model-specific HCPCS codes appear on the claim and these codes are not included in any current LCDs. When we monitor utilization of RT services during the Model, as described in section III.C.14.a, we will use the reasonable and necessary provisions as stated in applicable LCDs as one of our monitoring tools.

Comment: A commenter requested that we address prior authorization, which the commenter asserted could impact the outcomes and treatment choices in this Model. The commenter expressed concern that prior authorization requirements could increase administrative burden on participating clinicians who seek to deliver the highest quality of care and delay timely payment for covered services.

Response: We thank the commenter for voicing these concerns. RO Model services are not subject to prior authorization.

Comment: Commenters asked if allowable rates will be available for the new codes 30 days prior to program start date. Commenters asked if there will be an RVU associated with the new start and end codes and if there be unique start and end codes per diagnosis.

Response: 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. As described in section III.C.6.h, there are RVUs associated with the RO Model-specific HCPCS codes, but the SOE and which are modifiers, not codes do not have RVUs associated with them.

Comment: A commenter stated that the RO Model will require staff to determine which patients are primary Medicare from all other payers and establish separate processes between payers and between those who fall under the RO Model parameters and those who do not. The commenter stated this would include creating two sets of coding and billing processes just for

primary Medicare beneficiaries: one to report services included in the RO Model and one to report services not included and billed as fee-for-service for those services provided to a beneficiary who must participate in the Model but for whom some services provided are not included and billed differently.

Response: It is our understanding that RT providers and RT suppliers furnish and bill for RT services for patients with a variety of insurers and thus already have processes in place to accommodate multiple payer requirements. To clarify, non-included services will be billed separately and in the same manner as they would in the absence of the RO Model.

Comment: A commenter asked us to clarify if the 8 percent non-sequestration reconciliation withhold will be processed at the claim level so that adjustments can be applied to the original claims via remits.

Response: We believe the "8 percent" used by the commenter refers to the total of the discounts and withholds. The discounts and withholds are not subject to sequestration upon submission of an RO Model claim. Sequestration will be applied to reconciliation payment calculation that are based on FFS payments.

Comment: Commenters expressed concern about specific billing situations and asked for clarification on several situations. A commenter asked for clarification on how organizations should handle or bill for treatment of new manifestations of same cancer diagnosis within the same 90-day window (estimated 10-20 percent of patients). Another commenter, citing an example of a prostate cancer patient with bone metastasis or a lung cancer patient with brain metastasis, inquired if a patient presents with two separate diagnoses that are included within the Model, would the HCPCS codes be reported for both cancer type codes or would one take precedence over another? Commenters asked if this would this be considered a single episode or

separate episodes? Commenters also sought clarification on billing for non-RO Model codes. If a patient in an RO episode also is treated for a non-model code (for example, metastasis to adrenal gland), would those services be billed and paid for under FFS even though an RO episode is running concurrently? A commenter also asked for clarification on how RO participants should bill for non-model services which, if not for the Model, would be bundled under the existing OPPS RO Comprehensive ambulatory payment classification (C-APC)? The commenter recommended that providers and suppliers be permitted to bill separately under the OPPS for these other non-Model HCPCS and CPT® codes.

Response: 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 RT services. The RO participant can choose which RO Model-specific HCPCS to include on both the SOE and EOE claims. For example, the RO beneficiary is being treated with RT services for breast cancer and brain metastasis, the RO participant would likely choose the RO Model-specific HCPCS for breast cancer, which is appropriate. If an RO beneficiary has more than one included cancer type, but is receiving RT services for just one, the RO participant is expected to put the corresponding RO Model-specific HCPCS code on the SOE and EOE claims. For example, the RO beneficiary has breast cancer, but is being treated with RT services for just their brain metastasis, the RO participant must choose the RO Model-specific HCPCS for brain metastasis. If an RO beneficiary also receives included RT services for a non-included cancer type, FFS claims would be submitted with the corresponding ICD-10 codes and HCPCS codes. As proposed, the SOE and EOE claims must include the same RO Model-specific HCPCS code. RT services not included in Table 2 shall be billed FFS. To clarify, non-included services will be billed separately and in the same manner as they would in the absence of the RO Model.

Comment: Commenters sought clarification on secondary billing under the Model, requesting that we provide clarification in the final rule regarding the role of secondary payers and how they will be engaged as part of the claims processing and billing associated with implementing the Model. Typically, a secondary bill is sent directly from Medicare to the secondary payer. If a no-pay bill is sent to a secondary payer, it would not be paid. Commenters noted that it was particularly important for all participants to follow usual coding and billing pursuant to HIPAA transaction sets due to the impact on a beneficiary's secondary and MediGap insurance. Commenters noted that CMS did not address this topic in the Proposed Rule and stated that they expect that the Innovation Center would define new claim adjustment reason codes (CARC) and remittance advice reason codes (RARC) so this insurance, when secondary to Medicare, will not process co-payments for individual services. Instead, they will process applicable co-payments associated with each of the professional, dual, and technical episode payments when made and explained on the remittance advice from Medicare. Commenters asked that CMS verify and explain this process in the Final Rule to enable RO participants to better understand these important operational issues.

Commenters requested that CMS verify and explain the process for communication to secondary and MediGap insurance (that is, CARC/RARC codes) to ensure all participants have a clear understanding of the operational process for reimbursement. Commenters also noted that as other payers would be following typical FFS payment methodology, the "M" codes would not be accepted either. Commenters requested that we address the following questions: Will the Medicare beneficiary then be at risk for the 20 percent liability if denied? How would secondary payers adjudicate these claims? Many payers have 60-day timely filing deadline. With the

proposed billing model, commenters expressed concern that they would be at risk of timely filing for certain payers if those claims are not adjudicated.

Response: CMS liaisons to the secondary payers will provide RO Model-specific information to those payers including how the RO Model-specific HCPCS shall be processed. As noted in the proposed rule, we expect 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.

Comment: A commenter asked if hospitals are still allowed to add facility fees to their fees under the Model. If so, the commenter stated that the playing field would not be level and would favor HOPD over freestanding radiation therapy centers. The commenter also requested that we clarify if facility fees were included in our computation finding that freestanding centers billed more than HOPPS facilities. If so, the commenter requested that hospitals not be allowed to charge facility fees under the RO Model.

Response: As proposed, only RO Model-specific HCPCS codes are allowed on the SOE and EOE claims. Thus, this should not be a concern.

Comment: A commenter suggested that CMS should publish online an explicit list of providers and suppliers excluded from the Model including their names, addresses, and NPIs to ensure there's no confusion about which providers and suppliers are excluded from the Model. The commenter stated that this information would also emphasize that, should any of the professionals furnish services at a location included in the RO Model and their TIN/ZIP Code is not otherwise excluded from the Model, the participant would be required to report the HCPCS Level II code for the cancer type and the appropriate modifier(s). The commenter also suggested

that, if CMS believes it must require the use of a new modifier to signify services in a provider or supplier excluded from the Model, the agency allow the modifier to be reported with the usual RT planning, simulation, and management CPT® and HCPCS codes rather than ask for the cancer type HCPCS code to be reported. The PRT recommends that CMS utilize the information already required by HIPAA transaction sets (NPI, names, and addresses) for professional claims in order to determine if a provider or supplier is excluded from the Model, rather than creating a new modifier and additional operational burden for RT professionals.

Response: Only RO participants can use the RO Model-specific HCPCS codes. The claims system will determine inclusion in the Model by the site of service ZIP Code included on the claim. Non-participants would not be required to use a modifier to indicate they are not subject to RO Model billing requirements. To facilitate understanding and implementation of the billing and payment requirements, we encourage RO participants to access additional instructions for billing during the RO Model and using the RO Model-specific HCPCS codes provided by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter stated that freestanding centers are not authorized to bill directly to Medicare due to the consolidated billing requirements for SNF and hospital inpatient stays. In this scenario, the commenter believed the treatment delivery code would not be received for beneficiaries during a SNF or hospital inpatient stay who are also treated with RT services in a freestanding radiation therapy center.

Response: We have programmed the claims system to bypass all professional and institutional SNF consolidated billing edits/IURs for RO Model claims for any RO beneficiary that is currently in a Skilled Nursing Facility (SNF) stay.

Based on these public comments we are finalizing our proposals related to billing and payment at § 512.260 and § 512.265, with modification. Specifically, we are adding 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 was described in this section of the final rule. Additionally, as noted earlier in this section of the final rule, we are 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, we would like to clarify that we are finalizing at § 512.245(b) that if an RO beneficiary dies after both the PC and the TC of the RO episode have been initiated, we proposed that 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. And, if an RO beneficiary elects the MHB not only after the PC and TC of an RO episode has been initiated but also before the TC is initiated as long as the TC is initiated within 28 days following the initial treatment planning service (PC), the RO participant(s) will receive both installments of the episode payment amount (upon billing the RO Model-specific HCPCS codes and the SOE and EOE modifiers) regardless of whether the RO episode has been completed. We recognize that the TC may not always be furnished on the same day, as the PC, or within a few weeks of the PC, and we would like our policy not to delay hospice referrals.

8. Quality

We proposed to implement and score a set of quality measures, along with the clinical data elements (proposed in section III.C.8.e of the proposed rule (84 FR 34514) and discussed in section III.C.8.e of this final rule) according to the Aggregate Quality Score (AQS) methodology (described in section III.C.8.f of the proposed rule (84 FR 34519)). We proposed that beginning in PY1, the AQS would be applied to the quality withhold (described in section III.C.6.g(2) of proposed rule (84 FR 34509) and discussed in this final rule) to calculate the quality reconciliation payment amount due to a Professional participant or Dual participant as specified in section III.C.11 of the proposed rule (84 FR 34527) and this final rule. As proposed, results from selected patient experience measures based on the CAHPS® Cancer Care survey would be incorporated into the AQS for Professional participants and Dual participants starting in PY3. For Technical participants, results from these patient experience measures would be incorporated into the AQS starting in PY3 and applied to the patient experience withhold described in section III.C.6.g(3) of the proposed rule (84 FR 34509 through 34510) and this final rule.

a. Measure Selection

We proposed that the following set of quality measures would be included in the RO Model in order to assess the quality of care provided during episodes (84 FR 34514). We proposed that we would begin requiring annual quality measure data submission by Professional participants and Dual participants in March of 2021[44] for episodes starting and ending in PY1. Participants would continue to be required to submit quality measure data annually every March through the remainder of the Model performance period as described in section III.C.8.c of the

[44] We are finalizing the inclusion of quality measures in the RO Model in section III.C.8.b, and finalizing that the first annual quality measure data submission will occur in March 2022 as finalized in section III.C.8.c.

proposed rule (84 FR 34517 through 34518) and this final rule. These quality measures would be used to determine a participant's AQS, as described in section III.C.8.f of the proposed rule (84 FR 34519) and this final rule, and subsequent quality reconciliation amount, as described in section III.C.11 of the proposed rule (84 FR 34527) and this final rule.

We proposed that the AQS would be based on each Professional participant's and Dual participant's: (1) performance on the set of evidenced-based quality measures in section III.C.8.b of the proposed rule (84 FR 34515 through 34517) and this final rule compared to those measures' quality performance benchmarks; (2) reporting of data for the pay-for-reporting measures (those without established performance benchmarks) in section III.C.8.b(4) of the proposed rule (84 FR 34515 through 34517) and this final rule; and (3) reporting of clinical data elements on applicable RO beneficiaries in section III.C.8.e of the proposed rule (84 FR 34518) and this final rule. As stated in the section III.C.8.f.(1) of the proposed rule (84 FR 34519), in the absence of a MIPS performance benchmark, national benchmark, or historical performance from which to calculate a Model-specific benchmark from previous years' historical performance, a quality measure will be included in the calculation of the AQS as pay-for-reporting until a benchmark is established that will enable it to be pay-for-performance. Based on the considerations set forth in the proposed rule, we proposed the following measures for the RO Model beginning in PY1 and continuing thereafter:

- Oncology: Medical and Radiation - Plan of Care for Pain -*NQF*[45] *#0383; CMS Quality ID #144*

[45] National Quality Forum.

- Preventive Care and Screening: Screening for Depression and Follow-Up Plan -*NQF #0418; CMS Quality ID #134*
- Advance Care Plan -*NQF #0326; CMS Quality ID #047*
- Treatment Summary Communication – Radiation Oncology

We proposed adopting this set of quality measures for the RO Model for two reasons. First, the RO Model is designed to preserve or enhance quality of care, and these quality measures would allow us to quantify the impact of the RO Model on quality of care, RT services and processes, outcomes, patient satisfaction, and organizational structures and systems. Second, we believe the RO Model measure set would satisfy the quality measure-related requirements for the RO Model to qualify as an Advanced APM, and a MIPS APM, which we discuss in greater detail in section III.C.9 of this final rule. Because they have already been adopted in MIPS, we believe that the following measures meet the requirements of 42 CFR 414.1415(b)(2): (1) Oncology: Medical and Radiation - Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. We further believe that the Treatment Summary Communication—Radiation Oncology measure is evidence-based, reliable, and valid because it has been developed by stakeholders to ensure timely handoff communication and care coordination to referring health care providers and patients receiving radiation therapy treatment. We acknowledge that we did not propose an outcome measure for the RO Model as required under 42 CFR 414.1415; however, as we explained in the proposed rule (84 FR 34515), this is because there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first Qualifying APM Participants (QP) Performance Period. We have determined there are currently no outcome measures available or applicable for the RO Model so this requirement does not apply to the RO

Model. However, if a potentially relevant outcome measure becomes available, we would consider whether it is applicable and should be proposed to be included in the RO Model's measure set.

As stated in the proposed rule, we believe our proposed use of quality measures as described in our AQS scoring methodology in section III.C.8.f of the proposed rule (84 FR 34519) and this final rule would meet the current quality measure and cost/utilization MIPS APM criterion under 42 CFR 414.1370(b)(3). In selecting the proposed measure set for the RO Model, we sought to prioritize quality measures that have been endorsed by a consensus-based entity or have a strong evidence-based focus and have been tested for reliability and validity. We focused on measures that would provide insight and understanding into the Model's effectiveness and that would facilitate achievement of the Model's care quality goals. We also sought to include quality measures that align with existing quality measures already in use in other CMS quality reporting programs, such as MIPS, so that Professional and Dual participants would be familiar with the measures used in the Model. Finally, we considered cross-cutting measures that would allow comparisons of quality across episode payment models and other CMS model tests.

As we stated in the proposed rule, we believe the proposed measure set would provide the Model with sufficient measures for the Model performance period to monitor quality improvement in the radiation oncology sector, and to calculate overall performance using the AQS methodology; however, CMS may adjust the measure set in future PYs by adding or

removing measures as needed. If changes to the measure set are necessary, we will propose those changes in future rulemaking.[46]

We solicited comment on this proposal. The following is a summary of the public comments received on this proposal and our response:

Comment: Several commenters supported CMS' proposal to include quality measures and believed that quality measures will ensure that quality care is delivered under the RO Model.

Response: We thank the commenters and appreciate their support.

Comment: A few commenters expressed support for use of NQF-endorsed measures generally. Other commenters specifically opposed the inclusion of any measure that is not NQF-endorsed in the RO Model.

Response: While NQF endorsement is not required when selecting measures for the RO Model, we agree with the commenters that NQF endorsement is one of several important criteria to consider. Three of the quality measures that we proposed for the Model are currently NQF-endorsed. A fourth, the measure "Treatment Summary Communication," was initially endorsed by NQF in 2008, but was not subsequently brought by the measure steward for maintenance/re-endorsement. However, we believe the information captured by this measure is relevant to the RO Model and critical to patients' care continuity and coordination. We believe that any measure that is evidence based and would support the goals of the Model, that has been tested to produce valid and reliable results, and that is effective without being overly burdensome, may be appropriate for inclusion in the Model. Therefore, we do not believe that the lack of current NQF

[46] When there is reason to believe that the continued collection of a measure as it is currently specified raises potential patient safety concerns, CMS will take immediate action to remove a measure from the program and not wait for the annual rulemaking cycle. In such situations, we would promptly retire such measures followed by subsequent confirmation of the retirement in the next rulemaking. When we do so, we will notify participants and the public through the usual communication channels, which include RO Model website and emails to participants.

endorsement alone should preclude a measure's adoption since endorsement, as it is only one of several considerations.

Comment: A commenter recommended that CMS add additional measures to the RO Model and allow participants the opportunity to select a subset of measures from the larger set to report.

Response: In selecting measures for the RO Model, we sought to include a set of meaningful, parsimonious measures, reflective of the CMS Meaningful Measures framework[47] that balances the need for data about participant performance without creating undue burden on participants. One set of measures used by all RO participants will provide insight for CMS and the field as a whole into how care quality compares across multiple markets. Selective reporting of measures would hinder the ability of CMS to measure or analyze the impact of the Model on quality.

Comment: A few commenters expressed their belief that the Model should only include measures related to patient safety and health care provider engagement to ensure the delivery of high-quality care within the Model.

Response: We agree that patient safety is of paramount importance; we will assess patient safety via claims, site visits, and data that RO participants are required to submit for monitoring and evaluation. However, we believe it is important to capture elements of quality care that go beyond patient safety and health care provider engagement. The selected measures will encourage providers and suppliers to engage with CMS and their patients to ensure that patients are receiving high-quality care. All measures were selected based on clinical appropriateness for

[47] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html

RT services spanning a 90-day episode period. Additionally the Model must include a sufficient set of quality measures to qualify as a MIPS APM and an Advanced APM.

Comment: A couple of commenters recommended that national accreditation through the American College of Radiology (ACRO) or American Society for Radiation Oncology (ASTRO) should be sufficient to meet quality standards for the Model and that accredited PGPs in the Model should not need to report additional quality data to CMS. The commenters believed that the collection and submission of additional quality data to CMS is unlikely to add value to the effort to improving radiation oncology care. A commenter supported accreditation and believed it enhances quality of care. Another commenter supported American College of Radiology (ACR) accreditation for larger centers with a full-time radiologist on site.

Response: We agree 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. However, we do not believe that accreditation provides a full picture of quality care delivery in radiation oncology. As noted earlier in this final rule, the Model must include a set of quality measures to qualify as a MIPS APM and an Advanced APM, and as such, accreditation is not able to replace the RO quality measures without compromising the Model's qualification as a MIPS APM and Advanced APM. In addition, while we are not using accreditation status as a proxy for quality, as stated in section III.C.13.c we may at some point use an optional web-based survey to gather data from participants on administrative data points, including their accreditation status, indicating the importance of this information to understanding participants' activities.

Comment: We received numerous comments requesting the addition or development of additional RT measures to ensure the provision of high-quality care. Commenters specifically

recommended the following topics for measures: tracking the toxicity of treatment; the utilization of surface guided radiation therapy (SGRT); compliance with dose limits and radiation exposure; hospice referrals; and innovation in patient care management (for example, phone and email contact). Other commenters recommended that CMS consider quality measures supported by ASTRO, including: Cancer Stage Documented; External Beam Radiotherapy for Bone Metastases; Hormonal Therapy for Stage IC– IIIC; ER/PR Positive Breast Cancer; Adjuvant Hormonal Therapy for High-Risk Patients; and Chemotherapy for AJCC Stage III Colon Cancer Patients. A commenter recommended that CMS communicate a commitment to adopt clinical and staging measures by PY2. Another commenter requested CMS develop a process to accept recommendations of potential measures to be considered for implementation in the RO Model.

Response: We appreciate the suggestions of additional quality measures. As previously discussed, we proposed the four measures and the CAHPS® Cancer Care survey described in the proposed rule for PY1 because we believe these measures will allow us to monitor and evaluate quality in the radiation oncology sector; they align with existing measures being used in quality programs; and they will allow the Model to qualify as an Advanced APM and a MIPS APM. However, we will consider revisions to this measure set for future model years. We will continue to monitor other measures that become available and meet the criteria for the Model, including seeking opportunities to align with quality measure efforts conducted by professional societies. As we consider additional measures for inclusion in the Model, we will consider which measures will allow the most meaningful and parsimonious measure set to ensure continued RT quality, while requiring the least amount of burden on providers and suppliers. Throughout the Model performance period, we will be seeking input from stakeholders on

potential quality measure while continuing to monitor the RT field for new and promising measures.

Comment: We received many comments related to measuring RO Model outcomes addressing multiple topics including: (1) the importance of including an outcome measure in APMs; (2) suggestions for making progress on creating a radiation therapy-specific outcome measure for future implementation; and (3) alternatives to a clinical outcomes measure that CMS can use to track outcomes for RO beneficiaries. Many commenters expressed support for inclusion of an outcome measure related to RT care, with some commenters noting that an outcome measure is preferred for an Advanced APM.

Some commenters believe that an outcome measure is important for the Model to evaluate whether a high level of care quality is maintained throughout the Model performance period, with a commenter requesting an outcome measure specifically to ensure that hypofractionation does not cause harm. A commenter recommended that quality programs should have outcome, patient experience, and value measures. On the topic of outcome measure development, several commenters suggested that CMS collaborate with professional and specialty societies to identify metrics that meaningfully measure quality of cancer care and impact on outcomes (including survival). A commenter also recommended that CMS track patient outcomes via a Medicare-certified Qualified Clinical Data Registry (QCDR). Another commenter recommended using a clinical outcomes measures related to patient safety (including the incidence of various side effects that may accompany overexposure of healthy tissue to radiation) and the efficacy of treatment.

MedPAC specifically recommended using three claims-based measures, the second and third of which are currently used in the OCM : (1) the risk-adjusted proportion of patients with

all-cause hospital admissions within the six-month episode, (2) risk-adjusted proportion of patients with all-cause emergency department (ED) visits or observation stays that did not result in a hospital admission within the six-month episode, and (3) proportion of patients that died who were admitted to hospice for three days or more.

Response: For PY1, we proposed four measures. Several outcome measures (some of which are registry-based measures), including those suggested by commenters, were considered prior to the publication of the proposed rule. In the end, we did not include these outcome measures in the proposed measure set due to concerns over the significant challenge of attributing outcomes – such as those suggested by MedPAC including hospital admissions, ED visits, or proportion of patients that died who were admitted to hospice – directly to RT services.

We would have liked to use the same OCM outcome measures for the RO Model, but ultimately decided that it would be difficult to discern whether these outcomes occurred due to complications from RT service, chemotherapy by medical oncologists, or for other various reasons. As such, we believe that these measures would not meaningfully indicate high- versus low-quality RO participants. As stated in the proposed rule (84 FR 34514), while we believe it is preferable to include an outcome measure in an Advanced APM, there are currently no outcome measures specific to RO available for implementation. We appreciate commenters' suggestions for understanding outcomes related to care delivered under the RO Model, including the suggestion that CMS use QCDRs to track outcomes. We will monitor the progress in this area but note that Professional participants and Dual participants are not required to contract with a QCDR; thus we will not use these entities as a means of collecting outcome measures. We will continue to assess and consider advancements made by professional and specialty societies in the development of quality metrics to identify the availability of metrics that meaningfully measure

quality of RT care and impact on outcomes (including survival). As these are identified, we will consider proposing an appropriate outcome measure in future rulemaking.

Comment*:* A commenter recommended developing an outcome registry for incidents such as bone marrow transplants, CAR-T cell therapy, fractures, pain, hospitalizations, and other complications. Another commenter encouraged CMS to develop a central reporting mechanism for patients receiving relatively new, relatively expensive technologies and their outcomes.

Response: CMS is not developing a registry for use in the RO Model, but we appreciate this comment and acknowledge the value of registries to track treatment effects and health outcomes, while not increasing data collection burden for providers and suppliers. We will monitor registry development and assess the feasibility of using such registry data in the future.

Comment: A commenter urged CMS to consider the relationship between the 90-day episode period and the timing included in the RO Model's measure specifications, and requested CMS properly scope the measures to reflect care that is within the control of the radiation oncologist specifically within the 90-day episode window.

Response: We believe that the measures we are adopting are appropriate for inclusion in the RO Model. We selected all measures based on clinical appropriateness for RT services spanning a 90-day episode period. The measures are scoped to certain specifications, including time, which are important for validity and reliability of the measure results. We believe that radiation oncologists have an important role to play in ensuring that their patients have a plan to address beneficiary pain, that they communicate treatment with other providers and suppliers to ensure the RO beneficiaries are receiving coordinated care, and that they have been screened for depression and have an advance care plan. By encouraging radiation oncologists to provide guidance and care coordination as well as engage with patients throughout their treatments, we

believe these measures will improve both patients' outcomes and their experience of care. We believe both depression screening and advance care planning help RO beneficiaries ensure they are engaged and pursuing the best course of treatment for them.

Comment: A commenter expressed concern that the proposed quality measures are insufficient to measure whether RO participants are using high-quality equipment and other infrastructure they believe correlate with providing high-value care. This commenter recommended including quality measures that reflect variation in accreditation and equipment used for treatment.

Response: We appreciate the role of high-quality equipment in the delivery of care. We also understand that to achieve accreditation, a clinical organization must demonstrate high standards of patient care. We also note that, as discussed in section III.C.13.c, we may request the optional submission of additional administrative data through web-based surveys, such as how frequently the radiation machine is used on an average day and the RO participant's accreditation status. However, we continue to believe that quality measurement must be outcome-based, focusing on the patient and the episode of care, and not be based solely on the equipment or accreditation status. We will use clinical data elements in the RO Model to support monitoring and evaluation of the Model and may use these data to begin developing new outcome-based quality measures that may capture the effect of quality equipment and infrastructure.

Comment: Several commenters recommended a voluntary phase-in period to collect quality measure data, which they believe would allow practices to become operational within the Model and provide better data. A couple of commenters urged CMS to provide additional details

on quality measure and clinical data element collection and submission processes to give RO participants additional time to prepare their systems and comply with these requirements.

Response: We do not believe a voluntary phase-in period is necessary for the RO Model. RO participants' first submission for the set of quality measures for PY1 (beginning on January 1, 2021) as described in section III.C.8.b will begin in March 2022, as finalized in section III.C.8.c. We believe beginning the Model performance period on January 1, 2021 Model will allow RO participants to review and to develop best practices to facilitate their data collection and to work with EHR vendors to seek additional EHR support. We will provide additional information about measure collection on the RO Model Website: https://innovation.cms.gov/initiatives/radiation-oncology-model/.

Comment: A commenter expressed concern that EHR vendors will use the new requirements to generate additional fees for their products, thereby placing RO participants, especially those that are small and rural, at greater financial risk.

Response: We understand the commenter's concern about the cost of these requirements, but we note that three of the four proposed quality measures are already included in the MIPS program, so we expect that some of these measures may already be familiar to EHR vendors. In regard to small and rural providers and suppliers, please see section III.C.3.c of this final rule, which outlines the opt-out option for low-volume providers and suppliers.

Comment: A few commenters opposed the implementation of quality measures in the RO Model and suggested not implementing quality measures in the Model at all, stating their view that the measures would not yield information reflective of quality in a radiation oncology practice and would do little to encourage actual improvement in the quality of patient care.

Response: We disagree with commenters' assertions regarding the impact of quality measurement in the RO Model. We believe that including appropriate quality measures in the RO Model – as in other Innovation Center Alternative Payment Models (APMs) – is critical to monitoring beneficiary care and ensuring that quality of care is preserved or enhanced within an episode payment model in which CMS expenditures are reduced. Quality measures are in alignment with the CMS and Innovation Center goals of providing effective, safe, efficient, patient-centered, equitable, and timely care. Furthermore, if we did not finalize quality measures for the RO Model, it would not satisfy the requirements of an Advanced APM, nor a MIPS APM.

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

As we discussed in the proposed rule (84 FR 34515), we selected the four quality measures for the RO Model after conducting a comprehensive environmental scan that included stakeholder and clinician input and compiling a measure inventory. Three of the four measures are currently NQF-endorsed[48] process measures approved for MIPS.[49] We proposed for the three NQF-endorsed measures approved for MIPS (Plan of Care for Pain; Screening for Depression and Follow-Up Plan; and Advance Care Plan) to be applied as pay-for-performance, given that baseline performance data has been established.[50] The fourth measure in the RO Model (Treatment Summary Communication) would be applied as pay-for-reporting until such time that a benchmark can be developed, which is expected to be PY3, as discussed in section III.C.8.b of the proposed rule (84 FR 34515) and this final rule. As described in the proposed rule, all four

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[48] NQF endorsement summaries: http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx

[49] See the CY 2018 QPP final rule (82 FR 53568).

[50] Baseline performance is based on the entirety of data submitted to meet MIPS data reporting requirements for these measures and are not specific to radiation oncology performance.

measures are clinically appropriate for radiation oncology and were selected based on clinical appropriateness to cover RT spanning the 90-day episode period. These measures ensure coverage across the full range of cancer types included in the RO Model, and provide us the ability to accurately measure changes or improvements related to the Model's aims. In addition, we proposed the CAHPS® Cancer Care survey to collect information we believe is appropriate and specific to a patient's experience during an episode. We noted in the proposed rule that we believe these measures and the CAHPS® Cancer Care survey[51] will allow the RO Model to develop an Aggregate Quality Score (AQS) in our pay-for-performance methodology (described in section III.C.8.f of this final rule) that incorporates performance measurement with a focus on clinical care and patient experience.

(1) Oncology: Medical and Radiation - Plan of Care for Pain (NQF #0383; CMS Quality ID #144)

We proposed the *Oncology: Medical and Radiation - Plan of Care for Pain* ("Plan of Care for Pain") measure in the RO Model (84 FR 34515). This is a process measure that assesses whether a plan of care for pain has been documented for patients with cancer who report having pain. This measure assesses the "[p]ercentage 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."[52] As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50843), pain is the most common symptom in cancer, occurring "in approximately one quarter of patients with newly diagnosed

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[51] As discussed in section III.C.8.b(5) and III.C.8.f, the CAHPS® Cancer Care survey would be administered beginning in October, 2020, and we would seek to include measures in the aggregate quality score beginning in PY3.

[52] Oncology: Medical and Radiation - Plan of Care for Pain. American Society of Clinical Oncology. In Review for Maintenance of Endorsement by the National Quality Forum (NQF #0383). Last Updated: June 26, 2018.

malignancies, one third of patients undergoing treatment, and three quarters of patients with advanced disease."[53] Proper pain management is critical to achieving pain control. This measure aims to improve attention to pain management and requires a plan of care for cancer patients who report having pain to allow for individualized treatment.

As we noted in the proposed rule (84 FR 34515), we believe this measure is appropriate for inclusion in the RO Model because it is specific to an episode of care. It considers the quality of care of medical and radiation oncology and is NQF-endorsed. As we proposed, the RO Model would adopt the measure according to the most recent specifications, which are under review at NQF in Fall 2019 (and as of the drafting of this final rule are still under review). The current measure specifications are being used for payment determination within the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (beginning in FY2016 as PCH-15), the Oncology Care Model (OCM) (beginning in 2016 as a component of OCM-4), and the Merit-Based Incentive Payment System (MIPS) (beginning in CY2017 as CMS #144). We explained in the proposed rule that as long as the measure remains reliable and relevant to the RO Model's goals, we would continue to include the measure in the Model regardless of whether or not the measure is used in other CMS programs. If in the future we believe it necessary to remove the measure from the RO Model, then we will propose to do so through notice and comment rulemaking.

We noted in the proposed rule that this measure was currently undergoing triennial review for NQF endorsement via the NQF's Fall 2019 Cycle and while we expected changes to the measure specifications, we did not believe these changes would change the fundamental basis of the measure, nor did we believe they would impact the measure's appropriateness for

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[53] Swarm RA, Abernethy AP, Anghelescu DL, et al. Adult Cancer Pain: Clinical Practice Guidelines in Oncology. *Journal of the National Comprehensive Cancer Network: JNCCN*. 2013;11(8):992-1022. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915297/

inclusion in the RO Model. As of the drafting of this final rule, this measure is still under NQF review, but as we explained in the proposed rule, NQF endorsement is a factor in our decision to implement the Plan of Care for Pain measure, but it is not the only factor. If the measure were to lose its NQF endorsement, we noted in the proposed rule that we may choose to retain it so long as we believe it continues to support CMS and HHS policy goals. Therefore, we proposed the Plan of Care for Pain measure with the associated specifications available beginning in PY1. This measure would be a pay-for-performance measure and scored in accordance with our methodology in section III.C.8.f of this final rule.

As proposed (84 FR 34517), and as discussed further in section III.C.8.c of this final rule, we would require Professional participants and Dual participants to report quality measure data to the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. At the time of the proposed rule and at the time of the writing of the final rule, the current version of the Plan of Care for Pain measure specification requires that data will be reported for the performance year that covers the date of encounter. The measure numerator includes patient visits that included a documented plan of care to address pain. The measure denominator includes all visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain. Any exclusions can be found in the detailed measure specification linked in this section of this final rule.

For the RO Model, we proposed to use the CQM[54] specifications for this measure. Detailed measure specifications may be found at:

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[54] We note that we proposed to use "registry specifications." For consistency with QPP, we are now referring to registry specifications as CQM specifications to align with QPP's terminology.

https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_144_MIPSCQM.pdf

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters expressed support for implementing the Plan of Care for Pain measure, believing that the assessment reflected by this measure will improve the quality of patient care. A commenter asked CMMI to clarify the measure specification that would be used beginning in 2020, noting the specifications were changed for the 2019 MIPS performance year, but the measure steward is reverting to the 2018 specifications (to include those who report all pain, versus the 2019 specifications that only included reports of moderate or severe pain).

Response: We agree that this measure reflects an important area of assessment. We also note that where one measure is being used in multiple CMS programs, we seek to align measure specifications across programs and use the most up-to-date version as appropriate. As discussed in section III.C.8.d, measures also undergo non-substantive technical maintenance and we intend to use the most recent specifications unless those specifications are inconsistent with the specifications used in MIPS. In those situations, we would use the MIPS specifications. Thus, for each PY, we will utilize the specifications of the measure that aligns with the most recent MIPS year specifications.[55]

After consideration of the comments we received, we are finalizing as proposed to include the Oncology: Medical and Radiation - Plan of Care for Pain (NQF #0383; CMS Quality ID #144) Measure as a pay-for-performance measure beginning in PY1.

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[55] We intend to align with the most recent MIPS year specifications for each measure that is included in MIPS because such alignment will reduce burden for RO participants and permit comparisons between the MIPS and RO participants.

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

We proposed the *Preventive Care and Screening: Screening for Depression and Follow-Up Plan* ("Screening for Depression and Follow-Up Plan") measure in the RO Model (84 FR 34516)**.** This is a process measure that assesses the "[p]ercentage 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."[56] As we noted in the proposed rule, we believe this clinical topic is appropriate for an episode of care even though it is not specific to RT. We explained that we believe inclusion of this measure is desirable to screen and treat the potential mental health effects of RT, which is important because some of the side effects of RT have been identified as having a detrimental effect on a patient's quality of life and could potentially impact the patient beyond physical discomfort or pain. [57,58,59,60,61,62] We noted that this measure has been used for payment determination within OCM (beginning in 2016 as OCM-5) and MIPS (beginning in CY2018 as CMS #134) and is NQF endorsed. We also indicated that if we were to remove the measure from the RO Model, we would use notice and comment in rulemaking. As

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[56] Preventive Care and Screening: Screening for Depression and Follow-Up Plan. Centers for Medicare & Medicaid Services. Endorsed by the National Quality Forum (NQF #0418). Last Updated: Jun 28, 2017.

[57] Siu AL, and the US Preventive Services Task Force USPSTF. Screening for Depression in Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2016;315(4):380–387. doi:10.1001/jama.2015.18392, https://jamanetwork.com/journals/jama/fullarticle/2484345

[58]Meijer, A., Roseman, M., Milette, K., Coyne, J. C., Stefanek, M. E., Ziegelstein, R. C., … Thombs, B. D. (2011). Depression screening and patient outcomes in cancer: a systematic review. PloS one, 6(11), e27181. https://doi.org/10.1371/journal.pone.0027181

[59] Li, M., Kennedy, E. B., Byrne, N., Gérin-Lajoie, C., Katz, M. R., Keshavarz, H., . . . Green, E. (2016). Management of Depression in Patients With Cancer: A Clinical Practice Guideline. Journal of Oncology Practice, 12(8), 747-756. https://ascopubs.org/doi/10.1200/JOP.2016.011072

[60] Pinquart, M., & Duberstein, P. R. (2010). Depression and cancer mortality: A meta-analysis. Psychological Medicine, 40(11), 1797-1810. doi:10.1017/s0033291709992285, https://pubmed.ncbi.nlm.nih.gov/20085667/

[61] Massie, M. J. (2004). Prevalence of Depression in Patients With Cancer. Journal of the National Cancer Institute Monographs, 2004(32), 57-71. https://doi.org/10.1093/jncimonographs/lgh014

[62] Linden, W., Vodermaier, A., Mackenzie, R., & Greig, D. (2012). Anxiety and depression after cancer diagnosis: Prevalence rates by cancer type, gender, and age. Journal of Affective Disorders, 141(2-3), 343-351. doi:10.1016/j.jad.2012.03.025, https://pubmed.ncbi.nlm.nih.gov/22727334/

proposed, this measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our methodology described in section III.C.8.f of this final rule.

As noted in the proposed rule, discussed further in section III.C.8.c of this final rule, we would require Professional participants and Dual participants to report quality measure data to the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. The Screening for Depression and Follow-Up Plan measure specification states the data will be reported for the performance year that covers the date of encounter. The measure numerator includes patients screened for depression on the date of the encounter using an age-appropriate standardized tool and, if the screening is positive, a follow-up plan is documented on the date of the positive screen. The measure denominator includes all patients aged 12 years and older before the beginning of the measurement period with at least one eligible encounter during the measurement period. Any exclusions can be found in the detailed measure specification linked in this section in this final rule.

For the RO Model, we would use the CQM[63] specifications for this measure. Detailed measure specifications may be found at: https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_134_MIPSCQM.pdf

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters supported this measure. A commenter asserted the measure should be broadened to include screening for distress (for example, anxiety, stress, and social isolation) and whether follow-up care is being sought. Another commenter who supported

[63] We note that we proposed to use "registry specifications." For consistency with QPP, we are now referring to registry specifications as CQM specifications to align with QPP's terminology.

the measure recommended an exception be written into the specifications to exclude patients who were screened less than six months prior to the encounter within the measurement period. The commenter explained that this exception could be utilized to guard against the perception of gaming that the commenter believes exists in OCM practices that are screening patients for depression on a quarterly (or more frequent) basis, to perform better on the measure. This commenter also noted that the frequency of screening places burden on patients.

Response: We appreciate commenters' support for including this measure in the Model. We respect the commenter's concerns regarding the perception of gaming as related to this measure. While we understand the importance of mitigating gaming, we do not concur with the commenter's perception of gaming in OCM practices. CMS is not the measure steward, however, we will share the commenters' feedback on potential changes to the specifications with the measure steward for consideration especially with respect in recognition of the perception of gaming.

Comment: A few commenters recommended against adopting this measure, noting that (1) it is considered topped-out; (2) it is outside of the direct control of radiation oncologists (that is, typically the responsibility of primary care physicians or medical oncologists), and therefore not directly applicable to the RO Model; and (3) calculating the measure imposes a burden on providers and suppliers because the data is not captured in a discrete field in the medical record. These commenters suggested that CMS work with specialty societies, radiation oncologists, and other stakeholders to develop and validate appropriate measures for radiation therapy.

Response: We appreciate all of the comments regarding this measure and acknowledge the concerns that some commenters expressed. The RO Model will use the MIPS CQM version of this measure. For providers and suppliers that participated in MIPS and submitted the measure

through the MIPS CQM, this measure is not topped-out. Further, even if this measure were to become topped-out for the population of providers and suppliers who participate in MIPS, there is value to implementing measures that have topped-out in order to prevent a decrease in performance on this aspect of care. Further, establishing continuity in the quality measures implemented in the RO Model and MIPS will be a key factor in our assessment of the RO Model's performance over time, as it will allow for data comparison between the participating entities in each respective program. While screening for depression and follow-up care is not traditionally within the purview of radiation oncologists, we believe the RO Model presents an opportunity to address the need for more comprehensive understanding of patients' health when undergoing RT services. Care can be delivered more effectively when RO participants understand their patients' mental health, and the ramifications of their mental health on their care planning and care delivery. Specifically, we note this measure requires that a follow-up plan is documented on the day of a positive screening. In regard to provider and supplier burden, we expect that – given this is an existing MIPS measure – data are captured in EHRs, and/or EHR vendors will have capacity to establish needed collection fields. We will continue to monitor our measure set and other measures as they become available to ensure the RO Model measure set remains appropriate, meaningful and parsimonious.

Comment: A commenter recommended categorizing this measure as pay-for-reporting in the AQS methodology (as opposed to pay-for-performance) until a benchmark is established specific to radiation oncology patients, noting that the current MIPS benchmark for this measure would create an inappropriate cohort comparison.

Response: We believe that setting discrete benchmarks for different specialties does not align with CMS' goals for quality improvement. In addition, discrete benchmarks would create

undue complexity and possible confusion for RO participants who also participate in MIPS to have potentially two different benchmarks. Therefore, we will use the MIPS benchmark and finalize this measure as Pay-for-Performance in PY1.

After consideration of the comments we received, we are finalizing the proposal to include the Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality ID #134) Measure as a pay-for-performance measure beginning in PY1.

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

We proposed to include the *Advance Care Plan* measure in the RO Model (84 FR 34517). The Advance Care Plan measure is a process measure that describes 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 advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. This measure is not unique to the radiation oncology, but, as proposed, we believe that it would be appropriate for the RO Model because we believe that it is essential that a patient's wishes regarding medical treatment are established as much as possible prior to incapacity.

This measure is NQF endorsed[64] and has been collected for MIPS (beginning in CY2018 as CMS #047), making its data collection processes reasonably well established. If it becomes necessary to remove the measure from the Model, we would do so through notice and comment rulemaking. As proposed, this measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our methodology in section III.C.8.f of this rule.

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[64] As of April 2020 this measure is undergoing an annual endorsement update review at NQF. A modified specification was submitted for review by the measure developer.

As proposed (84 FR 34517), and as discussed further in section III.C.8.c of this rule, we would require Professional participants and Dual participants to report quality measure data the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. The current version (at the time of the proposed rule and the drafting of this final rule) of the Advance Care Plan measure specification states the data will be reported for the performance year that covers the date of documentation in the medical record. The measure numerator includes patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. The measure denominator includes all patients aged 65 years and older. Any exclusions can be found in the detailed measure specification linked in this section of this final rule.

As proposed, for the RO Model, we would use the CQM[65] specifications for this measure. Detailed measure specifications may be found at: https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_047_MIPSCQM.pdf

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters supported implementing the Advance Care Plan measure. A commenter noted advance care planning is associated with lower rates of ventilation, resuscitation, intensive care unit admission, earlier hospice enrollment, and decreased cost of care at the end of life. Another commenter noted advance care planning is a key activity in

[65] We note that we proposed to use "registry specifications." For consistency with QPP, we are now referring to registry specifications as CQM specifications to align with QPP's terminology.

cancer care planning and documenting a patient's goals and values can result in more personalized care plans. Finally, a commenter supported this measure but recommended allowing an exclusion for those patients who do not want to participate in advance care planning.

Response: We thank the commenters for their support. Regarding the comment to exclude patients who do not want to participate in advance care planning, we are implementing the measure using the current specifications, which have been tested and validated for reliability. We note that within the current specifications, the numerator 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. Thus, an exclusion for those patients who chose not to have such a plan is not necessary to performance on this measure.

Comment: A few commenters recommended not finalizing the Advance Care Plan measure, because they believe: (1) it is topped-out; (2) it is outside the direct control of radiation oncologists; (3) calculating the measure imposes a substantial burden on RO participants; and (4). this measure does not account for patients' receipt of survivorship care plans and may create duplication of effort.

Response: We appreciate all of the comments regarding this measure and acknowledge the concerns that some commenters expressed. As we stated in our discussion of the Screening for Depression and Follow-Up Plan measure, we are using the MIPS CQM version of this measure. This measure is not topped-out for the population of providers and suppliers who participate in MIPS and submitted their data through the MIPS CQM. There is also value to implementing measures that have topped-out, to prevent a decrease in performance on this aspect of care. While advance care planning may not be traditionally within the purview of radiation oncologists, we believe the Model presents an opportunity for RO participants to engage patients

in care planning. Further, establishing continuity in the quality measures implemented in the RO Model and MIPS will be a key factor in our assessment of the RO Model's performance over time, as it will allow for data comparison between the participating entities in each respective program. In regard to provider and supplier burden, we expect that – given this is an existing MIPS measure – data are captured in EHRs, and/or EHR vendors will have capacity to establish needed collection fields. Finally, we seek to clarify that the Advance Care Plan measure quantifies the number of patients who have an advance care plan or a surrogate decision-maker documented in the medical record, or documentation that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate. We do not see any overlap between this measure, and the process of providers and suppliers working with patients to develop Survivorship Care Plans. Survivorship Care Plans include information about a patient's treatment, the need for future check-ups and cancer tests, and potential long-term late effects of treatment, as well as ideas for health improvement.[66]

After consideration of the comments we received, we are finalizing as proposed to include the Advance Care Plan (NQF #0326; CMS Quality ID #047) Measure as a pay-for-performance measure beginning in PY1.

(4) Treatment Summary Communication – Radiation Oncology

We proposed the *Treatment Summary Communication – Radiation Oncology* ("Treatment Summary Communication") measure in the RO Model (84 FR 34517). The Treatment Summary Communication measure is a process measure that assesses the "[p]ercentage 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

[66] https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans

communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment."[67] As proposed, we believe this measure is appropriate for inclusion in the RO Model because it is specific to an episode of care. This measure assesses care coordination and communication between health care providers during transitions of cancer care treatment and recovery. While this measure is not currently NQF endorsed[68] and has not been used in previous or current CMS quality reporting, it has been used in the oncology field for quality improvement efforts, making considerations regarding data collection reasonably well-established. We would include the measure because, as we stated in the proposed rule, we believe it is valid and relevant to meeting the RO Model's goals. As proposed, this measure would be the one pay-for reporting measure included in the calculation of the AQS until a benchmark is established that will enable it to be pay-for-performance, which is expected to be beginning in PY3.

As proposed (84 FR 34517), and as discussed further in section III.C.8.c of this final rule, we would require Professional participants and Dual participants to report quality measure data to the RO Model secure data portal in the manner consistent with that submission portal and the measure specification. The current version (at the time of the proposed rule and the drafting of this final rule) of the Treatment Summary Communication measure specification states the data will be reported for the performance year that covers the date of the treatment summary report in the chart. The measure numerator includes patients who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care and to the patient

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[67] Oncology: Treatment Summary Communication – Radiation Oncology. American Society for Radiation Oncology. Endorsement removed by the National Quality Forum (NQF #0381). Last Updated: Mar 22, 2018.

[68] Treatment Summary Communication had previously been endorsed by NQF but was not brought by the measure steward for measure maintenance and re-endorsement; thus it is currently not endorsed.

within one month of completing treatment. The measure denominator includes all patients, regardless of age, with a diagnosis of cancer who have undergone brachytherapy or external beam radiation therapy. Any exclusions can be found in the detailed measure specification linked in this section of this final rule.

For the RO Model, we would use the registry specifications for this measure. Detailed measure specifications may be found at: http://www.qualityforum.org/QPS/0381.

The following is a summary of the public comments received on this proposal and our response:

Comment: A few commenters expressed support for the measure Treatment Summary Communication. A couple of commenters noted their desire for CMS to collect data beyond what this measure captures, and look at multidisciplinary treatment planning efforts across radiation oncology, surgery, and medical oncology. A couple of commenters expressed support for implementing this measure as pay-for-reporting in PYs 1-2 and encouraged CMS to test the measure for reliability and validity, and provide additional information to RO participants, before transitioning it to a pay-for-performance measure.

Response: We appreciate commenters' support and are finalizing this measure, using the current specifications, which have been tested and validated for reliability, in the RO Model as described in the proposed rule: pay-for-reporting in PY1 and PY2; and pay-for-performance in PYs 3-5. We believe the measure must be 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. We plan to provide information regarding the benchmark for the measure Treatment Summary Communication to RO participants via the RO Model website.

Comment: A few commenters expressed concerns regarding the specifications and/or endorsement status of this measure. A commenter specifically noted the measure was withdrawn from NQF consideration by the developer, and not submitted for NQF measure maintenance evaluation, thus it is no longer endorsed. Commenters noted that the lack of endorsed measure specifications can create inconsistency in how the measure is utilized; they also noted that this measure is not widely integrated into EHRs, thus creating burden for RO participants who will need to integrate the measure's data points into their EHRs. Another commenter noted that the measures should be implemented with the original specifications to document treatment summary communications that take place over a four-week period of a patient's care and recommended that CMS align how this measure's data is collected and reported – using the original four-week specification – across all CMS reporting programs.

Response: We appreciate commenters' concerns and will finalize the measure specifications as proposed. Where one measure is being used in multiple CMS programs or models, we seek to align measure specifications across programs and models and use the most up-to-date version as appropriate. Regarding NQF endorsement, we agree that NQF endorsement is an important, but not the sole, criterion for identifying measures for implementation. RO participants will be provided with educational materials that provide the specification details for each measure, which addresses the concerns expressed by commenters that lack of current NQF endorsement may lead to inconsistency in how the measure is operationalized within the RO Model.

Comment: A commenter requested clarification about how this measure would be fielded. Another commenter requested clarification that RO participants do not need to send a treatment summary to other PGPs if both have access to the same EHR.

Response: The intent of this measure is to ensure that the radiation oncology treatment documentation is appropriately transitioned to the physician responsible for the patient's ongoing care, as well as to the patient, to ensure safe and timely care coordination and care continuity post-treatment. If the referring PGP and RO participant are using the same EHR, appropriate communication must still occur with the patient, and referring PGP as appropriate, in order to meet the criteria for the measure numerator.

After consideration of the comments we received, we are finalizing as proposed to include the Treatment Summary Communication – Radiation Oncology as a pay-for-reporting measure beginning in PY1.

(5) CAHPS® Cancer Care Survey for Radiation Therapy

We proposed to have a CMS-approved contractor administer the *CAHPS® Cancer Care Survey for Radiation Therapy* ("CAHPS® Cancer Care Survey"), beginning April 1, 2020 and ending in 2025, to account for episodes that were completed in the last quarter of 2024 (84 FR 32517). We would use the CAHPS® Cancer Care Survey for inclusion in the Model as it is appropriate and specific to patient experience of care within an RO episode. Variations of the CAHPS® survey are widely used measures of patient satisfaction and experience of care and are responsive to the increasing shift toward incorporation of patient experience into quality measurement and pay-for-performance programs. Variations of the CAHPS® survey have been used within the PCHQR Program, Hospital OQR Program, MIPS, OCM, and others, making considerations regarding data collection reasonably well-established.

As we indicated in the proposed rule, we plan to propose a set of patient experience domains based on the CAHPS® Cancer Care Survey, which would be included in the AQS as pay-for-performance measures beginning in PY3, in future rulemaking.

The CAHPS® Cancer Care Survey proposed for inclusion in the RO Model may be found at https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html.

We solicited public comment on our proposal to administer the CAHPS® Cancer Care Survey for Radiation Therapy for purposes of testing the RO Model.

Comment: A couple of commenters recommended CMS implement the CAHPS® Cancer Care Survey in the Model earlier than PY3 due to the importance of collecting patient experience data to inform clinical care.

Response: We appreciate commenter's recommendations and agree with sentiment that collecting patient experience data is critical. We will begin fielding the CAHPS® Cancer Care Survey in PY1. The inclusion of patient experience measures in the calculation of the AQS will not begin until PY3, after future rulemaking, due to the time needed to derive and test which domains should be included in the AQS using data collected from the early years of the Model.

Comment: A few commenters requested clarification regarding who would administer the CAHPS® Cancer Care Survey. These commenters also expressed concern that the RO participant would have to bear the administrative and financial cost of fielding the survey.

Response: We would like to clarify that CMS will be accountable for fielding the CAHPS® Cancer Care Survey to RO beneficiaries. RO participants should not experience any additional cost as a result of implementation of the survey.

Comment: Several commenters did not support adopting, or recommended delaying implementation of, the CAHPS® Cancer Care Survey. A commenter asserted the timing of implementation of the RO Model would not allow participants enough time to prepare for fielding the survey. Another commenter stated the lack of current benchmarks would make it difficult to incorporate the measure into the AQS at PY3, and recommended delaying until PY4.

A third commenter suggested CMS pilot the CAHPS® Cancer Care Survey before including it as a measure in the AQS. Some commenters did not support adopting the CAHPS® Cancer Care Survey because they believe that it does not elicit meaningful data from patients. The commenters argued that: (1) the time lag between when a patient finishes a course of radiotherapy and when they receive the CAHPS® Cancer Care Survey makes it challenging to remember the specifics of their care experience; (2) the multi-disciplinary nature of oncology care, including RT services, makes it difficult for patients to tease out their specific RT experience; (3) the length of the survey and current administration modes (by mail or telephone, with no electronic option) is overwhelming to patients; (4) the mail or phone nature of fielding CAHPS® has the potential to be viewed by patients as a scam; and (5) the burden on patients who have to fill out multiple surveys, which may create timing issues for RO participants to comply with RO Model deadlines.

Response: We acknowledge there are significant challenges to implementing patient experience measures in any model or program; however, those challenges should not preclude making the effort to collect and analyze data on the patient experience, to achieve the ultimate goal of improving patient care. We note that AHRQ has tested the survey for reliability and validity to address issues of comparability across practices and patient characteristics. As such, we do not believe it is necessary to implement a pilot period prior to including this survey as a part of the AQS. Further, we reiterate that the CAHPS® Cancer Care Survey be fielded starting in PY1 but not included in the AQS methodology as a pay-for-reporting measure until PY3, after future rulemaking. Finally, we do not believe a delay in implementation to help RO participants prepare for fielding the survey is needed, given that CMS will administer the survey.

Comment: Some commenters expressed concern with the use of the CAHPS® Cancer Care Survey for other methodological reasons, including: (1) the survey is not endorsed by NQF; (2) lack of sufficient testing of the survey to ensure comparability of performance scores based on practice size and type, patient characteristics, and/or geographic regions; (3) the need to harmonize the survey with the CAHPS® Hospice survey; (4) the lack of a strategy for ensuring that RO beneficiaries do not receive both surveys during what is already a stressful and anxious time; (5) inherent biases against HOPDs that may be found in patient experience surveys, due to HOPDs often having fewer resources for staffing, capital, and amenities compared to PGPs and free standing radiation therapy centers, which may correlate with lower patient experience scores; and (6) potential overlap in the CAHPS® Cancer Care Survey and the Outpatient and Ambulatory Surgery (OAS) CAHPS® survey, which could negatively affecting response rates for either or both survey(s).A commenter recommended that CMS investigate electronic modes of fielding the CAHPS® Cancer Care Survey.

Response: We appreciate commenters sharing their methodological concerns and acknowledge that collecting patient experience data is a challenging effort. We will consider these comments as we implement the Model and begin reviewing the survey data, and where necessary, we will seek to address them in future rulemaking. Regarding NQF endorsement, we agree that NQF endorsement is an important, but not the sole, criterion for identifying measures for implementation. Regarding testing the survey in the Model, AHRQ has tested the survey for reliability and validity to address issues of comparability across practices and patient characteristics.

We will begin administering the survey in PY1 for baseline data collection, to set appropriate benchmarks, and to identify other methodological issues such as effects of overlap

with OAS CAHPS® on the response rate. We plan to propose via rulemaking a set of patient experience domains based on the CAHPS® Cancer Care Survey, which would be included in the AQS as pay-for-performance measures beginning in PY3. Information on the established benchmarks will be made available on the RO Model website. Regarding survey mode(s) and administration, CMS will be responsible for survey administration to beneficiaries in the RO Model and will ensure survey methods are consistent with the CAHPS® specifications, including potential overlap with other CAHPS® surveys. CMS will field the survey as specified to ensure reliability and validity of survey response data. Further information about the survey development, testing, and fielding can be found on the survey website.[69] We note that the version of the CAHPS® Cancer Care Survey that will be used was specifically developed for radiation therapy, which we believe addresses the commenter's concern about being able to appropriately consider RT care experiences.

Comment: A few commenters suggested creating a new patient experience measure to replace the use of the CAHPS® Cancer Care Survey. A commenter suggested that the patient experience measure should be developed in a way that eliminates bias against HOPDs, which the commenter says often have a less favorable payer mix than PGPs and freestanding radiation therapy centers. Another commenter noted that while patient experience measures are good indicators of whether and how changes are being implemented in care, an actual patient experience measure that reflects the RO Model should be developed at an accelerated pace.

Response: We agree that innovation in the collection of patient experience data is important to pursue, and we welcome advancements in this area. However, we also believe that

[69] CAHPS® Cancer Care Survey. https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html

the need to understand patients' experiences of care is critical, and cannot be delayed while other measures are being developed. For these reasons, we are finalizing adoption of the CAHPS® Cancer Care Survey and will continue to evaluate new measures of patient experience for future consideration.

After reviewing the comments received on our proposed quality measures, we are finalizing, with one modification in regard to the start date, our proposal to include a set of four quality measures for PY1. Instead of submitting quality measures data beginning in March, 2021, as proposed, RO participants will submit data beginning in March, 2022, based on RO episodes in PY1 (January 1, 2021, through December 31, 2021), consistent with other changes to the timing of Model implementation. We are also finalizing our proposal to have a CMS-approved contractor administer the CAHPS® Cancer Care Survey for Radiation Therapy, with a modification that the survey will be administered beginning in April 2021 rather than in 2020.

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

We proposed to use the following data collection processes for the four quality measures described in section III.C.8.b(1) through (4) of this final rule beginning in PY1 (84 FR 34517).

First, we proposed requiring Professional participants and Dual participants to report aggregated quality measure data, instead of beneficiary-level quality measure data. These data would be used to calculate the participants' quality performance, as discussed in section III.C.8.f(1) of the proposed rule (84 FR 34519) and this final rule, and subsequent quality reconciliation payments on an annual basis.

Second, we proposed requiring that quality measure data be reported for all applicable patients (that is, not just Medicare beneficiaries or beneficiaries with episodes under the Model) based on the numerator and denominator specifications for each measure (84 FR 34517). As

proposed, we believe collecting data for all patients who meet the denominator specifications for each measure from a Professional participant or Dual participant, and not just Medicare beneficiaries, is appropriate because it is consistent with the applicable measure specifications, and any segmentation to solely the Medicare populations would be inconsistent with the measure and add substantial reporting burden to RO participants. If a measure is already reported in another program, then the measure data would be submitted to that program's reporting mechanism in a form, manner, and at a time consistent with the other program's requirements, and separately submitted to the RO Model secure data portal in the form, manner and at the time consistent with the RO Model requirements.

As proposed, similar to the approach taken for the QPP,[70] the RO Model would not score measures for a given Professional participant or Dual participant that does not have at least 20 applicable cases according to each measure's specifications. However, unlike the Quality Payment Program, if measures do not have at least 20 applicable cases for the participant, we would not require the measures to be reported. In this situation, an RO participant would enter "N/A-insufficient cases" to note that an insufficient number of cases exists for a given measure.

As proposed, we would provide Professional participants and Dual participants with a mechanism to input quality measure data. We would create a template for Professional participants and Dual participants to complete with the specified numerator and denominator for each quality measure (and the number of cases excluded and exempt from the denominator, as per measure specifications' exclusions and exemptions allowances), provide a secure portal, the RO Model secure data portal , for data submission, and provide education and outreach on how

[70] 42 CFR 414.1380(b)(1)(iii).

to use these mechanisms for data collection and where to submit the data prior to the first data submission period.

We proposed that Professional participants and Dual participants would be required to submit quality measure data annually by March 31 following the end of the previous PY to the RO Model secure data portal (84 FR 34518). In developing the March 31 deadline, we considered the quality measure reporting deadlines of other CMS programs in conjunction with the needs of the Model. For PY1, participants will submit quality measure data for the time period noted in the measure specifications. We stated if a measure is calculated on an annual CY basis, participants would not be required to adjust the reporting period to reflect the model time period. We stated that alignment to the measure specifications used in MIPS would likely reduce measure reporting burden for RO participants. RO participants would submit measure data based on the individual measure specifications set forth in sections III.C.8.b(1) through (4), unless CMS were to specify different individual measure specifications. RO Model measure submissions would only satisfy the RO Model requirements. Measures submitted to any other CMS program would need to continue to be made in accordance with that program's requirements unless specifically noted. A schedule for data submission would be posted on the RO Model website: https://innovation.cms.gov/initiatives/radiation-oncology-model/.

We proposed to determine that Professional participants and Dual participants successfully collected and submitted quality measure data if the data are accepted in the RO Model secure data portal. Failure to submit quality measure data within the previously discussed requirements would impact the RO participant's AQS, as discussed in section III.C.8.f of the proposed rule (84 FR 34519) and this final rule.

We proposed that the CAHPS® Cancer Care Survey for Radiation Therapy would be administered by a CMS contractor according to the guidelines set forth in the survey administration guide or otherwise specified by CMS. Prior to the first administration of the survey, we would perform education and outreach so RO participants will have the opportunity to become more familiar with the CAHPS® Cancer Care Survey process and ask any questions.

The following is a summary of public comments received and our response:

Comment: Several commenters recommended that CMS pay for RO participants to establish quality data reporting because of the potential for high costs required to collect and report Model quality metrics. A couple of commenters drew comparison to OCM, which the commenters stated included additional payment for collecting quality data. A commenter suggested that CMS could assist with reporting cost by adding a patient management fee.

Response: We thank the commenters for their suggestions. We note that the OCM does not include a payment to participants to collect quality data. To the extent that commenters may be referring to the Monthly Enhanced Oncology Services (MEOS) payment, we note that this payment is for the provision of Enhanced Services, as defined in the OCM Participation Agreement, to OCM Beneficiaries. We would also clarify that CMS will be paying for the administration of the CAHPS® Cancer Care Survey and RO participants will not have additional costs for the survey. We do not believe additional payments or an additional patient management fee are warranted at this time.

Comment: A commenter supported CMS' proposal to align the RO Model with other quality reporting programs and require at least 20 applicable cases according to each measure's specification for scoring purposes.

Response: We thank the commenter for their support.

Comment: A few commenters requested clarity on how participants will report aggregated quality measure data and whether the RO Model secure data portal will function similarly to the MIPS portal.

Response: 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. The process for submitting data through the RO Model secure data portal will be provided via technical support and education efforts that take place following the final rule publication. We intend to announce the availability of these support and education opportunities on the RO Model website.

Comment: A commenter requested more information on the quality measure and clinical data elements template, and noted that use of a template will increase staff time, practice overhead costs, and because these data elements may not be discrete fields within the EHR, someone may have to transcribe information out of the medical record for submission in either electronic form, or via a template.

Response: We will provide education and outreach to help RO participants understand the quality measures and clinical data elements collection and submission systems, including the template. As discussed in section III.C.8.b, based on stakeholder feedback, we are finalizing the collection of quality measures data beginning in PY1 (January 1, 2021) with the first submission due in March 2022, so RO participants will have additional time to become familiar with the template. As discussed in section III.C.8.e, based on stakeholder feedback, we are finalizing the collection of clinical data elements beginning in PY1 (January 1, 2021) with the first submission due in July 2021. We also note that we plan to provide the final list of clinical data elements on the RO Model website prior to the start of PY1, and provide similar education and outreach. We

are committed to working with EHR vendors to facilitate data collection for quality measures and clinical data element.

Comment: A couple of commenters urged CMS to consider allowing practices to use relevant third parties for data collection and reporting, as it does in other quality reporting programs.

Response: We intend to provide additional information about the submission of data, prior to the PY1 data reporting start date on the RO Model website. This information will include whether we find it would be appropriate to permit third-party data submission.

Comment: Many commenters opposed the inclusion of all patients in the measure collection, asserting the Model's quality measure requirements should only include Medicare patients. Several of these commenters noted that including all patients is outside the scope of the Model. Others stated including non-Medicare patients will create additional labor and require additional electronic health record (EHR) updates and, if those updates are not successful, that RO participant will have to provide manual collection and reporting, which they argue is unduly burdensome, especially on mid-size and smaller practices. A couple of commenters expressed concern that reporting data on non-Medicare beneficiaries may result in a violation of privacy.

Response: We are requiring RO participants to report aggregated numerator and denominator data, not individual patient-level data, for all patients as defined in the measure specifications in the manner consistent with the quality measure specifications, and not just Medicare patients. It is important that the Model collect measures in the manner specified to ensure submission consistency, and reliability of the data to comport with how the measure is currently specified and implemented in MIPS and other quality initiatives. In addition, there is inherent value to including all patients, regardless of payer type, when assessing quality. We

believe a policy of submitting aggregated quality measure information in a manner consistent with the measure specifications is not a violation of patient privacy because it does not include the sharing of personally identifiable information. Further, this is consistent with data submission policy in MIPS. Finally, aggregated data can provide valuable population-level perspective on the quality of care delivery.

Comment: A few commenters opposed the proposal to use a separate portal and a new website for data collection and quality measure reporting for measures already submitted to CMS, stating this would create additional operational burden for providers and suppliers. Other commenters expressed concern about the burden, and the potentially significant programming changes required, if RO Model measures were separated from MIPS, and if hospitals were not developing similar systems. Commenters encouraged CMS to simplify quality reporting by using the current quality reporting mechanisms instead of creating yet another process for reporting quality data. A commenter requested clarification on whether quality measure reporting could come from clinical pathways and/or Clinical Decision Support (CDS) systems.

Response: We appreciate the concern regarding establishment of a new infrastructure specific to this model. However, because the RO Model reaches across three different care settings, operational considerations necessitate the creation of one portal that all entities can use. The process for submitting data through the RO Model secure data portal will be provided via technical support and education efforts that take place following the final rule publication, so all RO participants have time to become familiar with the infrastructure and processes prior to required reporting. In addition, we note that the RO Model secure data portal will serve not only as a data submission system, but also as the portal for RO participants to access claims data that they can request through the Model.

Comment: Several commenters opposed the Model's reporting requirements and suggested they be reduced or not finalized because they believe the requirements constitute significant new administrative and financial burdens on providers and suppliers, especially on small providers and suppliers. A couple of commenters urged CMS to carefully consider the burden associated with quality and clinical data collection requirements, and ensure that only the most meaningful and least burdensome information is collected. Commenters noted that RO participants will be spending a significant amount of time and resources shifting their business models to the new alternative payment model.

Response: As part of the Meaningful Measures Initiative, we are committed to quality priorities that align CMS' strategic goals and individual measures and initiatives that demonstrate that quality for our beneficiaries is being achieved. The quality measures chosen for the RO Model address concrete quality topics, which reflect core issues that are important to ensuring high quality care and better patient outcomes during RT treatment. We acknowledge the burden that reporting places on RO participants, and we seek to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience in alignment with the *Patients Over Paperwork Initiative.*[71] We believe the quality measures selected for inclusion in the RO Model balance both the importance of quality measurement and the concerns regarding burden as we strive to select the most parsimonious measure set to ensure quality and support RO Model compliance with other concurrent programs, including MIPs and QPP. Finally, for those practices that have concerns about burden in relation to their volume of radiotherapy patients, we note that the Model includes a low volume opt-out option, described in detail in section III.C.3.c.

[71] https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html

Comment: A commenter was supportive of the proposal to not require that measures be submitted via CEHRT.

Response: We appreciate the commenter's support.

Comment: A few commenters recommended that all of the Model's quality measures be scoped as eCQMs so RO participants can use the certified EHR in which they have already invested, instead of utilizing a third-party registry or reverting to claims-based measurement. A commenter strongly rejected any non-eCQMs because of its belief that registry-based measures will significantly increase the burden associated with quality reporting by forcing providers and suppliers to utilize a third-party registry at costs over and above previous investments in EHRs.

Response: We are using the registry specifications for the measures in the RO Model because they are the most widely used method of data submission, which will enable more participants to submit data with the least impact on workflow. Additionally, we believe the data from registry measures are both highly reliable and valid. Further, we agree that eCQMs and CEHRT are valuable tools to help provide patient-centric care and we plan to provide structured data reporting standards so that existing EHRs can be adjusted if necessary in anticipation of the RO Model. Some EHRs may support data extraction, reducing any additional reporting burden on RO participants, which may increase the quality and volume of reporting. We also believe that it is important that RO participants have the option to extract the necessary data elements manually to ensure all RO participants are able to submit the required data.

Comment: A commenter opposed submitting registry-based measures, noting it would stymie CMS' move toward interoperability and electronic end-to-end reporting. The commenter argued that it would require new workflows that will need to be developed in order to accurately

attribute patients to the Model from multiple outpatient sites that are not historically attached to our electronic data base.

Response: While we remain committed to moving towards increased interoperability and electronic reporting, we are using the registry specifications for measures in the RO Model because registry data is the most widely used type of data submission tool, which will enable more RO participants to submit data with least impact on workflow. We note that while the data collected via registries are considered reliable and valid, we are not requiring that RO participants utilize a registry data system to satisfy data submission to CMS. The Model will implement this measure based on the specifications used in MIPS, that is, registry data. Additionally, we are not asking RO participants to attribute patients; participants will report aggregate performance, consistent with the measure specifications.

Comment: A few commenters supported the use of EHRs but expressed concern with the feasibility of EHR development in accordance with the Model start date. These commenters asserted their belief that it is unlikely that many, if any, EHR vendors will have adequate time to make meaningful changes to the EHR to reduce the reporting burden on RO participants. Commenters further stated EHR vendors must assess their priorities and planned projects to accommodate the timing of CMS models, and noted this requirement would impact planning because participants must financially plan for the likely significant charges to upgrade current systems, or to plan for new systems, putting them at significant financial risk. These commenters therefore requested CMS delay implementation of this requirement until vendors have enough time to implement and upgrade current systems.

Response: We appreciate commenter's concerns regarding the feasibility of EHR development in accordance with the Model start date. Continued EHR development is an

important part of our ongoing effort to support electronic health record data. The Model performance period begins on January 1, 2021, which means the first submission of clinical data elements will not occur until July of 2021 (this submission timeframe is different than that for submitting quality measures, which occurs in March following a PY). This will allow RO participants additional time to work with EHR vendors to develop appropriate fields. We will also provide which clinical data elements are included in the RO Model on the RO Model website and will provide those reporting standards to EHR vendors and the radiation oncology specialty societies prior to their inclusion in the Model. Our goal is to structure data reporting standards so that existing EHRs could be adjusted, if necessary, in anticipation of the measure and clinical date element requirements. Additionally, we note that RO participants will continue to have the option to extract the necessary data elements manually.

After consideration of the commenters' feedback, we are finalizing our proposals for the data collection processes for the four quality measures described in section III.C.8.b(1) through (4) of this final rule beginning in PY1 with the first annual submission in March 2022 and continuing thereafter. The process for submitting data through the RO Model secure data portal will be provided via technical support and education efforts that take place following the final rule publication. We intend to announce the availability of these support and education opportunities on the RO Model website.

d. Maintenance of Technical Specifications for Quality Measures

As part of its regular maintenance process for NQF-endorsed performance measures, NQF requires measure stewards to submit annual measure maintenance updates and undergo Maintenance of Endorsement review every three years. In the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and

relevance of the measure and will confirm existing or minor specification changes with NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and reviews measures for continued endorsement in a specific three-year cycle. We noted in the proposed rule that NQF's annual and/or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures. Additionally, as described in the proposed rule, the Model includes measures that are not NQF-endorsed, but we anticipate they would similarly require non-substantive technical updates to remain current.

We received no comments on this proposal and therefore are finalizing this policy as proposed.

e. Clinical Data Collection

We proposed to collect clinical information on certain RO beneficiaries included in the Model from Professional participants and Dual participants that furnish the PC of an episode for use in the RO Model's pay-for-reporting approach and for monitoring and compliance, which we discussed more fully in sections III.C.8.f(1) and III.C.14 of the proposed rule (84 FR 34519; 84 FR 34531) and this final rule. As proposed (84 FR 34518), on a pay-for-reporting basis, we would require Professional participants and Dual participants to report basic clinical information not available in claims or captured in the quality measures, such as cancer stage, disease involvement, treatment intent, and specific treatment plan information, on RO beneficiaries treated for five types of cancer under the Model: (1) prostate; (2) breast; (3) lung; (4) bone metastases; and (5) brain metastases, which we proposed to require as part of § 512.275. We would determine the specific data elements and reporting standards prior to PY1 of the Model and would communicate them on the Model website. In addition, as we described in the

proposed rule, we proposed to provide education, outreach, and technical assistance in advance of this reporting requirement.

We believe this information is necessary to achieve the Model's goals of eliminating unnecessary or low-value care. We have also heard from many stakeholders that they believe incorporating clinical data is important for developing accurate episode prices and understanding the details of care furnished during the episode that are not available in administrative data sources. As proposed, we would use these data to support clinical monitoring and evaluation of the RO Model. These data may also be used to inform future refinements to the Model. We also proposed that we may also use it to begin developing and testing new radiation oncology-specific quality measures during the Model.

To facilitate data collection, we proposed to share the clinical data elements and reporting standards with EHR vendors and the radiation oncology specialty societies prior to the start of the Model. Our goal is to structure data reporting standards so that existing EHRs could be adjusted in anticipation of this Model. Such changes could allow for seamless data extraction, reduce the additional reporting burden on providers and suppliers, and may increase the quality of reported data. Providers and suppliers may also opt to extract the necessary data elements manually. All Professional participants and Dual participants with RO beneficiaries treated for the five cancer types, as previously listed, would be required to report clinical data through the RO Model secure data portal. We would create a template for RO participants to complete with the specified clinical data elements, provide a secure RO Model secure data portal for data submission, and provide education and outreach on how to use these mechanisms for data collection and where to submit the data prior to the first data submission period.

We also proposed to establish reporting standards. All Professional and Dual participants would be required to submit clinical data twice a year, in July and January[72], each PY for RO beneficiaries with the applicable cancer types that completed their 90-day RO episode within the previous 6 months. This would be in addition to the submission of quality measure data as described in section III.C.8.c of the proposed rule (84 FR 34519).

We solicited specific comment and feedback on the five cancer types for which we proposed to collect clinical data, which data elements should be captured for the five cancer types, and potential barriers to collecting data of this type. The following is a summary of the public comments received and our response.

Comment: A couple of commenters supported the collection of clinical data elements because it would require Professional participants and Dual participants to report basic clinical information not available in claims or captured in the proposed quality measures, which the commenters believe will encourage better care. Another commenter supported tracking data on clinical care because it improves patients care.

Response: We thank commenters for supporting our proposal to collect information on clinical data elements.

Comment: A few commenters responded to our request for comments on clinical data elements reporting. A commenter recommended that CMS only request clinical data elements that guide treatment decisions. Another commenter recommended including only the most clinically relevant information. Some commenters provided suggestions for the following clinical data elements: clinical treatment plan; therapeutic status; elements that would align with

[72] We are clarifying that the first submission for PY1 would be made in July of PY1 and the second submission for clinical data for PY1 would be made in January of PY2. The submission schedule for the following PYs would be similar and the final submission for PY5 would occur in January 2026.

the Surveillance, Epidemiology, and End Results (SEER) cancer database; the results of Prostate-Specific Antigen (PSA) tests; information related to the American Joint Committee on Cancer (AJCC) staging system and the histology of the malignancy for lung, breast and prostate; "D'Amico" or the National Comprehensive Cancer Network (NCCN) risk grouping; site of the lesion information; existence, and number, of metastases; patient performance status submitted (Karnofsky Performance Status or Eastern Cooperative Oncology Group (ECOG) status); and information relating to whether medical physicists have reviewed the chart. Other commenters recommended collecting data on RO participants' use of standardized clinical pathways and/or CDS and whether the treatment is curative, palliative, or benign. A commenter recommended including the reporting of site of treatment, dose specification (for example, "95 percent of specified dose to 95 percent of the planning treatment volume") and number of fractions as clinical data elements. Other commenters suggested that clinical and staging data elements should be collected for complete RO episodes and original primary cancer type for brain and bone metastases.

Response: We thank commenters for their suggestions. We will review each suggestion carefully as we consider which clinical data elements to include as part of the RO Model.

Comment: A few commenters opposed all clinical data reporting requirements. Some commenters opposed the clinical data elements because of the perceived financial burden, noting that without structured EHR fields to report, participants have increased burden to report the measures manually or through a registry, without significant benefit to patients. One of these commenters also expressed concern with the lack of information about how CMS would use this data. Another commenter argued that CMS should only require clinical data submissions once it commits to incorporating those data into payment rates' risk adjustments.

Other commenters urged CMS to carefully weigh the necessary and appropriate uses for the data against the significant time, effort, and administrative burden required in order to report those data. Another commenter opposed clinical data elements reporting because it believes the reporting would be uncompensated and reduce productivity. Another commenter strongly opposed the collection of clinical data elements because the commenter believes much of the clinical data element information that CMS is considering is already available in Surveillance, Epidemiology, and End Results (SEER) Incidence Data.

Response: We believe that collecting clinical data elements for use in the RO Model is necessary to achieve the Model's goals of supporting evidence-based care. We appreciate the recommendation that the Model align with the SEER Incidence Database, however we believe that the geographic areas captured by SEER do not align with the RO Model CBSAs. We have heard from many stakeholders that they believe incorporating clinical data is important for developing accurate episode prices and understanding the details of care furnished during an RO episode that are not available in administrative data sources, specifically claims. We will use these data to support clinical monitoring and evaluation of the RO Model. These data may also be used to inform future refinements to the Model. We may also use it to begin developing and testing new radiation oncology-specific quality measures during the Model. In keeping with our goal of reducing burden, we intend to align with other federal programs to the greatest extent practicable while continuing to collect meaningful and parsimonious data sets.

Comment: A few commenters expressed concern about requiring the reporting of clinical data elements for patients not participating in Medicare. One was concerned that such reporting could impose significant administrative burdens on RO participants in order to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA).

Response: We would like to clarify that while quality measures used in the RO Model will include non-Medicare beneficiary data collected in the aggregate, we intend only to require clinical elements data reporting for Medicare beneficiaries in the Model (RO beneficiaries).

Comment: Several commenters recommended delaying or phasing-in the implementation of the clinical data requirement until the data can be submitted by all RO participants in a useful and meaningful way. A few commenters urged CMS to delay the quality reporting requirements for the Model for at least six months, while another requested 18 months, asserting the lack of granularity in the proposed rule will prevent vendors from updating reporting specifications. A couple of commenters recommended delaying clinical data element collection until PY2.

Response: We thank the commenters for their suggestions on either delaying or phasing in the implementation of the clinical data elements requirement. As discussed in section III.C.1 we are finalizing the Model performance period to begin January 1, 2021, and publishing the final rule several months in advance of this start date, in order to provide RO participants with sufficient time to prepare for their inclusion in the Model. During this time, we plan to provide the clinical data elements on the RO Model website and provide education and outreach support to encourage the efficient collection and submission of this data. We believe finalizing the Model performance period to begin on January 1, 2021, will allow RO participants time to develop best practices to facilitate their data collection, and work with EHR vendors to seek additional EHR support as needed.

Comment: Several commenters urged CMS to consider the HL7® FHIR®-based mCODE™ (Minimal Common Oncology Data Elements) to collect and assemble a core set of structured data elements for oncology EHRs. Commenters recommended mCODE™ based on their belief that the use of mCODE™ would structure data reporting standards so that existing

EHRs could be adjusted in anticipation of this Model, which would allow better data extraction and reduce the additional reporting burden on providers and suppliers, and may increase the quality of reporting and their belief that clinical data elements considered by mCODE™ would address CMS' goal of collecting meaningful clinical data elements information. Another commenter recommended HL7® more generally because of its belief that it would reduce duplicative entries and reduce errors.

Response: Participants will be required to report clinical data through the RO Model secure data portal at the time and in a manner specified by CMS. While we are aware of HL7® mCODE™, we are not confident that it will be immediately accessible to the full breadth of RO participants due to technical requirements of HL7® and it may not be feasible to test and implement by the beginning of the Model performance period; therefore, we believe that our RO Model secure data portal will provide the easiest, most accessible access for most RO participants. We continue to monitor developments in EHR and interoperability. We also continue to engage with health care providers and EHR vendors to align the information about the most meaningful clinical data elements to include in the RO Model, and ensure that the greatest number of RO participants can implement the data collection process with the least amount of burden.

Comment: A commenter strongly urged CMS to encourage implementation of bidirectional data flow between the applicable clinical pathways and/or CDS systems, and the EHR, which it believes would reduce duplicative data entry and time-intensive information searches by the physician when a data element is already present in the EHR.

Response: We thank the commenter for their suggestion and support the improvement of reporting pathways. We encourage RO participants to explore efficiencies within their EHR

systems and other data platforms; however, we do not wish to prescribe EHR requirements to participants and vendors.

Comment: A couple of commenters encouraged CMS to partner with the Office of the National Coordinator for Health Information Technology (ONC) to require that certified EHRs store and transmit a minimum set of oncology data elements, which would allow their use under current and future Innovation Center models. Another commenter requested clarification regarding the applicability of the ONC 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule and expressed concern that while vendors have to comply with federal regulations, they could pass these costs to physicians.[73]

Response: We believe advancing interoperability is an important step in healthcare quality improvement and that putting patients at the center of their health care and ensuring they have access to their health information is highly desirable. We are committed to working with the ONC to address interoperability issues and achieve complete access to health information for patients in the health care system. We will continue to work with ONC and other federal partners toward interoperability and the secure and timely exchange of health information with the clear objectives to improve patient access and care, alleviate health care provider burden, and reduce overall health care costs while considering provider and supplier costs. We will also assess opportunities to coordinate on a minimum set of oncology data elements. Finally, we appreciate and understand the concern that EHR vendors may pass some of the costs of regulatory compliance on to the physicians; however, we believe that is it possible that most of

[73] https://www.federalregister.gov/documents/2019/04/23/2019-08178/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

the information requested will already be included as part of the EHR and will provide valuable information to RT providers and RT suppliers.

Comment: A few commenters recommended that CMS should narrow the focus and use of clinical data required for reporting and ensure that all required data elements are consistently documented in structured and discrete fields, and further asserted CMS should not require the submission of any data elements that are not captured in structured fields by most major EHR vendors. These commenters urged CMS to work with EHR vendors prior to the Model start date to establish structured fields for all mandatory reporting requirements.

Response: As we review which clinical data elements are appropriate for inclusion in the RO Model, we will consider which clinical data elements are already documented and available in the structured and discrete fields of the EHR; however, availability in the EHR will not be the sole consideration in determining which clinical data elements to include because we believe that the highest priority with respect to any clinical data elements collected is that they inform our understanding of RT services, and this priority should not be limited to clinical data elements that are already collected. CMS will notify participants via the RO Model website prior to the start of PY1 about which clinical data elements will be included in the Model. RO participants will be required to report clinical data through the RO Model secure data portal.

Comment: A couple of commenters recommended that CMS establish reporting standards and timelines that provide enough time for EHR vendors to implement corresponding report updates that enable discrete capture, and for RO participants to collect complete and accurate clinical data.

Response: We plan to share the proposed clinical data elements and procedural instructions for reporting information at a time and manner specified by CMS with EHR vendors

and the radiation oncology specialty societies prior to the start of PY1. Our goal is to structure data reporting so that existing EHRs could be adjusted in anticipation of the RO Model. Such changes could allow for seamless data extraction and reduce the additional reporting burden on RO participants, and may increase the quality of reporting.

Comment: A commenter appreciated the decision that CMS share the planned elements, and procedures for reporting them, with EHR vendors and radiation oncology specialty societies, and requested that CMS also share this information with oncology clinical pathways developers. This commenter encouraged CMS to consider taking clinical pathway extracts of these data to satisfy requisite reporting.

Response: We thank the commenter for the suggestion that CMS consider allowing the submission of clinical pathway extracts of data elements to satisfy this aspect of the reporting requirements. In the process of determining the clinical data elements, CMS will conduct outreach with multiple stakeholders, including oncology clinical pathways developers. However, we do not believe that only using the clinical pathways is a feasible way to collect clinical data elements information across all RO participants at this time. In the future, we will consider ways to integrate clinical pathways into the clinical data element collection process.

After considering public comments, we are finalizing at § 512.275(c) the proposal to collect basic clinical information not available in claims or captured in the quality measures, describing cancer stage, disease characteristics, treatment intent, and specific treatment plan information, on RO beneficiaries treated for five types of cancer under the Model: (1) prostate; (2) breast; (3) lung; (4) bone metastases; and (5) brain metastases. We will determine the specific data elements prior to PY1 of the Model and will communicate them on the RO Model website, with data collection starting in PY1.

We are also clarifying that clinical data will be submitted to CMS consistent with the instructions for reporting such as at the time and manner specified by CMS. We have modified the text of the regulation at § 512.275(c) to clarify that paragraph (c) applies to the reporting of quality measures and clinical data elements and that such reporting is in addition to the reporting described in other sections of this rule. We have also modified the regulatory text at § 512.275(c) such that the list of clinical data element categories we proposed in the proposed rule (that is, cancer stage, disease characteristics, treatment intent, and specific treatment plan information on beneficiaries treated for specific cancer types) is an exhaustive list.

Table 11 includes the four RO Model quality measures and CAHPS® Cancer Care Survey, the level at which measures will be reported, and the measures' status as pay-for-reporting or pay-for-performance, as described in section III.C.8.b of this final rule. The table also includes the RO Model clinical data elements collection, and years, also documented in section III.C.8.e of this final rule.

**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 |

f. Connect Performance on Quality Measures to Payment

(1) Calculation for the Aggregate Quality Score

We proposed that the AQS would be based on each Professional participants and Dual participant's: (1) performance on the set of evidenced-based quality measures in section III.C.8.b of the proposed rule (84 FR 34515 through 34517) and this final rule compared to those measures' quality performance benchmarks; (2) reporting of data for the pay-for-reporting measures (those without established performance benchmarks) in section III.C.8.b(4) of the proposed rule (84 FR 34515 through 34517) and this final rule; and (3) reporting of clinical data elements on applicable RO beneficiaries in section III.C.8.e of the proposed rule (84 FR 34518) and this final rule.

A measure's quality performance benchmark is the performance rate a Professional participant or Dual participant must achieve to earn quality points for each measure in section

III.C.8.b.[74] We believe a Professional participant's or Dual participant's performance on these quality measures, as well as successful reporting of pay-for-reporting measures and clinical data elements, would appropriately assess the quality of care provided by the Professional participant or Dual participant.

Given the importance of clinical data for monitoring and evaluation of the RO Model, and the potential to use the data for model refinements or quality measure development, we proposed to weight 50 percent of the AQS on the successful reporting of required clinical data and the other 50 percent of the AQS on quality measure reporting and, where applicable, performance on those measures. Mathematically, this weighting would be expressed as follows:

**Aggregate Quality Score = 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)**

We proposed that quality measures would be scored as pay-for-performance or pay-for-reporting, depending on whether established benchmarks exist, as stated in section III.C.8 of this rule. To score measures as pay-for-performance, each Professional participant's and Dual participant's performance rates on each measure would be compared against applicable MIPS program benchmarks, where such benchmarks are available for the measures. We proposed to select the measures as pay-for-performance for PY1 from the list of MIPS quality measures: (1) Advance Care Plan; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; (3) Oncology: Medical and Radiation - Plan of Care for Pain. The MIPS Program awards up to ten points (including partial points) to participants for their performance rates on

[74] Benchmarks will be based on existing MIPS benchmarks, or other national benchmark where available. For measures without existing benchmarks, we plan to develop our own benchmarks.

each measure, and we would score RO participants' quality measure performance similarly using MIPS benchmarks.[75] For example, when a Professional or Dual participant's measured performance reaches the performance level specified for three points, we will award the participant three points. If applicable MIPS benchmarks are not available, we would use other appropriate national benchmarks for the measure where appropriate. If a national benchmark is not available, we would calculate Model-specific benchmarks from the previous year's historical performance data. If historical performance data are not available, then we would score the measure as pay-for-reporting and will provide credit to the Professional participant or Dual participant for reporting the required data for the measure. We would specify quality measure data reporting requirements on the RO Model website. Once benchmarks are established for the pay-for-reporting measures, we would seek to use the benchmarks to score the measures as pay-for-performance in subsequent years.

As stated earlier in this rule, measures may also be scored as pay-for-reporting. Professional participants and Dual participants that report a pay-for-reporting measure in the form, time, and manner specified in the measure specification would receive ten points for the measure. Professional participants and Dual participants that do not submit the measure in the form, time, and manner specified would receive zero points. As discussed in section III.C.8.b(4) of the proposed rule (84 FR 34517) and this final rule, the Treatment Summary Communication measure will be the only pay-for-reporting measure in PY1.

The total points awarded for each measure included in the AQS would also depend on the measure's weight. We would weight all four quality measures (those deemed pay-for-

[75] The benchmarks are published annually at this CMS site: https://qpp.cms.gov/about/resource-library

performance as well as pay-for-reporting) equally and aggregate them as half of the AQS. To accomplish that aggregation as half of the AQS, we would award up to ten points for each measure, then recalibrate Professional participants' or Dual participants' measure scores to a denominator of 50 points. CAHPS® Cancer Care Survey for Radiation Therapy results discussed in section III.C.8.b(5) of this final rule would be added into the AQS beginning in PY3, and we would propose the specific weights of the selected measures from the CAHPS® survey in future rulemaking. We would also specify weights for new measures if and when the Model adopts additional measures in the future.

In cases where Professional participants and Dual participants do not have sufficient cases for a given measure – for example, if a measure requires 20 cases during the applicable period for its calculation to be sufficiently reliable for performance scoring purposes – that measure would be excluded from the participant's AQS denominator calculation and the denominator would be recalibrated accordingly to reach a denominator of 50 points. This recalibration is intended to ensure that Professional participants and Dual participants do not receive any benefit or penalty for having insufficient cases for a given measure.

For example, a Professional or Dual participant might have sufficient cases to report numerical data on just three of five RO Model measures, meaning that it has a total of 30 possible points for the quality measures component of its AQS. If the Professional participant or Dual participant received scores on those measures of nine points, four points, and seven points, it will have scored 20 out of 30 possible points on the quality measures component. That score is equivalent to 33.33 points after recalibrating the denominator to 50 points ((20/30) * 50 = 33.33). In instances where a Professional participant or Dual participant fails to report quality reporting data for a measure in the time, form and manner required by the RO Model as described in

section III.C.8.c will not meet the reporting requirements and will receive zero out of ten for that measure in the quality portion of the AQS, as the example in Table 13 represents. If the same Professional participant or Dual participant scored the same 20 points on three measures, but failed to report the necessary data on a fourth measure, its AQS denominator would be set at 40 possible points. Its AQS would then be equivalent to 25 points after recalibrating the denominator to 50 points ((20/40) * 50 = 25).

In the proposed rule, we stated that our assessment of whether the Professional or Dual participant has successfully reported clinical data would be based on whether the participant has submitted the data in the time period identified and has furnished the clinical data elements to us as requested, as discussed in section III.C.8.c of the proposed rule (84 FR 34517 through 34518) and this final rule. We stated that Professional participants and Dual participants would either be considered "successful" reporters and receive full credit for meeting our requirements, or "not successful" reporters and not receive credit. We stated that we would define successful reporting as the submission of clinical data for 95 percent of RO beneficiaries with any of the five diagnoses listed in section III.C.8.e of the proposed rule (84 FR 34518 through 34519) and this final rule. We also stated that if the Professional participant or Dual participant does not successfully report sufficient clinical data to meet the 95 percent threshold, it would receive 0 out of 50 points for the clinical data elements component of the AQS. As previously discussed, we are finalizing our proposed clinical data elements reporting requirements, and we plan to post these requirements via the RO Model website prior to PY1.

To calculate the AQS, we proposed to sum each Professional or Dual participant's points awarded for clinical data reporting with its aggregated points awarded for quality measures to reach a value that would range between 0 and 100 points. As discussed earlier in this rule, we

would recalibrate the points we award for measures to a denominator of 50 points. We would then divide the AQS by 100 points to express it as a percentage.

To illustrate the calculation of the AQS score, two examples are included in this final rule. Table 12 details the AQS calculation for a Professional participant or Dual participant that did not meet the minimum case requirements for one of the pay-for-performance measures.

**TABLE 12 EXAMPLE: AQS CALCULATION DETAILS: DID NOT MEET MINIMUM CASE REQUIREMENTS FOR PAY-FOR-PERFORMANCE MEASURE**

**ALL NUMBERS ARE ILLUSTRATIVE ONLY**

| | 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 *Did not meet 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 (h) | | 88.3 | 100 | h = f+g |
| **AQS (i)** | | 88.3% | | i = participant score of h/maximum points of h |

Table 13 details the AQS calculation for a Professional or Dual participant that did not meet the reporting requirements for the clinical data elements or the pay-for-reporting measure.

**TABLE 13 EXAMPLE: AQS CALCULATION DETAILS: DID NOT MEET REPORTING REQUIREMENTS FOR PAY-FOR-REPORTING MEASURE**

**ALL NUMBERS ARE ILLUSTRATIVE ONLY**

| | Notes | Participant Score | Maximum Points | Formula |
|---|---|---|---|---|
| **Quality Measures** | | | | |
| Measure 1 (a) | Pay-for-performance | 4.5 | 10 | |
| Measure 2 (b) | Pay-for-performance | 5 | 10 | |
| Measure 3 (c) | Pay-for-performance | 1 | 10 | |
| Measure 4(d) | Pay-for-reporting *Did not report data as required* | 0 | 10 | |
| Subtotal (e) | | 10.5 | 40 | e = a+b+c+d |
| Weighted to 50% (f) | | 13.1 | 50 | f = (participant score of e* 50) / maximum points of e |
| **Clinical Data Elements (g)** | <95% of applicable RO beneficiaries | 0 | 50 | |
| Total (h) | | 13.1 | 100 | h = f+g |
| **AQS (i)** | | 13.1% | | i = participant score of h/maximum points of h |

We believe that this method has the benefits of simplicity, normalization of differences in reported measures between RO participants, and appropriate incorporation of clinical data reporting.

We solicited public comment on the calculation for the AQS methodology. The following is a summary of the public comments received on this proposal and our response:

Comment: Several commenters opposed the 95 percent threshold for successful clinical data element reporting based on their belief this threshold would not allow for the various scenarios where obtaining clinical data, especially from the time of initial diagnosis, is not feasible, would require significant time and resources to obtain, or be overly burdensome. A

couple of commenters recommended that CMS begin with a 70 percent reporting requirement and reassess whether that level can be increased in future years. A few commenters recommended a score of 75 percent rather than 95 percent. A commenter recommended a score of 80 percent to receive full credit for reporting clinical data elements in the AQS. A commenter recommended that we adopt a partial points policy for clinical data elements reporting so that participants are not confronted with a pass/fail requirement in the AQS.

Response: We thank commenters for this feedback. We remain concerned that adopting a lower threshold than the proposed 95 percent for successful clinical data elements reporting would result in RO participants reporting data that is less useful for future quality measure development.

Comment: A commenter urged CMS to adopt a three- to six-month reporting window for clinical data elements, which would allow RO participants to abstract and validate data for reporting to CMS following completion of an RO episode. The commenter suggested that the time period for submission should be contingent on volume and practice resources and suggested that RO participants should be given 90 days for 75 percent of submissions, and 180 days for 85 percent submissions.

Response: We believe 95 percent is the appropriate threshold for clinical data element reporting because of the value in obtaining this information, which we believe will allow us to ensure that the data collected are as complete as practicable and provide an accurate reflection of the clinical profile of the RO participant's patient population. We believe that staggering the requirements will increase the operational complexity of the Model and make it harder for participants to comply with the requirements, whereas maintaining the 95 percent requirement as

a consistent and simple standard of reporting submitted twice a year in July and in January ensures that RO participants understand what is expected of them well ahead of time.

Comment: A commenter encouraged CMS to maintain the link between quality measures and prospective payments, which would allow the Model to qualify as an Advanced APM because then the Advanced APM bonus would be available to participating radiation oncologists if they are designated as Qualified APM Participants.

Response: We thank the commenter and agree regarding the benefits associated with maintaining the link between quality measures and prospective payments. Our intent is to ensure that the Model will qualify as an Advanced APM starting in PY1.

Comment: A commenter argued that the Model's relative scoring methodology, where RO participants are assessed against each other rather than against absolute benchmarks, means that RO participants can be penalized significantly on measures even when they perform at high levels, as measured by percentages. The commenter noted that this result means little differentiation among health care providers' performance but significant differences in payments and suggested that CMS instead consider adopting an absolute scoring method. The commenter also argued that scoring RO participants against each other discourages sharing lessons learned or best practices, which the commenter believed is not an optimal quality improvement strategy.

Response: We understand the commenter's concerns but disagree with the commenter's assessment of a relative scoring method rather than absolute performance scoring. The principal advantage of a relative performance scoring system is that it bases performance goals on real-world performance rather than on goals that could otherwise be perceived as arbitrary. While MIPS benchmarks are adopted in advance, they are based on historical performance data and thus allow us to assess practices based on real-world performance. We expect RO participants to

strive to deliver high quality evidence-based care for all patients consistent with established and emerging best practices. However, we will consider the commenter's concern as we adopt benchmarks in future years for the Treatment Summary Communication and CAHPS® Cancer Care survey measures.

Comment: A few commenters noted that the proposed rule did not specify which benchmarks or data collection types CMS would use for RO Model measures. A commenter recommended CMS adopt MIPS benchmarks and data collections to ensure an easy transition and maintain alignment between quality reporting programs. A commenter suggested that an RO participant's performance could be based on regional or national comparisons, while another recommended using performance-level quintiles. A commenter recommended using the MIPS benchmarks to align the Model's quality reporting with other CMS programs.

Response: We would like to clarify that, as stated in the proposed rule (footnote 57 at 84 FR 34519), we would base benchmarks on MIPS benchmarks where available, and that we would develop benchmarks for those measures that do not have MIPS benchmarks. We agree with the commenter that adopting MIPS benchmarks where available will align the Model and MIPS. We would also like to clarify that we proposed to adopt the registry specifications for the Model's measures – see, for example, 84 FR 34516 ("For the RO Model, we propose to use the registry specifications for [the Plan of Care for Pain] measure") which include data collection procedures.

Comment: Some commenters noted that some of the 2019 MIPS benchmarks are topped-out for some of the Model's measures and expressed concern that RO participants will therefore not receive the full 10 points for submitting data on those measures. A commenter argued that CMS should provide as much flexibility as possible to RO participants earning points so that

they can earn back their quality withholds. Another commenter recommended that scoring should be stratified by performance-level quintiles.

Response: We thank the commenters for this feedback. As we noted in section III.C.8.b, there can be value to retaining topped-out measures. We further note that in the absence of other clinically appropriate measures, retaining topped-out measures may give us the best possible assessment of clinical care quality available. We believe we have adopted an effective and parsimonious measure set aimed precisely at the commenter's goal of providing as much flexibility as possible to RO participants to earn points. We are finalizing the list of measures and scoring methodology as proposed and encourage stakeholders to continue new measure development efforts.

Comment: Some commenters recommended that CMS calculate the AQS using pay-for-reporting on the four quality measures for at least the Model's first year – with a commenter extending that recommendation to the second year – before transitioning to a pay-for-performance program. A commenter asserted this delay would permit participants to become familiar with the Model's quality measures and implement workflow changes. Another commenter argued that such a delay would enable the agency to clarify its benchmarks for quality reporting and provide participants enough time to become familiar with them. The commenter also recommended that we provide confidential feedback reports with performance information that can be reviewed and corrected, as done in other CMS quality programs.

Response: We thank the commenters for this feedback. We note that RO participants will not be required to submit quality measure data on PY1 RO episodes until March 2022, which also provides time for familiarization. During PY1 and before the first submission in March 2022, we will provide education, outreach, and feedback reports to help participants

understand the quality and clinical data elements collection and submission systems. Between the availability of national benchmarks for the three pay-for-performance measures and the time period in which RO participants will have access to information about these measures, we believe it is appropriate to retain these measures as pay-for-performance beginning in PY1 as originally proposed. Starting in PY2 (once quality measure data for PY1 has been submitted) and continuing thereafter, we intend to provide detailed and actionable information to RO participants related to their performance in the Model, as described in section III.C.14.c. of the proposed rule (84 FR 34532). We intend to determine the design of and frequency of those reports in conjunction with the RO Model implementation and monitoring contractor.

Comment: A commenter stated its appreciation for our proposals to align our quality programs and for establishing a clear distinction between pay-for-performance and pay-for-reporting requirements.

Response: We thank the commenter for supporting our plan to align quality programs and distinguish our reporting requirements.

After consideration of the public comments that we have received, we are finalizing the AQS calculation as proposed and finalizing the definition of the AQS at § 512.205.

(2) Applying the AQS to the Quality Withhold

We proposed to use the following method to apply the AQS to the amount of the quality withhold that could be earned back by an RO participant (84 FR 34522). We would multiply the Professional participant's or Dual participant's AQS (as a percentage) against the 2 percent quality withhold amount. For example, if a Professional participant or Dual participant received an AQS of 88.3 out of a possible 100, then the Professional participant or Dual participant would 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 $2,465.68[76], the example AQS of 88.3 would result in a quality reconciliation payment amount of $43.64 ($2,465.68 * 1.77% = $43.64).[77]

We proposed to continue to weight measures equally in PY1 through PY5 unless we determined that the Model needs to emphasize specific clinical transformation priorities or added new measures. Any updates to the scoring methodology in future PYs will be proposed and finalized through notice and comment rulemaking. There may be some variation in the measures that we score to calculate the AQS for Professional participants and Dual participants should they be unable to report numerical data for certain measures due to sample size constraints or other reasons. However, as discussed in the proposed rule, we do not anticipate that variation will create any methodological problems for the Model's scoring purposes.

The AQS would be calculated approximately eight months after the end of each PY and applied to calculate the quality withhold payment amount for the relevant PY. Any portion of the quality withhold that is earned back would be distributed in an annual lump sum during the reconciliation process as described in section III.C.11 of this final rule.

We solicited public comments on our proposal to apply the AQS to the amount of the quality withhold in section III.C.6.g(2) of the proposed rule (84 FR 34509).

The following is a summary of the public comments received on this proposal and our response:

Comment: A commenter expressed concern about the AQS's structure and its interactions with incentives, noting that every participant would receive the quality withhold, but

[76] This number refers to the result in line (j) in Table 5 from the proposed rule.
[77] This number is prior to the geographic adjustment and sequestration being applied.

top performers would receive incentive payments over a year later. The commenter also asserted that most practices would receive a net payment cut because they would not earn the full withhold back.

Response: We thank the commenter for these concerns. However, we view the trade-offs associated with the Model's incentive payment timing as necessary within the framework of an episode-payment model that will, by design, accelerate much of the episode-based payments to RO participants. We will endeavor to calculate individual quality measure scores and an annual AQS, produce reports, and determine payment adjustments as swiftly as possible. While we agree with the commenter's sentiment that some RO participants will see a payment reduction, we note that the number of participants and the amount of the reduction will depend on a number of factors, including episode price as determined by the pricing methodology discussed in section III.C.6, and their performance on the AQS. We note that in any case, one of the benefits of the RO Model is bundling payments for all included RT services rather than remitting them piecemeal over the course of the RO episode. Finally, we note that section III.C.7 of this final rule states that RO participants will be able to receive EOE payments as early as day 28 of the RO episode, a change from the proposal to reimburse the final half of the episode payment after the 90-day episode period is over.

Comment: A commenter suggested that CMS consider rewarding top-performing providers and suppliers with additional reimbursements rather than subjecting them to a quality withhold. The commenter argued that this type of incentive structure would be consistent with the Quality Payment Program and would move Medicare policy away from focusing on penalties, as the commenter suggested has been prevalent in hospital quality programs.

Response: With respect to the AQS, RO participants will not be able to earn back more than the quality withhold. However, we believe that top performers in the Model will have the opportunity, via the Model's payment methodology, and the Advanced APM and MIPs incentives, to earn total payments in excess of their historical payments. For this reason, we believe that the Model's design serves to incentivize all RO participants to strive for high quality and earn the available incentive payments.

Comment: A commenter expressed support for the Model's proposed measures but argued that it is unrealistic to expect RO participants to score 100 percent for all measures. The commenter suggested that we adopt an 80 percent performance threshold for full credit within the quality portion of the AQS.

Response: We thank the commenter for this suggestion, but we do not believe that establishing firm thresholds within the AQS calculation would serve our quality improvement goals. We continue to believe that the Model's scoring structure must encourage consistent improvement in the Model's quality metrics, and we are concerned that establishing a scoring threshold as suggested by the commenter would offer disincentives for continued improvement. While we agree with the commenter that we do not expect RO participants to score 100 percent on all quality measures, we do not agree that we should therefore adopt a scoring "curve" or other form of adjustment that would offer full credit for performance at levels below the measure's benchmark.

After consideration of the public comments that we have received, we are finalizing our proposed policy to apply the AQS to the Quality Withhold to begin in PY1 as finalized in section III.6.g(2).

9. The RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit-based Incentive Payment System APM (MIPS APM)

As we stated in the proposed rule, we anticipate that the RO Model will be both an Advanced APM and a MIPS APM. For purposes of the Quality Payment Program, the RO participant, specifically either a Dual participant or a Professional participant, would be the APM Entity.

We proposed that we would establish an "individual practitioner list" under the RO Model (84 FR 34522). We proposed that this list would be created by CMS and sent to Dual participants and Professional participants to review, revise, certify, and return to CMS so that CMS would be able to make QP determinations and calculate any applicable APM Incentive Payments, and to identify any MIPS eligible clinicians who would be scored for MIPS based on their participation in this MIPS APM. The individual practitioner list would serve as the Participation List (as defined in the Quality Payment Program regulations at 42 CFR 414.1305) for the RO Model. We proposed to codify the term "individual practitioner list" for purposes of the RO Model in § 512.205 of our proposed regulations.

We proposed, at 84 FR 34522, that the individuals included on the individual practitioner list would include physician radiation oncologists who are eligible clinicians participating in the RO Model with either a Dual participant or a Professional participant as described in section III.C.3.b of this final rule. Eligible clinicians who are identified on the Participation List for an Advanced APM during a QP Performance Period may be determined to be Qualifying APM Participants (QPs) as specified in our regulations at 42 CFR 414.1425, 414.1435, and 414.1440. Similarly, under the current Quality Payment Program rules, MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS

APM would be scored for MIPS using the APM scoring standard as provided in our regulation at 42 CFR 414.1370. We proposed that only Professional participant physicians and Dual participant physicians included on the individual practitioner list would be considered eligible clinicians participating in the RO Model, for purposes of the Quality Payment Program.

We proposed that we would create and provide each Dual participant and Professional participant with an individual practitioner list prior to the start of each PY (84 FR 34522). We proposed that the Dual participants and Professional 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. In the case of a Dual participant or Professional participant that begins the RO Model after the start of PY, but at least 30 days prior to the final QP snapshot date of that PY, we proposed that CMS would create and provide the new Dual participant or Professional participant with an individual practitioner list.

In order to certify the list, we proposed that an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the list (84 FR 34522). We proposed that the certified individual practitioner list would include all individual practitioners who have reassigned their rights to receive Medicare payment for the provision of RT services to the TIN of the RO participant. We proposed that the individual with the authority to bind the RO participant must agree to comply with the requirements of the RO Model before the RO participant certifies the list. We note that we did not propose that HOPDs that are Technical participants be a part of this list process because as HOPDs they are paid by OPPS, which is not subject to the Quality Payment Program. The RO participants may make changes to the individual practitioner list that has been certified at the beginning of the performance year. In order to make additions to the list, we proposed that the RO participant

must notify CMS within 15 days of an individual practitioner becoming a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely addition would be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice of the addition, the addition would be effective on the date of the notice. We proposed that the notice must be submitted in a form and manner specified by CMS.

We proposed that in order to remove an individual practitioner from the list, the RO participant must notify CMS within 15 days after an individual practitioner ceases to be a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely removal would be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice (84 FR 34522). If the RO participant fails to submit timely notice of the removal, the removal would be effective on the date of the notice. The notice must be submitted in a form and manner specified by CMS. Further, we proposed that the RO participant must ensure that the individuals included on the individual practitioner list maintain compliance with the regulation at § 424.516, including notifying CMS of any reportable changes in status or information (84 FR 34522-34523). We proposed that the certified individual practitioner list would be used for purposes related to QP determinations as specified in 42 CFR part 414 subpart O. We also stated that if the Dual participant or Professional participant did not verify and certify the individual practitioner list by the deadline specified by CMS, the unverified list would be used for scoring under MIPS using the APM scoring standard (84 FR 34523). We proposed to codify these provisions relating to the individual practitioner list at § 512.217.

We proposed that in order to be an Advanced APM, the RO Model must meet the criteria specified in our regulation at 42 CFR 414.1415 (84 FR 34523). First, in order to be an Advanced APM, an APM must require participants to use certified EHR technology (CEHRT). For QP Performance Periods beginning in 2019, to meet this requirement, an Advanced APM must require at least 75 percent of eligible clinicians in the APM Entity or, for APMs in which HOPDs are the APM Entities, each HOPD, to use CEHRT to document and communicate clinical care to their patients or other health care providers pursuant to 42 CFR 414.1415(a)(1)(i). We 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 in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Further, we proposed that within 30 days of the start of PY1, the RO participant would be required to certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Annual certification would be required prior to the start of each subsequent PY.

We solicited public comments on our proposal. The following is a summary of the public comments received on this proposal and our responses:

Comment: A commenter commended CMS' dedication to implementing more Advanced APMs that would allow specialists the opportunity to become a QP. Specifically, the commenter suggested that there is insufficient opportunity for specialists to qualify for QP status under the Quality Payment Program, and therefore the commenter applauds CMS' dedication to improving this.

Response: We appreciate this commenter's support of our proposal.

Comment: A commenter requested clarification on the RO Model's status as an Advanced APM. Specifically, this commenter stated that its radiation oncologists are part of a

larger multi-specialty practice that currently reports to CMS under the MIPS program. The commenter requested clarification on whether the entire group would be participating as an Advanced APM Entity or just the radiation oncologists.

Response: In the proposed rule, we proposed that we will provide RO participants with an individual practitioner list. We also proposed a process whereby RO participants would review, have the opportunity to modify, and certify this list. The certified list that includes only physician radiation oncologists who have reassigned their rights to receive Medicare payment for the provision of RT services to the TIN of the RO participant would be used for purposes related to QP determinations as specified in 42 CFR part 414 subpart O. Only those individual practitioners included on the certified list would be considered participants under the RO Model for purposes of the Quality Payment Program, including identifying eligible clinicians who would be eligible to attain QP status under the Model. On further reflection, we have reconsidered our statement in the proposed rule that an unverified list would be used for scoring under MIPS. After further consideration, we are concerned that use of an unverified list might result in incorrect or unauthorized payments and adjustments under the Quality Payment Program, potentially jeopardizing program integrity.

Comment: A couple of commenters opposed the processes proposed around the Individual Practitioner List. One commenter opposed the proposal that the Individual Practitioner List must be reviewed and certified annually, stating that this was too great an administrative burden for participants. Another commenter requested that CMS allow participants to have 60 days to notify CMS of changes to the QP list, rather than 15 days as proposed. This commenter suggested that if RO participants meet this 60-day reporting deadline, the changes would take effect as of the effective date specified in the notice to CMS. If

participants do not meet this deadline, then addition or removal would be effective on the date that the participant notifies CMS.

Response: We disagree with the commenter who believes the annual certification process of the individual practitioner list is unduly burdensome. We have proposed this certification process so that the RO participant would have the chance to review and verify that the list we intend to use for QP determinations is accurate, and if it is not accurate, to notify us of the inaccuracies so a correct list can be used for those determinations. We proposed this process to limit burden on RO participants, as we will be creating a draft version for their review rather than asking RO participants to draft and compile a list for our review that would then need to be certified. Further, we proposed that if the RO participant does not certify the list we will still use the uncertified list for MIPS scoring. While we had previously proposed to still use an uncertified list, we are not finalizing this provision. Upon further consideration and based on commenters' requests for clarity around the RO Model's status as an Advanced APM, we are instead finalizing that RO participants on an uncertified list would not be considered participants in an APM Entity for purposes of the Quality Payment Program as defined at §414.1305. We are codifying these provisions relating to the individual practitioner list at § 512.217.

We also disagree with the commenter who proposed that RO participants should have 60 days to notify us of changes to their individual practitioner list. However, we agree that 15 days may be an insufficient period of time for participants to review, correct, and return the list to us. We will modify this proposal to allow for a 30-day period. We believe 30 days will be a sufficient amount of time for RO participants to review and submit corrections, as other models currently being tested by the Innovation Center also require 30-day period to review and return

similar lists. Further, we believe 30 days is a reasonable compromise between the commenter's proposed 60-day period and our original 15-day proposal.

Comment: A few commenters stated that some practices may need a hardship exemption from the proposed Model requirements to use the 2015 Edition CEHRT due to insufficient internet connectivity, extreme and uncontrollable circumstances, or lack of control over the availability of CEHRT. One of these commenters stated that low-volume practices are excluded from the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and its Promoting Interoperability performance category requirement to use 2015 Edition CEHRT, which is a proposed requirement for the RO Model. This commenter further maintained that including low-volume practices in the RO Model would require these practices, which haven't had to use 2015 Edition CEHRT under MIPS, to make significant financial investments in technology and substantial time investments in software installations and training while adapting to the new value-based reimbursement methodology, which would be detrimental to these practices' ability to continue operations and reduce access for patients to receive radiation therapy. This commenter also stated that practices with insufficient internet connectivity, which are typically located in rural areas, are allowed to annually apply for a hardship exception from the MIPS Promoting Interoperability performance category and its requirement to use 2015 Edition CEHRT, and if these practices are included in the RO Model, they will be forced to invest significant resources and time as participants of the RO Model and could be forced to discontinue operations, decreasing access to cancer treatment options for patients.

Response: There are very few RT providers and RT suppliers in these rural areas such that, if included in the RO Model, the rural areas would likely not generate enough episodes to be included in the Model. As such, we believe that our proposed CEHRT requirements are not

unduly burdensome for rural RT providers and RT suppliers, and a hardship exemption from the CEHRT requirement is unnecessary. We would note that while we do not believe a hardship exemption is necessary for the CEHRT requirement, we are finalizing in section III.C.3.c a low volume opt-out that may help address these commenters' concerns.

Comment: A couple of commenters requested clarification on which edition of CEHRT CMS is requiring for RO participants to use. One of these commenters recommended that the edition that RO uses should align with other quality reporting programs. This commenter also questioned why participants must certify their intent to use CEHRT at the beginning of the performance year, and not at the end.

Response: In the RO Model, we have proposed to align our CEHRT requirements with the regulatory requirements of the Quality Payment Program as stated at 42 CFR 414.1415(a). This relies on the definition of CEHRT as defined, and periodically updated, at 42 CFR 414.1305, which currently specifies the use of 2015 Edition Base EHR edition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria. Using this definition of CEHRT aligns RO Model requirements with the requirements of the Quality Payment Program as well as other Advanced APMs being tested by the Innovation Center. We believe certifying an intent to use CEHRT at the beginning of the performance year, as opposed to the end of the performance year, is appropriate and it aligns with requirements in other Advanced APMs being tested by the Innovation Center.

After considering public comments, we are finalizing with modification our proposals relating to the RO Model as an Advanced APM regarding the CEHRT and Participation List requirements. We clarify 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, as described at 42 CFR 414.1305. We are also finalizing, with modification, that if the Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, RO participants on the unverified list are not recognized as participants in an APM Entity for purposes of the Quality Payment Program. We have codified at § 512.217(a) that we will create and provide each Dual participant and Professional participant with an individual practitioner list, upon the start of each performance year. We have made edits to § 512.217(b) for clarity and readability. That provision has been revised to state that, within 30 days of receipt of the individual practitioner list, the RO participant must review the individual practitioner list, correct any inaccuracies in accordance with to § 512.217(d), and certify the list (as corrected, if applicable) in a form and manner specified by CMS and in accordance with § 512.217(c).

We have also made edits to § 512.217(d) for clarity and readability. This provision has been revised to state that, the RO participant must notify CMS of a change, including additions or removals, to its individual practitioner list within 30 days. Further, we have clarified at § 512.217(d)(2)(i) 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 at § 512.205.

Next in the proposed rule, at 84 FR 34523, we explained the second criterion to be an Advanced APM, which is that 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 as specified at 42 CFR 414.145(b)(1). 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 evidenced-based, reliable, and valid.

We noted in the proposed rule that we discussed the RO Model's quality measure set in section III.C.8.b of the proposed rule. We discussed our intention to use the results of the following quality measures when determining payment to Professional participants and Dual participants under the terms of the RO Model, as discussed in detail in section III.C.8.f of the proposed rule and this final rule: (1) Oncology: Medical and Radiation – Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan; and (4) Treatment Summary Communication – Radiation Oncology. The quality measures we proposed to use for the RO Model are measures that are either finalized on the MIPS final list of measures, or determined by CMS to be evidence based, reliable, and valid. As we indicated in the proposed rule, we believe that these measures would meet the criteria under 42 CFR 414.1415(b) (84 FR 34523).

In addition to the quality measure requirements listed earlier, under 42 CFR 414.1415(b)(3), the quality measures upon which an Advanced APM bases payment must include at least one outcome measure. This requirement does not apply if CMS determines that there are no available or applicable outcome measures included in the MIPS quality measures list for the APM's first QP Performance Period. We noted in the proposed rule that there currently are no such outcome measures available or applicable for the RO Model's first QP Performance Period (84 FR 34523). If a potentially relevant outcome measure becomes available, we would consider it for inclusion in the RO Model's measure set.

The third criterion to be an Advanced APM is that 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. As we stated in the proposed rule, we expect that the RO Model will meet the generally applicable financial risk standard in accordance with 42 CFR 414.1415 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 (84 FR 34523).

The regulation at 42 CFR 414.1415(c)(1) requires that "to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following: (i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians; (ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or (iii) Require the APM Entity to owe payment(s) to CMS." We stated in the proposed rule that the RO Model would meet this standard because CMS would not pay the RO participant more for RT services than the episode payment amount (84 FR 34523).

The regulation at 42 CFR 414.1415(c)(3) sets the standard for a nominal amount of risk for Advanced APMs other than Medical Home Models at either "eight percent of the average estimated total Medicare Parts A and B revenues of participating APM Entities" for QP Performance Periods in 2017 through 2024 or "three percent of the expected expenditures for which the APM Entity is responsible for under the APM" for all QP Performance Periods.

For the RO Model, as we discussed in the proposed rule (84 FR 34523), the APM Entities would be at risk for all costs associated with RT services as discussed in section III.C.5.c of the proposed rule and this final rule beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, and therefore, would be

at 100 percent risk for all expenditures in excess of the expected amount of expenditures, which are the previously discussed episode payments. As proposed, RO participants would not receive any additional payment or reconciliation from CMS (beyond the participant-specific professional episode payment or participant-specific technical episode payment) to account for any additional medically necessary RT services furnished during the 90-day episode. Effectively, this means that when actual expenditures for which the APM Entity was responsible under the APM exceed expected expenditures, the RO participant would be responsible for 100 percent of those costs without any stop-loss or cap on potential losses. This would satisfy the requirement under 42 CFR 414.1415(c)(3)(i)(B) because, for example, if actual expenditures are 3 percent more, or 5 percent more, or 7 percent more than the expected expenditures for which an RO participant is responsible under the model, the RO participant is 100 percent liable for those additional 3 percent, 5 percent, or 7 percent of costs without any limit to the total amount of losses they may incur.

Additionally, as we stated in the proposed rule (84 FR 34523-34524), we anticipated that the RO Model would meet the criteria to be a MIPS APM under the Quality Payment Program starting in PY1 (January 1, 2020) if the start date is finalized as January 1, 2020 or in PY2 (January 1, 2021) if finalized as April 1, 2020. MIPS APMs, as defined in 42 CFR 414.1305, are APMs that meet the criteria specified under 42 CFR 414.1370(b). Currently, pursuant to 42 CFR 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. We proposed to use the same individual practitioner list developed to identify the relevant eligible clinicians for purposes of making QP determinations and applying the APM scoring standard under the Quality Payment Program.

In the CY 2021 PFS proposed rule, we proposed to terminate the APM scoring standard effective January 1, 2021 (85 FR 50303). We also proposed to establish a new APM Performance Pathway, which, if finalized, would be an optional MIPS reporting and scoring pathway for MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of a MIPS APM (85 FR 50285). We also proposed to allow APM Entities to report to MIPS via any available submission mechanism, on behalf of all MIPS eligible clinicians in the APM Entity group (85 FR 50304). If these proposals are finalized in the forthcoming CY 2021 PFS final rule, MIPS eligible clinicians participating in the RO Model would have the option to report to MIPS using the APM Performance Pathway, and they would have the option to report to MIPS as individuals, groups, or APM Entities.

In the proposed rule we noted that the following proposals would apply to any APM Incentive Payments made for eligible clinicians who become QPs through participation in the RO Model:

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

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

We solicited comment on our proposals. The following is a summary of the public comments received on these proposals and our responses:

Comment: A few commenters expressed concern regarding the risk that will be involved for participants in the RO Model. A commenter stated that if the RO Model is structured as largely as proposed, then participation will be a significant, risky, and costly undertaking. One of these commenters requested that CMS redesign the Model payment to allow for two-sided risk. Another commenter expressed concern with the lack of a cap on downside risk and opposed the current, uncapped risk structure. This commenter suggested that the RO Model should establish risk at the levels finalized by CMS for other APMs. A few commenters requested that CMS include stop-loss provisions in the RO Model. These commenters stated that RO Participants would bear 100 percent of the risk for all RT services provided in excess of the bundle payments, and that this high degree of risk is inappropriate for a mandatory model. They also maintained that this lack of stop-loss protection runs counter to the majority of CMS APMs such as the BPCI Advanced Model, the CJR Model, the Shared Savings Program, and OCM, which all cap downside risk. These commenters suggest that CMS should establish a stop-loss provision to mitigate this high degree of risk and to ensure that the RO Model does not place substantial financial burden on RO participants. A commenter suggested implementing a stop-loss provision using the encounter data CMS proposes to require participants to submit.

Response: We appreciate the commenters' concerns and feedback around the level of risk in the RO Model, and regarding a stop-loss provision under the Model. We believe that the heavy weight of the RO participants' historical experience in their participant-specific RO payment amount, combined with the low volume opt-out option (see section III.C.3.c), minimizes the potential losses that an RO participant may face. However, we understand that

there are some circumstances where RO participants that have fewer than 60 episodes in the baseline period will not qualify to receive a historical experience adjustment and may experience significant increases or reductions to what they were historically paid in FFS. We are adopting a stop-loss limit of 20 percent to the RO Model for these RO participants that were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule. Please reference section III.C.6.e(4) for more information on the stop-loss policy.

We understand the commenters' concerns with the level of risk in this Model compared with other Innovation Center models. Section 1833(z)(3)(D) of the Act, as added by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114-10), established certain requirements for APMs including a requirement that an APM Entity bear financial risk for monetary losses that are in excess of a nominal amount or be a medical home expanding under 111A(c) of the Act. In rulemaking, we have established this generally applicable nominal amount standard to mean that an Advanced APM must put the APM Entities at risk for at least eight percent of the average estimated total Medicare Parts A and B revenue of all providers and suppliers participating APM Entities or at least 3 percent of the expected expenditures for which an APM Entity is responsible under the APM, as codified in § 410.1415(c)(3). In designing and implementing other models, we have established various levels of risk at and above these minimum amounts. As such, we believe that the level of risk we have established for the RO Model, is above the minimum level specified in the generally applicable nominal amount standard that we established for the Quality Payment Program. Furthermore, the level of risk is appropriate and in line with the levels of risk of other Advanced APMs being tested by the Innovation Center, including the stop-loss policy described in section III.C.6e(4) The stop-loss limit of 20 percent aligns with stop-loss limits set by other models such as the

BPCI Advanced and CJR Models. Further, we would like to note that the RO Model does have two-sided risk; participants that provide services more efficiently than the RO episode price yield savings, while those that provide services less efficiently than the RO episode price yield losses.

Comment: A commenter requested that providers and suppliers that are required to participate in the RO Model should have every possible assurance that their participation will qualify them for exemption from MIPS and will earn them the APM incentive for participation in an Advanced APM. This commenter stated that they understand that CMS cannot guarantee that providers and suppliers will meet the minimum payment or patient volume requirement to be a qualifying participant, but the agency should finalize a structure that squarely satisfies each of the requirements for an Advanced APM.

Response: We appreciate the commenter's views on the design of the RO Model as an Advanced APM. We believe that we have designed the Model in such a way that we expect that the RO Model will be determined to be both an Advanced APM and a MIPS APM starting on January 1, 2021. As such, 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, and thereby exempt from the MIPS reporting requirements and payment adjustment for the relevant year. Under the structure of the Quality Payment Program, not all eligible clinicians in the RO Model will necessarily achieve QP status or earn an APM Incentive Payment for their participation in the Advanced APM, but we believe there are other inherent benefits to the RO participant. Furthermore, based on our actuarial analysis we believe that most eligible clinicians will achieve QP status during the course of the RO Model.

Other benefits for participating in the RO Model as it is designed as an Advanced APM and a MIPS APM include a chance to be an early adopter of a value-based payment arrangement

model. As CMS in general, and the health care industry specifically, turns to more value-based payment arrangements, early adopters of these models may have an advantage over their peers who have not participated in these models. Additionally, eligible clinicians in the RO Model who are MIPS eligible clinicians (those not excluded from MIPS as QPs, Partial QPs, or on another basis) will be considered participants in a MIPS APM for purposes of MIPS reporting and scoring rules.

Comment: MedPAC did not support CMS' proposal that the RO Model would qualify to be an Advanced APM. MedPAC stated that the RO Model does not meet two of the principles that MedPAC has developed for Advanced APMs: clinicians should receive a 5 percent incentive payment only if the eligible entity in which they participate 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 stated that incentive payments should not be awarded for simply participating in an APM entity but should be contingent on quality and spending performance. They stated that the RO Model does not follow this first principle, as clinicians who participate in the RO Model through an eligible entity and have a sufficient share of revenue coming through the Model would receive an incentive payment, whether or not the entity limits costs per episode or improves quality. MedPAC also stated that the RO Model does not follow their second 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, as the RO Model entities are only responsible for spending on certain RT services within a 90-day episode of care. They are not held accountable for spending on other services provided to beneficiaries in the Model, such as E&M visits, tests, ED visits, or hospital admissions. Entities would also have an incentive to reduce the cost per episode while increasing the total number of episodes. In

addition, there is not a single entity that would be responsible for episode spending because CMS would make separate episode payments for the TC and PC portions of the episode, unless an entity is a Dual participant that provides both the TC and PC portions of an episode. MedPAC further disagreed with CMS' decision to not propose any outcome measures for the Model, and they disagree with CMS' determination that there are currently no outcome measures available or applicable for the RO Model. MedPAC states that OCM uses three claims-based outcome measures to determine performance-based payments: risk-adjusted proportion of patients with all-cause hospital admissions within the six-month episode, risk-adjusted proportion of patients with all-cause emergency department (ED) visits or observation stays that did not result in a hospital admission within the six-month episode, and proportion of patients that died who were admitted to hospice for three days or more. MedPAC stated that CMS should consider using similar outcome measures for the RO Model, as both OCM and the RO Model focus on cancer treatment. They also stated that use of claims-based outcome measures in the RO Model would enable CMS to hold providers and suppliers accountable for the quality of their care and allow CMS to evaluate whether prospective episode payments for RT services reduce spending without causing negative outcomes. Finally, MedPAC stated that claims-based outcome measures, such as readmission rates, do not impose a reporting burden on providers and suppliers and are part of MIPS.

Response: We appreciate MedPAC's analysis of the Quality Payment Program and the RO Model, but we disagree that the RO Model should not qualify as an Advanced APM. We believe the additional principles that MedPAC has established can be used as analytic tools when analyzing Advanced APMs, they do not align with or take the place of 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, and as such are not necessary requirements when making an Advanced APM determination. Specifically, as codified at 42 CFR 414.1415, the criteria for Advanced APMs are as follows: (1) the APM requires use of CEHRT, (2) payment under the APM is based on MIPS-comparable quality measures, and (3) the APM requires participants to assume more than nominal financial risk. As articulated in this section of this final rule, we believe that he RO Model satisfies each of these criteria.

**Required use of CEHRT**: During the Model performance period, the RO participant will be required to annually certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a). Further, within 30 days of the start of PY1, the RO participant will be required to certify its intent to use CEHRT throughout such model year in a manner sufficient to meet the requirements pursuant to 42 CFR 414.1415(a).

**Payment based on MIPS-comparable quality measures**: We intend to use the results of the following quality measures when determining payment to Professional participants and Dual participants under the terms of the RO Model, as discussed in detail in section III.C.8.f of this final rule: (1) Oncology: Medical and Radiation – Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan; and (4) Treatment Summary Communication – Radiation Oncology. Further, the quality measures we use for the RO Model are measures that are either finalized on the MIPS final list of measures, or determined by CMS to be evidence-based, reliable, and valid. In addition to the quality measure requirements listed earlier, under 42 CFR 414.1415(b)(3), the quality measures upon which an Advanced APM bases payment must include at least one outcome measure. This requirement does not apply if CMS determines that there are no available or applicable outcome

measures included in the MIPS quality measures list for the APM's first QP Performance Period. CMS has determined that there currently are no such outcome measures available or applicable for the RO Model's first QP Performance Period.

Furthermore, with regards to MedPAC's comments about the RO Model using similar outcome measures that are employed by OCM, we thank MedPAC for the suggestion. We considered using the same OCM outcome measures for the RO Model, but ultimately decided that it would be difficult to discern whether these outcomes occurred due to complications from RT services, chemotherapy by medical oncologists, or for other various reasons. As such, we believe that these measures would not meaningfully indicate high- versus low-quality RO participants.

**Financial Risk**: The regulation at 42 CFR 414.1415(c)(1) requires that "to be an Advanced APM, an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following: (i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians; (ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or (iii) Require the APM Entity to owe payment(s) to CMS." As we explained in the proposed rule and in this section of the final rule, the RO Model would meet this standard because CMS would not pay the RO participant more for RT services than the episode payment amount.

The regulation at 42 CFR 414.1415(c)(3) sets the standard for a nominal amount of risk for Advanced APMs other than Medical Home Models at either "eight percent of the average estimated total Medicare Parts A and B revenues of participating APM Entities" for QP

Performance Periods in 2017 through 2024 or "three percent of the expected expenditures for which the APM Entity is responsible for under the APM" for all QP Performance Periods.

For the RO Model, most APM Entities, with the exception of those RO participants that qualify for the stop-loss policy as described in section III.C.6.e(4) and codified at § 512.285(f), would be at risk for all costs associated with RT services (described in section III.C.5.c of this final rule) beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, and therefore, would be at 100 percent risk for all expenditures in excess of the expected amount of expenditures, which are the previously discussed episode payments. RO participants would not receive any additional payment or reconciliation from CMS (beyond the participant-specific professional episode payment or participant-specific technical episode payment) to account for any additional medically necessary RT services furnished during the 90-day episode. Effectively, this means that when actual expenditures for which the APM Entity was responsible under the APM exceed expected expenditures, the RO participant would be responsible for 100 percent of those costs without any stop-loss or cap on potential losses, except for the participants that qualify for the stop-loss policy, as previously stated. This would satisfy the requirement under 42 CFR 414.1415(c)(3)(i)(B) because, for example, if actual expenditures are 3 percent more, or 5 percent more, or 7 percent more than the expected expenditures for which RO participants are responsible under the Model, RO participants are 100 percent liable for those additional 3 percent, 5 percent, or 7 percent of costs. Most participants are without any limit to the total amount of losses they may incur. For the subset of RO participants that are limited to the total amount of losses they may incur because they are eligible for the stop-loss policy, that limit is set

to 20 percent of expected expenditures for which the RO participants are responsible for under the RO Model.

Finally, while MedPAC has created these additional principles that it believes should be achieved for a model to be an Advanced APM, these additional principles have not been codified in the Quality Payment Program regulations as necessary requirements of Advanced APMs. Even though meeting these principles is not a requirement for Advanced APM status, we are responding to these comments to better explain our reasoning behind the RO Model being proposed as an Advanced APM.

First, regarding the APM Incentive Payment, MedPAC believes the APM incentive payment should only be paid if the APM participant is successful in controlling cost, improving quality, or both, and if the APM participant is at financial risk for total Part A and Part B spending. The Quality Payment Program statute and regulations provide different standards for eligible clinicians to earn an APM incentive payment, and for an APM to be considered an Advanced APM, based on the required assumption of financial risk; the Quality Payment Program provides for the APM incentive payment to encourage clinicians to move into value-based payment through Advanced APMs. Additionally, in the RO Model we are specifically testing different pricing methodologies for the RT services provided, not the other costs associated with the beneficiary's care.

Second, regarding the move from FFS payments to a value-based payment system, MedPAC believes that since RO participants are only held accountable for spending on certain RT services within the episode of care and not held accountable for spending on other services provided to the RO beneficiary, the RO participants are not properly incentivized to reduce the total cost of care. We generally disagree that such broad incentives are necessary for Advanced

APM status. Specifically, the Advanced APM criterion codified at 42 CFR 414.1415(c) does not specify that a financial risk must be based on a total cost of care arrangement. Additionally, we did not design the RO Model to be a total cost of care model. Instead it was designed so that each RO episode only covers RT services. We limited the Model in this way because we believe that these services are in the control of the RT provider and RT supplier, and they are the entities at risk in the Model. Further, there has never been a requirement in the Quality Payment Program that one entity must be at risk for the entire cost of the episode. As we have previously stated, in the RO Model we are specifically testing different pricing methodologies for the RT services provided, not the other costs associated with the beneficiary.

Comment: A commenter suggested that CMS should structure the final RO Model so that all RO participants will be QPs in an Advanced APM for purposes of the Quality Payment Program, assuming minimum participation requirements are met. Additionally, although we did not request comments on our projection, discussed further in section VII.C.3 of the Regulatory Impact Analysis, that 83 percent of physician participants, measured by their unique NPI, would achieve QP status and receive the APM Incentive Payment under the Quality Payment Program at some point (for at least one QP Performance Period) during the Model performance period, some commenters suggested that all physicians participating in the RO Model should receive the APM incentive payment as compensation for participation in a mandatory model that requires quality measure and clinical data reporting. Commenters stated that CMS was issuing an unfunded mandate in cases where physicians did not receive the APM Incentive Payment.

Response: Under the structure of the Quality Payment Program, not all eligible clinicians will necessarily earn an APM Incentive Payment for their participation in an Advanced APM. Specifically, in accordance with 42 CFR 414.1430, eligible clinicians must achieve certain

threshold levels of participation in the Advanced APM in terms of payment amounts or patient counts in order to achieve QP status and qualify for an APM Incentive Payment. Therefore, we believe there are other inherent benefits to the RO participant including the chance to be an early adopter of a value-based payment arrangement. As CMS in general, and the health care industry specifically, turns to more value-based payment arrangements, early adopters of these models will have an advantage over their peers who have not participated in these models. Additionally, eligible clinicians in the RO Model who are MIPS eligible clinicians (those not excluded from MIPS as QPs, Partial QPs, or on another basis) will be considered participants in a MIPS APM for purposes of MIPS reporting and scoring rules.

We appreciate the comments on our QP projections, but we must use the APM Incentive Payment calculation methodology as specified at 42 CFR 414.1450 to determine which eligible clinicians meet the QP threshold required to achieve QP status and receive the APM Incentive Payment. As such, just as we cannot summarily award QP status to all RO participants, we cannot automatically make an APM Incentive Payment to all eligible clinicians in the RO Model. All eligible clinicians are required to meet the QP threshold for Medicare Part B professional services payments or patients in an Advanced APM in order to achieve QP status and receive the APM incentive payment. In addition to the 83 percent of RO Model physicians who are expected to be QPs, 9 percent are expected to be partial QPs at some point during the Model performance period, resulting in 92 percent of RO Model physicians becoming QPs or partial QPs at some point. We would note that while partial QPs do not earn the APM Incentive Payment, they do have the option to decide whether to be subject to the MIPS reporting requirements and payment adjustment, which would otherwise be required.

Comment: A commenter requested that the 5 percent APM incentive payment that is available through 2024 should be extended as the RO Model is just becoming available to radiation oncologists, and prior to this, the radiation oncology community has not had an Advanced APM available that would qualify physicians in the radiation oncology specialty for this bonus.

Response: We appreciate the commenter's feedback on the availability of the APM Incentive Payment to eligible clinicians who have been determined to be QPs participating in Advanced APMs. The APM Incentive Payment is limited based on statute to payment years 2019 through 2024 as specified in section 1833(z)(1)(A) of the Act.

After considering public comments, we are finalizing our proposals, with modification, that, effective January 1, 2021, at least one of the quality measures upon which the RO Model bases payment will 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 evidenced-based, reliable, and valid. This modification means that quality data collection and reporting for the RO Model will begin with PY1 on January 1, 2021, which means that we expect the Model to qualify as both an Advanced APM and a MIPS APM beginning on January 1, 2021. Final CMS determinations of Advanced APMs and MIPS APMs for the 2021 performance period will be announced via the Quality Payment Program website at https://qpp.cms.gov/. We are finalizing our proposal to use the results of the following quality measures, finalized in section III.C.8.b of this final rule, when determining payment to Professional participants and Dual participants under the terms of the RO Model, as discussed in detail in section III.C.8.f: (1) Oncology: Medical and Radiation—Plan of Care for Pain; (2) Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and (3) Advance

Care Plan; and (4) Treatment Summary Communication—Radiation Oncology. As there currently are no available or applicable outcome measures included in the MIPS quality measures list for the RO's Model's first QP Performance Period, we will not be including an outcome measure in this final rule. However, if a potentially relevant outcome measure becomes available, we would consider whether such an outcome measure should be included in the RO Model's measure set, and if so, use notice and comment rulemaking to propose adding it.

We are finalizing with modification, that most APM Entities, the RO participants, with the exception of those RO participants that qualify for the stop-loss provision as described in (see section III.C.6.e(4) and codified at § 512.285(f), will be at risk for all costs associated with RT services, as defined in section III.C.5.c of this final rule, beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, and therefore, will be at 100 percent risk for all expenditures in excess of the expected amount of expenditures, which are the previously discussed episode payments. As discussed earlier in this section, based on these finalized provisions, the RO Model would meet the criteria to be an Advanced APM.

Based on the changes we made to the start date of the Model performance period in this final rule, we anticipate that the finalized RO Model will meet the criteria to be a MIPS APM under the Quality Payment Program starting in PY1 on January 1, 2021, instead of the proposed PY1 (January 1, 2020) or PY2 (January 1, 2021) as we had indicated in the proposed rule. We are also finalizing with modification to use the individual practitioner list to identify the relevant eligible clinicians for purposes of making QP determinations and determining those MIPS eligible clinicians who are also considered participants in a MIPS APM under the Quality Payment Program. We also clarify that currently, MIPS APMs, as defined in 42 CFR 414.1305,

are APMs that meet the criteria specified under 42 CFR 414.1370(b). As indicated in the current 42 CFR 414.1370(a), 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. We are using the same individual practitioner list developed to identify the eligible clinicians in the APM Entity for purposes of the Quality Payment Program.

We also note that we are finalizing that all requirements concerning the review and certification of the individual practitioner list will be required in PY1 (beginning January 1, 2021). This includes the requirement that Dual participants and Professional participants must review and certify the first individual practitioner list within 30 days of receiving the list upon the start of PY1. Further, we are finalizing as proposed, and codified at § 512.220(b), that participants must use certified EHR technology (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 PY1.

Finally, we note that the following provisions being finalized in other sections of this final rule will apply to any APM Incentive Payments made for eligible clinicians who become QPs through participation in the RO Model:

- Our finalized provisions regarding monitoring, audits and record retention, and remedial action, as described in section II.F and III.C.14.
- Our finalized provision in section III.C.10.c, which explains that technical component payments under the RO Model will 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

As explained in the proposed rule, we believe it would be necessary to waive certain requirements of title XVIII of the Act solely for purposes of carrying out the testing of the RO Model under section 1115A (b) of the Act. Each of the waivers, which we discussed in detail, would be necessary to ensure that the Model test's design provides additional flexibilities to RO participants, including flexibilities around certain Medicare program requirements.

a. Waiver of Hospital Outpatient Quality Reporting (OQR) Program Payment Adjustment

In the proposed rule, we stated that we believe that it would be necessary for purposes of testing the RO Model to waive the Hospital OQR Program payment reduction authorized under section 1833(t)(17)(A) of the Act. Under the Hospital OQR Program, subsection (d) hospitals are required to submit data on measures on the quality of care furnished by hospitals in outpatient settings. Further, section 1833(t)(17)(A)(i) of the Act states that subsection (d) hospitals that fail to meet Hospital OQR Program requirements receive a two percentage point reduction to their outpatient department (OPD) fee schedule increase factor. The fee schedule increase factor is applied annually to increase the OPPS conversion factor, which is then multiplied by the relative payment weight for a particular Ambulatory Payment Classification (APC) to determine the payment amount for the APC. Not all OPPS items and services are included in APCs for which the payment is determined using the conversion factor. For this reason, we only apply the 2 percent reduction to APCs – identified by status indicators – for which the payment is calculated by multiplying the relative payment weight by the conversion factor.

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in a form and manner, and at a time, specified

by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for many services under the OPPS. To reduce the OPD fee schedule increase factor for hospitals that fail to meet the Hospital OQR Program reporting requirements, we calculate two conversion factors – a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the "reporting ratio" to indicate that it applies to hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. Thus, our policy is to apply the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for a year (83 FR 59108-59110).

In the proposed rule, we proposed that for purposes of APCs that contain RO Model-specific HCPCS codes, we would waive the requirement under section 1833(t)(17)(A)(i) of the Act that the Secretary reduce the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act for a year by 2.0 percentage points for a subsection (d) hospital that does not submit, to the Secretary in accordance with paragraph (17), data required to be

submitted on measures selected under that paragraph with respect to such a year. RO Model-specific HCPCS codes would be mapped to RO Model-specific APCs for payment purposes under the OPPS. This waiver would apply only to the APCs that include only the new HCPCS codes that are created for the RO Model, rather than all APCs that package radiation HCPCS codes, and would only apply when a hospital does not meet requirements under the Hospital OQR Program and would otherwise be subject to the 2.0 percentage point reduction. Only Technical participants using the RO Model-specific HCPCS codes would be paid under the Model; APCs not included in the Model, and thus not using the RO Model-specific HCPCS codes, would continue to be paid under the OPPS and subject to the 2.0 percentage point reduction under the Hospital OQR Program when applicable. We stated in the proposed rule that we believed this waiver would be necessary in order to equally evaluate participating HOPDs and freestanding radiation oncology centers on both cost and quality.

The RO Model is a test of a site-neutral pricing methodology, where payment rates are calculated in the same manner regardless of the setting (in this case, HOPDs and freestanding radiation therapy centers) and paid prospectively based on episodes of care. While payment amounts may vary across RO participants, the calculation of how much each RO participant would be paid for the PC and TC of the RO episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. Therefore, in the proposed rule we stated our belief that applying the Hospital OQR Program payment reduction would undermine our goal of site-neutral payments under the RO Model because it could affect HOPDs, but not freestanding radiation therapy centers, creating additional variables that could complicate a neutral comparison. As we stated in the proposed rule, if the requirement to apply the Hospital OQR Program payment reduction were not waived, the

participant-specific technical episode payments made with respect to services furnished by RO participants in HOPDs that are billed under the technical RO Model-specific HCPCS codes may be decreased due to the Hospital OQR Program payment reduction. Meanwhile, the Hospital OQR Program payment reduction would not apply to participating freestanding radiation therapy centers, which are paid under the PFS not OPPS. In the proposed rule, we discussed our belief that the potential differences between participant-specific technical episode payments made for services furnished in HOPDs and those made under the PFS that would be caused by the application of the Hospital OQR Program payment reduction would be problematic for the RO Model test by creating potentially misaligned incentives for RO participants. The Hospital OQR Program payment reduction may interfere with how the RO Model pricing methodology has been conceptualized and therefore impact the model evaluation by introducing additional variability into RO participants' payments, thereby making it harder to discern whether the episode-based bundled payment approach is successful.

For these reasons, we believed that it would be necessary to waive the requirement to apply the Hospital OQR Program payment reduction under section 1833(t)(17)(A)(i) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payments made for services billed under the technical RO Model-specific HCPCS codes. As such, we proposed to waive application of the 2.0 percentage point reduction under section 1833(t)(17) of the Act for only those APCs that include only RO Model-specific HCPCS codes during the Model performance period.

We solicited comment on our proposal to waive application of the Hospital OQR Program 2.0 percentage point reduction through use of the reporting ratio for APCs that include the new HCPCS codes that are created for the RO Model during the Model performance period. We received no comments, and therefore, are finalizing our proposal as proposed.

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

As we stated in the proposed rule, under section 1848(q)(6)(E) of the Act and 42 CFR 414.1405(e), the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) generally apply to the amount otherwise paid under Medicare Part B with respect to covered professional services furnished by a MIPS eligible clinician during the applicable MIPS payment year. We 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 payments made for services furnished by a MIPS eligible clinician and billed under the professional RO Model-specific HCPCS codes because we believed that it would be necessary solely for purposes of testing the RO Model.

The RO Model is a test of a site-neutral pricing methodology, where payment rates are calculated in the same manner regardless of the setting and paid prospectively based on episodes of care. While payment amounts may vary across RO participants, the calculation of how much each RO participant would be paid for the PC and TC of the RO episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. Therefore, in the proposed rule we stated our belief that applying the MIPS payment adjustment factors would undermine our goal of site-neutral payments under the RO Model.

As we stated in the proposed rule, if the requirement to apply the MIPS payment adjustment factors were not waived, the participant-specific technical episode payments made with respect to services furnished by MIPS eligible clinicians in freestanding radiation therapy

centers that are billed under the professional RO Model-specific HCPCS codes may be increased or decreased due to the MIPS payment adjustment factors. In contrast, the MIPS payment adjustment factors would not apply to payments of claims processed under the OPPS, and as a result, would not apply to the participant-specific technical episode payments made to participating HOPDs. In the proposed rule, we stated our belief that the potential differences between participant-specific technical episode payments made for services furnished in freestanding radiation therapy centers and those made under the OPPS that would be caused by the application of the MIPS payment adjustment factors would be problematic for the RO Model test by creating potentially misaligned incentives for RO participants as well as other challenges for the Model evaluation. Further we stated our belief that without this waiver, RO participants may be incentivized to change their behavior and steer beneficiaries towards freestanding radiation therapy centers if they expect the MIPS payment adjustment factors will be positive, and away from freestanding radiation therapy centers if they expect the MIPS payment adjustment factors will be negative.

Dual and professional RO participants that bill for the participant-specific professional episode payments for RT services using RO Model-specific HCPCS codes will be subject to payment adjustments under the Model based on quality performance through the quality withhold. The MIPS payment adjustment factors are determined in part based on a MIPS eligible clinician's performance on quality measures for a performance period. In the proposed rule, we stated our belief that subjecting an RO participant to payment consequences under both MIPS and the Model for potentially the same quality performance could have unintended consequences. The MIPS payment adjustment factors may interfere with how the RO Model pricing methodology has been conceptualized and therefore impact the model evaluation by

introducing additional variability into RO participants' payments thereby making it harder to discern whether the episode-based bundled payment approach is successful. For these reasons, in the proposed rule we stated our belief that it would be necessary 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 payments made for services billed under the professional RO Model-specific HCPCS codes.

We solicited comment on our proposal to waive the MIPS payment adjustment factors. The following is a summary of the public comments received on this proposal and our response:

Comment: Many commenters disagreed with this proposal, arguing that it would unfairly penalize clinicians for their efforts to comply with MIPS requirements, particularly in MIPS performance years 2018 and 2019, prior to the Model start. In particular, clinicians who performed well in MIPS believed that waiving MIPS payment adjustments would result in lower RO Model payments than they were due, based on their positive performance in MIPS.

Response: We understand commenters' concerns regarding fair payment for participation in MIPS. Upon further consideration, we are not finalizing our proposal to waive the MIPS payment adjustment factors for the PC of RO Model payments. We believe the concerns raised by commenters outweigh our original policy rationale in that CMS does not want to create a general disincentive for participation in Advanced APMs by waiving MIPS Adjustments that may positively impact RO participants' payments. As such, we are finalizing that the MIPS payment adjustment factors will apply to participant-specific professional episode payments for the PC of RT services furnished by a MIPS eligible clinician. The MIPS payment adjustment factors will also continue to apply to RO participants' payments for covered professional services furnished by a MIPS eligible clinician that are outside the RO Model as they usually

would. Because we expect that the RO Model will be an Advanced APM, we anticipate 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).

After considering public comments, we are finalizing our proposal at § 512.280(c) with modification to only waive the MIPS payment adjustment factors for the TC of RO Model payments. We are not finalizing our proposal to waive the MIPS payment adjustment factors for the PC of RO Model payments. We have modified the text of the regulation at § 512.280(c) to more closely align with the proposed policy as described in the preamble to the proposed rule. 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 Technical Component Payments in Calculation of the APM Incentive Payment Amount

In the proposed rule, we stated that we believed that it would be necessary for purposes of testing the RO Model to exclude payments for the technical RO Model-specific HCPCS codes (to the extent they might be considered payments for covered professional services as defined in section 1848(k)(3)(A) of the Act) from the "estimated aggregate payment amounts for covered professional services" used to calculate the APM Incentive Payment amount under § 1833(z)(1)(A) of the Act and codified at 42 CFR 414.1450(b). We specifically believe it is necessary to exclude the technical RO Model-specific HCPCS codes from the calculation of estimated aggregate payments for covered professional services as defined in 42 CFR 414.1450(b)(1). The RO Model HCPCS codes are split into a professional component and a technical component to reflect the two types of services provided in the Model by the three

different RO participant types: PGPs, HOPDs, and freestanding radiation therapy centers, across different service sites. RO participants will bill the Model-specific HCPCS codes that are relevant to their RO participant type.

In the proposed rule, we discussed our belief that this waiver was necessary because, under 42 CFR 414.1450, 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 as defined in section 1848(k)(3)(A) of the Act. The technical RO Model-specific HCPCS codes include the codes that we have developed to bill the services on the included RT services list that are considered "technical" (those that represent the cost of the equipment, supplies and personnel used to perform the procedure).

If the requirement to include payments for the technical RO Model-specific HCPCS codes in the calculation of the APM Incentive Payment amount were not waived, PGPs furnishing RT services in freestanding radiation therapy centers (which are paid under the PFS) participating in the Model will have technical RT services included in the calculation of the APM Incentive Payment amount, but PGPs furnishing RT services in HOPDs (which are paid under OPPS) participating in the Model would not have technical RT services included in the calculation of the APM Incentive Payment amount. We believe these potential differences between participant-specific technical episode payments processed and made under the PFS and those made under the OPPS would be problematic for the Model test by creating potentially misaligned incentives between and among RO participants, as well as other challenges for the Model evaluation. Specifically, we believe that, without this waiver, some RO 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 technical episode payments, producing unwarranted increases in their APM Incentive Payment amount. In the proposed rule, we discussed our belief that this would prejudice the model testing of site neutral payments as well as potentially interfering with the Model's design to incentivize participants to preserve or improve quality by tying performance to incentive payments if participant behavior is focused on maximizing the APM Incentive Payment.

For these reasons, we stated our belief that it would be necessary to waive the requirements of 42 CFR 414.1450(b) to the extent they would require inclusion of the technical RO Model-specific HCPCS codes as covered professional services when calculating the APM Incentive Payment amount.

We solicited public comments on our proposal to exclude the Technical Component from the APM Incentive Payment calculation. The following is a summary of the public comments received on this proposal and our response:

Comment: Many commenters disagreed with this proposal, stating that not including the TC in the payment amount used to calculate the APM Incentive Payment could make it difficult to offset any reduced payments that occur as a result of RO Model participation. Several commenters stated that not including the TC in the APM Incentive Payment calculation undercuts the spirit and letter of MACRA's intent of encouraging clinicians to assume risk and participate in APMs. These commenters stated this was the case because a lower APM Incentive Payment, resulting from exclusion of the TC in the payment calculation, would fail to adequately compensate eligible clinicians for participation in the RO Model, which is an Advanced APM. A few commenters suggested including a portion of the TC payment in the APM Incentive calculation, as opposed to none of it.

Response: We disagree with commenters' recommendations to include part or all of the TC in the payment amount used to calculate the APM Incentive Payment. The reasons for this policy are threefold. First, the TC payment of the RO Model is, generally speaking, not a payment for professional services. Rather, it is a payment for technical services (those that represent the cost of equipment, supplies, and personnel used to perform a procedure). We do not believe it would be appropriate under the RO Model for payments for technical services to be included in the APM Incentive Payment calculation. Second, inclusion of the TC payment of the RO Model in the APM Incentive Payment calculation would potentially prejudice the Model testing of site neutral payments, since PGPs furnishing RT services in HOPDs (which are paid under OPPS) would not have the TC included in the calculation. We believe that if we included the TC payment of the RO Model in the APM Incentive Payment calculation, we would create a situation that may inadvertently incentivize Professional participants to change their treatment pathways so that TC services are furnished in a freestanding radiation therapy center instead of an HOPD in an attempt to increase the amount of services rendered that would count towards their APM Incentive Payment. By not including the TC payment of the RO Model in the APM Incentive Payment calculation, we will be treating the TC payment the same no matter where the location the service is rendered and thus preventing potentially prejudicing the Model testing of site neutral payments.

After considering public comments, we are finalizing our 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. Additionally, we would note that we have revised our projections regarding the number of expected QPs in the RO Model to also include physicians participating

in the RO Model who we would expect to qualify as partial QPs under the Quality Payment Program.

d. General Payment Waivers

In the proposed rule, we discussed our belief that it is necessary for purposes of testing the RO Model to waive requirements of certain sections of the Act, specifically with regard to how payments are made, in order to allow the RO Model's prospective episode payment to be fully tested. Therefore, we 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 professional and technical component payments for RT services to be made as set forth in the RO Model. We believe that waiving section 1848(a)(1) of the Act will be necessary because otherwise many of the RO Model payment rates will be set by the PFS;

- 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 technical component services to be paid as set forth in the RO Model because otherwise the participant-specific technical episode payment will be set by the OPPS (we note that the waiver of OPPS payment will be limited to RT services under the RO Model); and

- Section 1833(t)(16)(D) of the Act regarding payment for stereotactic radiosurgery (a type of RT covered by the RO Model) to allow the payments for technical component services to be paid as set forth in the RO Model because RO Model payment amounts would be modality agnostic and episodic such that all treatments and duration of treatment for this cancer type are paid the same amount.

We proposed to waive these requirements because these statutory provisions establish the current Medicare FFS payment methodology. Without waiving these specific provisions of the Act, we would not be able to fully test whether the prospective episode pricing methodology tested under the RO Model (as discussed in section III.C.6 of this final rule) was effective at reducing program expenditures while preserving or enhancing the quality of care. Specifically, the RO Model will test whether adjusting the current fee-for-service payments for RT services to a prospective episode-based payment model will incentivize physicians to deliver higher-value RT care. Without waiving the requirements of statutory provisions that currently determine payments for RT services, payment for RT services would be made using the current FFS payment methodology and not the pricing methodology we are testing through the Model.

We solicited public comments on the general payment waivers. The following is a summary of the public comments received on this proposal and our response:

Comment: Some commenters stated that CMS will not be able to fully test the RO Model as proposed unless CMS also waives section 1833(t)(2)(H) of the Act, which provides that "with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered [outpatient department services] that classify such devices separately from the other services (or group of services)" paid under the OPPS "in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007."

Response: We appreciate these comments and agree that in order to finalize the RO Model as proposed a waiver of section 1833(t)(2)(H) is necessary. In particular, section 1833(t)(2)(H) requires separate payment for devices of brachytherapy, but the RO Model will

utilize episode-based payment, which means that CMS will make a single payment for the radiation service including for brachytherapy and any other services that were furnished as part of the episode.

Comment: A commenter stated that CMS should not waive section 1833(t)(2)(H) of the Act, but should instead incorporate the requirements of that provision into the proposed RO Model by paying separately for brachytherapy sources outside of the RO Model payment bundles using Medicare's current system of coding and reimbursement for brachytherapy sources.

Response: We appreciate the comment, but disagree that we should pay separately in the RO Model for brachytherapy source payments provided in HOPDs. One of the primary objectives for the RO Model is to test an episode-based payment. Without waiving this provision, we would not be testing the RO Model as an episode-based payment model as proposed and intended.

We received no comments on the general payment waivers we proposed and therefore are finalizing these provisions without modification. Additionally, after considering public comments, we are also finalizing an additional waiver of section 1833(t)(2)(H) of the Act as some commenters have suggested. This provision requires separate payment of brachytherapy sources provided in HOPDs. As we are testing new payment methodologies for RT services including brachytherapy sources provided in HOPDs, we believe that it is necessary to waive this provision of the Act.

e. Waiver of Appeals Requirements

In the proposed rule, we discussed our belief that it was necessary for purposes of testing the RO Model to waive section 1869 of the Act specific to claims appeals to the extent otherwise

applicable. We proposed to implement this waiver so that RO participants may utilize the timely error and reconsideration request process specific to the RO Model in section III.C.12 of this rule to review potential RO Model reconciliation errors. We noted in the proposed rule that, if RO participants have general Medicare claims issues they wish to appeal (Medicare claims issues experienced by the RO participant that occur outside the scope of the RO Model, but during their participation in the RO Model), then the RO participants should continue to use the standard CMS claims appeals procedures under section 1869 of the Act.

We proposed to implement this waiver because the pricing methodology for the RO Model is unique and as such we have developed a separate timely error notice and reconsideration request process that RO participants will use in lieu of the claims appeals process under section 1869 of the Act.

In section III.C.12 of the proposed rule (84 FR 34528 through 34529), we discussed the process for RO participants to contest the calculation of their reconciliation payment amounts, the calculation of their reconciliation repayment amounts, and the calculation of their AQS. Reconciliation payment amount means a payment made by CMS to an RO participant as determined in accordance with § 512.285. This process would ensure that individuals involved in adjudicating these timely error notices and reconsideration requests on these issues would be familiar with the payment model being implemented and would ensure that these issues are resolved in an efficient manner by individuals with knowledge of the payment model.

Our proposal does not limit Medicare beneficiaries' right to the claims appeals process under section 1869. We noted, in the specific circumstance wherein a health care provider acts on behalf of the beneficiary in a claims appeal, section 1869 applies.

We solicited public comments on the waiver of appeal requirements. The following is a summary of the public comments received on this proposal and our response:

Comment: A commenter supported the fact that our proposal does not limit Medicare beneficiaries' right to the claims appeals process under section 1869. The commenter believed it is imperative that RO beneficiaries have the same rights as other Medicare beneficiaries to appeal coverage decisions they believe to be unfounded.

Response: We appreciate the commenter's support.

After considering public comments, we are finalizing, without modification, our proposed waiver of appeals requirements, specifically to waive section 1869 of the Act specific to claims appeals for RO Model claims

f. Waiver of Amendments Made by Section 603 of the Bipartisan Budget Act of 2015

In the proposed rule, we discussed our belief that it was necessary for purposes of 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 identified by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), which amended section 1833(t)(1)(B)(v) of the Act and added paragraph (t) (21) to the Social Security Act. Sections 1833(t)(1)(B)(v) and (t) (21) of the Act exclude certain items and services furnished by certain off-campus provider-based departments (non-excepted off-campus provider-based departments (PBDs)) from the definition of covered outpatient department services for purposes of OPPS payment, and direct payment for those services to be made "under the applicable payment system" beginning January 1, 2017. We established the PFS as the "applicable payment system" for most non-excepted items and services furnished in non-excepted off-campus PBDs (81 FR 79699) and, in order to facilitate payment under the PFS, we apply a PFS relativity adjuster that is currently set at 40 percent of

the OPPS rate (82 FR 53027). We also require OPDs to use the modifier "PN" on applicable OPPS claim lines to identify non-excepted items and services furnished in non-excepted off-campus PBDs. The modifier triggers application of the PFS relativity adjuster in CMS' claims processing systems.

Under the RO Model, we proposed to waive requirements under section 1833(t)(1)(B)(v) and (t)(21) of the Act for all RO Model-specific payments to applicable OPDs. If a non-excepted off-campus PBD were to participate in the RO Model, it would be required to submit RO Model claims consistent with our professional and technical billing proposals in section III.C.7. In addition, we proposed to not apply the PFS relativity adjuster to the RO Model payment and instead pay these participants in the same manner as other RO participants because the RO Model pricing methodology's design as discussed in section III.C.6.c of this final rule sets site-neutral national base rates, and adding the PFS relativity adjuster to the RO Model payment for RO participants that are non-excepted off-campus PBDs would disrupt this approach and introduce a payment differential. In the proposed rule, we discussed our belief that 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.

We solicited public comments on payment waivers. We received no comments on this policy and are finalizing it as proposed.

11. Reconciliation Process

We proposed that we would conduct an annual reconciliation for each RO participant after each PY to reconcile payments owed to the RO participant with payments owed to CMS due to the withhold policies discussed in section III.C.6.g of the proposed rule (84 FR 34527). We proposed that this annual reconciliation would occur in the August following a PY in order

to allow time for claims run-out, data collection, reporting, and calculating results.[78]

In the example we provided in the proposed rule, the annual reconciliation for PY1 would apply to episodes initiated January 1, 2020 (or April 1, 2020) through December 31, 2020, and the annual reconciliation for PY1 would occur in August of 2021. We stated that an annual reconciliation is appropriate because incomplete episodes and duplicate RT services as described in section III.C.6.a of the proposed rule and this final rule may result in additional payment owed to an RO participant or owed to CMS for RT services furnished to an RO beneficiary in those cases.

The following is a summary of the comments we received on the proposal for the annual reconciliation to occur in August following a PY and our responses to these comments:

Comment: 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. A commenter requested that CMS prospectively reimburse RO participants for their payment withholds to ensure that they do not have a gap in revenue. Another commenter recommended that reconciliation should be conducted every six months. Another commenter suggested that the RO Model implement a reconciliation to occur immediately following the performance year with a final reconciliation to account for claims runout.

Response: Changes made elsewhere in this final rule reduce the financial burden associated with the timing of reconciliations. Specifically, as noted in section III.C.6.g of this final rule, we will reduce the incorrect payment withhold from 2 percent to 1 percent and not

[78] Claims run-out is the period of time that CMS allows for the timely submission of claims by providers and suppliers before reconciliation.

begin the quality withhold until PY1. The patient experience withhold will not begin until PY3. If reconciliation were to be conducted every six months, this would require RO participants to submit quality measure data more frequently, which would increase provider burden.

We would like to clarify that we are adding 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. We also are finalizing the definition of "true-up reconciliation" at § 512.205 to mean the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run out for all RO episodes initiated in the applicable PY. We also would like to clarify that the true-up reconciliation process is only related to the incorrect payment withhold, and we will not conduct a true-up reconciliation for the quality withhold or the patient experience withhold.

Moreover, an additional reconciliation, if done a few months prior to what we call the initial reconciliation before allowing for a reasonable claim run-out, would be based on incomplete data. We believe this would unduly complicate the reconciliation process. In the case of an initial reconciliation, CMS calculations will use claims data available at that time for claims run-out and expect to provide RO participants with a reconciliation report in August of the subsequent year following the applicable PY. With respect to the concerns about patient access to care, the commenter did not explain how the timing of reconciliation in a mandatory model would affect patient access to care. We do not expect that reconciliation timing will have any impact on patient access to care. With respect to the commenter who requested that CMS prospectively reimburse RO participants for their payment withholds, we understand the commenter to be requesting that CMS eliminate the payment withhold. We decline to do so

because the withhold reserves money for purposes of reconciling duplicate RT services and incomplete episodes, which protects the financial integrity of the model and reduces any immediate negative financial impact on RO participants due to reconciliation. As a result of the stop-loss policy described in section III.C.6.e(4) we are finalizing this provision with modification to add a stop-loss reconciliation amount to the reconciliation process, as codified at § 512.285(f). We would like to clarify that we are adding a definition at § 512.205 for "stop-loss reconciliation," which means the amount owed to RO participants that have fewer than 60 episodes during 2016-2018 for the loss incurred under the Model and were furnishing included RT services at [insert date 60 days after the date of publication in the **Federal Register**] in the CBSAs selected for participation as described in § 512.285(f).

We have also modified the text of the regulation at § 512.285 to describe how reconciliation payments and repayment amounts are calculated and what details are provided in the reconciliation report as described in the preamble to the proposed rule. We have made a number of non-substantive editorial and organizational changes to streamline and improve the clarity of the regulation text at § 512.285. We note that the proposed rule indicated that reconciliation would occur annually in August. Although this final rule provides that reconciliation will occur annually, we are removing the language indicating that reconciliation will always occur in August, and instead state that initial reconciliation could occur as early as August, because we may require additional flexibility depending on the availability of data and other considerations. If the RO participant fails to timely pay the full repayment amount, CMS will recoup the repayment amount from any payments otherwise owed by CMS to the RO participant, including Medicare payments for items and services unrelated to the RO Model, and interest will be charged in accordance with 42 CFR 405.378.

a. True-Up Process

We proposed that we would conduct an annual true-up of reconciliation for each PY. We proposed to define the term "true-up" as the process to calculate additional payments or repayments for incomplete episodes and duplicate RT services that are identified after claims run-out. More specifically, we proposed that we would true-up the PY1 reconciliation approximately one year after the initial reconciliation results were calculated. This would align the PY2 reconciliation of the following year with the PY1 true-up, thereby allowing for a full claims run-out on PY1, and reducing any potential confusion for RO participants that may be caused by receiving multiple reconciliation reports in close succession. We proposed to follow the same process for each subsequent performance year. Under our proposal, we would conduct a true-up of PY1 in August 2022, a true-up of PY2 in August 2023, and so forth.

We solicited public comments on our proposal for a true-up process. The following is a summary of the comment we received on our proposal and our response to the comment:

Comment: A commenter recommended eliminating the true-up process to streamline the reconciliation process.

Response: We thank this commenter for the suggestion. We believe that the true-up process requires little effort on the part of RO participants and that it is necessary to properly account for additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after a full 12-month claims run-out. Eliminating the true-up process could lead to a gaming opportunity where RO participants might wait to submit claims until after the claims run-out period used in the first reconciliation for a PY. The net reconciliation payment or repayment amount owed for the PY is the sum of (h)(1) and (f)(2) in the reconciliation example provided in section III.C.11.b. We are finalizing this provision

concerning the true-up process with modification to codify the true-up process at § 512.285(g). We note that in the proposed rule we provided examples of the timing of the PY1 and PY2 true-ups. Given the change in the Model performance period, we are clarifying that we will conduct the PY1 true-up reconciliation as early as August 2023, and the PY2 true-up reconciliation as early as August 2024, and so forth. While we have every expectation that all reconciliations and true-up reconciliations will occur in August, we recognize that in exceptional circumstances, there could be a modest delay in performing such reconciliations. For this reason, we are revising the regulation text at §512.285(a) to remove reference to conducting annual reconciliations "in August."

We are finalizing our 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 reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY." Specifically, the proposed definition has been revised to replace the term "payments or repayments" with the defined terms "reconciliation payments" and "repayment amounts." In addition, we have replaced the phrase "that are identified after claims run-out" with the more precise "that are identified after initial reconciliation" and included the time frame for claims run-out.

b. Reconciliation Amount Calculation

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

• Calculate the incorrect episode payment amount. We proposed to 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 RO episodes furnished during that PY by that RO participant).[79] This would determine the amount owed to the RO participant by CMS based on total payments made to the RO participant for incomplete episodes and duplicate RT services for a given PY, if applicable. An 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.

• For Professional participants during the Model's performance period: We proposed that if the RO participant is a Professional participant, then we would add the Professional participant's incorrect episode payment amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the participant's AQS (as a percentage) against the total two-percentage point maximum amount as described in section III.C.8.f(2).

• For Technical participants in PY1 and PY2: We proposed that if the RO participant is a Technical participant then the Technical participant's reconciliation amount would be equal to the incorrect episode payment amount. There would be no further additions or subtractions.

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[79] Please note that the final rule reduced the incorrect payment withhold amount from the proposed 2 percent to 1 percent, discussed in section III.C.6.g of this final rule.

• For Technical participants in PY3, PY4, and PY5: We proposed to add the Technical participant's incorrect episode payment amount to the patient experience reconciliation amount, in section III.C.6.g(3). Technical participants and Dual participants could earn up to the full amount of the patient experience withhold (1 percent of the technical episode payment amounts) for a given performance year based on their results from the patient-reported CAHPS® Cancer Care Radiation Therapy Survey.

• For Dual participants in PY1 and PY2: We proposed to add the Dual participant's incorrect episode payment amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the Dual participant's AQS (in percentage terms) against the total two-percentage point maximum withhold amount as described in section III.C.8.f(2).

• For Dual participants in PY3, PY4, and PY5: We proposed to add the Dual participant's incorrect episode payment amount to the quality reconciliation amount. The quality reconciliation amount would be determined by multiplying the participant's AQS (in percentage terms) against the total two-percentage point maximum withhold amount as described in section III.C.8.f(2). Then, we would add the Dual participant's patient experience reconciliation amount to this total.

The geographic adjustment and the 2 percent adjustment for sequestration would be applied to the incorrect payment withhold, quality withhold, and patient experience withhold amounts during the reconciliation process. Beneficiary coinsurance would be waived for the reconciliation payment and repayment amounts, meaning that the RO participant may not collect

20 percent of what is owed to CMS from the RO beneficiary, and CMS will not collect 20 percent of what it owes the RO participant from the RO beneficiary.

We provided an example reconciliation calculation for a Professional participant in Table 10 of the proposed rule. The numbers listed in that table are illustrative only. In the example in the proposed rule, the incorrect payment withhold amount for the Professional participant would be $6,000 or 2 percent of $300,000 (the total payments for the participant after the trend factor, adjustments, and discount factor have been applied). The Professional participant would owe CMS $3,000 for duplicate payments due to claims submitted on behalf of beneficiaries who received RT services by another RT provider or RT supplier during their RO episode. Lastly, the Professional participant would owe CMS $1,500 for cases of incomplete episodes whereby the PC of the RO episode was billed and due to death or other reason, the TC was not billed by the time of reconciliation. In the example in the proposed rule, the payments for duplicate RT services and incomplete episodes would be subtracted from the incorrect payment withhold amount to render $1,500 due to the RO participant from CMS for the incorrect episode payment amount (a). This amount would then be added to the quality reconciliation amount (b). The quality withhold amount for this RO participant would be $6,000 or 2 percent of $300,000. This RO participant's performance on the AQS would entitle them to 85 percent of the quality withhold, and, therefore, when the quality reconciliation amount (b) is added to the incorrect payment withhold amount (a), and a total reconciliation payment of $6,600 (c) is due to the RO participant from CMS for that performance year. We note that the example in the proposed rule does not include the geographic adjustment or the 2 percent adjustment for sequestration.

We solicited public comment on our proposal on calculating reconciliation amounts. The following is a summary of the comments we received on our proposal and our responses to these comments:

Comment: A commenter requested clarification as to how beneficiary coinsurance would be accounted for in reconciliation and repayment amounts, stating that there are conflicting interpretations of "waiving" beneficiary coinsurance.

Response: To clarify, we are waiving the beneficiary coinsurance obligation when an RO participant owes CMS money (repayment amount) or CMS owes the RO participant money (reconciliation payment). Thus, no beneficiary coinsurance will be collected on these amounts. We have clarified our regulation text on this issue at § 512.285(i)(3). We will provide RO participants with additional instructions for billing, particularly as it pertains to how beneficiary coinsurance will be accounted for in reconciliation. Additional instructions will be made available through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

Comment: A commenter requested that detailed information be provided on reconciliation reports so that RO participants could attribute data by clinician and category.

Response: We thank the commenter for this suggestion and we will take this into consideration as we design the reconciliation reports.

After considering public comments on section III.C.11 of the proposed rule, we are finalizing our 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. Please note that because of the change to the incorrect payment withhold in this final rule, described in

section III.C.11 of this rule, we have provided an updated example reconciliation calculation for a Professional participant in Table 14, which reflects that change. The numbers listed in the table are illustrative only. In this example, the total incorrect payment withhold amount for this Professional participant is $3,000 or 1 percent of $300,000 (the total payment amounts for the RO episodes initiated in the PY for this RO participant after the trend factor, adjustments, and discount factor have been applied). The Professional participant owes CMS $3,000 for duplicate RT services due to claims submitted on behalf of RO beneficiaries who received any included RT services (duplicate RT services) from another RT provider or RT supplier during their RO episode. Lastly, in this example, the Professional participant owes CMS $1,500 for cases of incomplete episodes where the PC of the RO episode was billed, and due to death or another reason, the TC was not billed by the time of reconciliation and for cases of incomplete episodes where the RO beneficiary switched RT provider or RT supplier before all the included RT services in the RO episode had been furnished. In this example, the payments for duplicate RT services and incomplete episodes would be subtracted from the incorrect payment withhold amount to render $1,500 due to CMS from the RO participant for the incorrect episode payment amount (a). This amount is then added to the quality reconciliation amount (b). The quality withhold amount for this participant is $6,000 or 2 percent of $300,000. This RO participant's performance on the AQS entitles him or her to 85 percent of the quality withhold, and, therefore, when the quality reconciliation amount (b) is added to the incorrect payment withhold amount (a), and a total reconciliation payment of $3,600 (d) is due to the RO participant from CMS for that performance year. We note that in this example the RO participant did not qualify to receive a stop-loss reconciliation amount (c) as codified at § 512.285(f) and, therefore, no value is listed.

We note that this example does not include the geographic adjustment or the 2 percent adjustment for sequestration.

We are finalizing the reconciliation process at § 512.285 as proposed with the following clarification: CMS uses the reconciliation process to identify any reconciliation payment owed to an RO participant or any repayment amount owed by an RO participant to CMS. For instance, in the case where the SOE for the PC is billed, yet the SOE for the TC is not billed, CMS will owe the RO participant only the FFS amount for the RT services included in the PC that was billed by the RO participant for that RO beneficiary. If, in this case, the RO participant was paid $2,000 for the first episode payment of the PC and only furnished one planning service, which under FFS would be reimbursed at $200, and no SOE for the TC was billed within 28 days, then the RO participant's repayment amount would be $1,800 for this RO episode, and this would be accounted for during reconciliation. Also, for any incomplete episode that is reconciled to FFS amounts because the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished, the RO beneficiary owes the RO participant(s) that initiated the PC or TC 20 percent of the FFS amount for the RT services that were furnished during that RO episode, not 20 percent of the episode bundled payment (see section III.C.6.i of this final rule). For any RO episode that involves one or more duplicate RT services, the payment for the RO participant that initiated the PC or TC will be reconciled by reducing the RO participant's episode payment by the FFS amount of the duplicate RT services furnished by the RT provider or RT supplier that did not initiate the PC or TC.

This means that for any RO episode that involves one or more duplicate RT services, the RO participant that initiated the PC or TC is owed the bundled payment less the FFS amount for the RT services furnished by the RT provider or RT supplier that did not initiate the PC or TC.

The other RT provider or RT supplier that furnished RT services to that beneficiary, whether an RO participant or not, will be paid FFS for those RT services. The FFS amount to be subtracted from the bundled payment of the RO participant that initiated the PC or TC of that RO episode, however, cannot exceed the participant-specific professional episode payment amount or the participant-specific technical episode payment amount that the RO participant received for the RO episode. If the FFS amount to be subtracted for duplicate RT services exceeds the participant-specific professional episode payment amount or the participant-specific technical episode payment amount, CMS will not subtract more than the participant-specific professional episode payment amount or participant-specific technical episode payment amount received by the RO participant.

**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

In the proposed rule, we stated that we believed it would be necessary to implement timely error notice and reconsideration request processes under which RO participants may dispute suspected errors in the calculation of their reconciliation payment amount or repayment amount (in section III.C.11 of the proposed rule and this final rule), or AQS (in section III.C.8.f of the proposed rule and this final rule) as reflected on an RO reconciliation report that has not been deemed final. Therefore, we 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. We note that, if RO participants have Medicare FFS claims or decisions they wish to appeal (that is, Medicare FFS issues experienced by the RO participant that occur outside the scope of the RO Model but during their participation in the RO Model), then the RO participants should continue to use the standard CMS procedures through their Medicare Administrative Contractor.

Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims decisions made by CMS. However, we proposed that we would waive the requirements of section 1869 of the Act specific to claims appeals as necessary solely for purposes of testing the RO Model. Specifically, we believe it would be necessary to establish a means for RO participants to dispute suspected errors in the calculation of their reconciliation payment amount, repayment amount, or AQS. Having RO participants utilize the standard claims appeals process under section 1869 of the Act to appeal the calculation of their reconciliation payment amount, repayment amount, or AQS would not lead to timely resolution of disputes because MACs and other CMS officials would not have access to beneficiary attribution data, and the standard claims appeals process hierarchy would not engage the

Innovation Center and its contractors until late in the process. Accordingly, we proposed a two-level process for RO participants to request reconsideration of determinations related to calculation of their reconciliation payment, repayment amount, or AQS under the RO Model. The first level would be a timely error notice process and the second level to be reconsideration review process, as subsequently discussed. The processes here are based on the processes implemented under certain models currently being tested by the Innovation Center.

As proposed, only RO participants may utilize the first and second level of the reconsideration process, unless otherwise stated in other sections of this subpart. We believe that only RO participants should be able to utilize the process because non-participants would not receive calculation of a reconciliation payment amount, repayment amount, or AQS, and would generally have access to the section 1869 claims appeals processes to appeal the payments they receive under the Medicare program.

1. Timely Error Notice

As we explained in the proposed rule, in some models currently being tested by the Innovation Center, CMS provides model participants with a courtesy copy of the settlement report for their review, allowing them to dispute suspected calculation errors in that report before the payment determination is deemed final. Other models currently being tested by the Innovation Center make model-specific payments in response to claims or on the basis of model beneficiary attribution that are similarly subject to a model-specific process for resolving disputes. In some models currently being tested by the Innovation Center, these reconsideration processes involve two levels of review.

Building off of these existing processes, we proposed for the first level of the reconsideration process to be a timely error notice. Specifically, 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 under the terms of this part. As proposed, the RO participant would have 30 days from the date the RO reconciliation report is issued to provide their timely error notice (see § 512.290). This would be subject to the limitations on administrative and judicial review as previously described in section II.K. Specifically, an RO participant could not use the timely error notice process to dispute a determination that is precluded from administrative and judicial review under section 1115A(d)(2) of the Act and § 512.170. We proposed that this 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, we 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 would reserve the right to an extension upon written notice to the RO participant. We proposed to codify this timely error notice policy at § 512.290(a).

We solicited comment on this proposal. The following is a summary of the public comments received on this proposal and our response:

Comment: Two commenters requested additional time to review reconciliation reports and submit potential errors to CMS. A commenter suggested extending the timeline to a 90-day period for participants to review and submit a timely error notice. Another commenter suggested extending the timeline to a 45-day period for participants to review and submit a timely error notice.

Response: We agree with commenters that providing additional time may benefit some RO participants in identifying and understanding calculation errors. We would note that increasing the timeline to 45 days, as a commenter suggested, would align our processes with those used in the CJR model. We want to reiterate that we are committed to paying RO participants accurately and correctly and believe that the calculation error process serves an important function in achieving that goal. The procedures for processing and issuing reconciliation payment amounts and repayment amounts that we are finalizing in section III.C.11 of this final rule require specific timeframes in order to process these payments properly and promptly. As such we believe the need for extending the deadline for submission of notices of calculation error should be balanced with our goal to issue reconciliation payment amounts and repayment amounts promptly. Therefore, to address the commenters' concerns while balancing our need to finalize payment determinations promptly, this final rule provides that a notice of calculation error must be received by CMS within 45 days after the issuance of a reconciliation report.

After considering public comments, we are finalizing our 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). Additionally, we are modifying the regulatory text at § 512.290(a) to align the regulatory text with the proposal discussed in the preamble of the proposed rule that would permit RO participants to contest errors found in the RO reconciliation report, but not the RO Model pricing methodology or AQS methodology. We are removing proposed § 512.290(a)(4), which stated that an RO participant must have submitted a timely error notice on an issue not precluded from administrative or judicial review as a

condition of using the reconsideration review process described in § 512.290(b). That provision is unnecessary because § 512.290(b) specifies that the reconsideration process may be invoked only to contest CMS' response to a timely error notice. Finally, we have made technical changes in § 512.290(a) to refer to the timely error notice in a consistent manner.

2. Reconsideration Review

We also proposed a second level of the reconsideration process that would permit RO participants to dispute CMS' response to the RO participant's identification of errors in the timely error notice, by requesting a reconsideration review by a CMS reconsideration official. As is the case for many models currently being tested by the Innovation Center, we proposed that the CMS reconsideration official will be a designee of CMS who is authorized to receive such requests who was not involved in the responding to the RO participant's timely error notice. To be considered, we proposed that the reconsideration review request must be submitted to CMS within 10 days of the issue date of CMS' written response to the timely error notice. The reconsideration review request would be submitted in a form and manner specified by CMS.

As there will not otherwise be a timely error notice response for the reconsideration official to review, in order to access the reconsideration review process, we proposed that an 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. Specifically, where the RO participant does not timely submit a timely error notice with respect to a particular reconciliation payment amount, reconciliation repayment amount, or AQS, we proposed that the reconsideration review process would not be available to the RO participant with respect to the RO participant's reconciliation payment amount, the

calculation of the RO participant's repayment amount, or the calculation of the RO participant's AQS.

In the proposed rule, we explained that if the RO participant did timely submit a timely error notice and the RO participant is dissatisfied with CMS' response to the timely error notice, the RO participant would be permitted to request reconsideration review by a CMS reconsideration review official. To be considered, we proposed that the reconsideration review request must be submitted within 10 days of the date of CMS's response to the timely error notice and must provide a detailed explanation of the basis for the dispute, including 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.

As proposed, the reconsideration review would be an on-the-record review (a review of the memoranda or briefs and evidence only) conducted by a CMS reconsideration official. 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. In the proposed rule, we proposed that 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. As this would be the final step of the Innovation Center administrative dispute resolution process, we proposed that the determination made by the CMS reconsideration official would be binding and not subject to further review. This reconsideration review process is consistent with other resolution processes used throughout the agency. We proposed to codify this reconsideration review process at § 512.290(b).

We solicited public comment on our provisions regarding the reconsideration review process. The following is a summary of the public comments received on this proposal and our responses to these comments:

Comment: A few commenters requested additional time for RO participants to submit a reconsideration request.

Response: We appreciate these comments and are sympathetic to the requests from commenters for more time for RO participants during the reconsideration review process, however we believe our modification to the timeline of the timely error notice deadline allows RO participants more time to contemplate their error notice because we have given them more time to flesh out the issues before submitting a timely error notice. Further, with the extended timeline for submission of timely error notices and the 10-day deadline for reconsideration requests is consistent with the timelines around timely error and reconsideration requests in the CJR Model.

We are committed to paying RO participants accurately and correctly and believe that the timely error and reconsideration review processes as proposed serve an important function in achieving that goal. The procedures for processing and issuing reconciliation payment amounts and repayment amounts that we are finalizing in section III.C.11 of this final rule require specific timeframes in order to process these payments properly and promptly. Similar processes have

been developed and are utilized in other CMS models. As such we believe the need for extending the deadline for submission of reconsideration review requests should be balanced with our goal to issue reconciliation payment amounts and repayment amounts promptly.

Comment: A commenter suggested that CMS should be held to a similarly strict time standard for the reconsideration review process as the RO participant is. They further suggest that CMS should be strictly bound to a timeline, and not have the flexibility allowed by making all reasonable efforts to respond to the reconsideration review within 60 days of receipt of the final position paper. The commenter believes CMS and the RO participant should be given the same amount of time during their portions of the reconsideration review, and if CMS goes over that time limit, the RO participant's position should be accepted and the final payment amount, repayment amount, or AQS should reflect that.

Response: We appreciate the commenter's suggestion that we must also adhere to a time standard when responding to the RO participant during the reconsideration review process. We would reiterate that we are committed to paying RO participants accurately and correctly, and we believe that the timely error and reconsideration review processes as proposed serve an important function in achieving that goal. We note that the proposed timeline and the flexibility proposed for our final decision on the reconsideration review aligns with the timelines being utilized in other models being tested by the Innovation Center. As such, we believe the timeline as proposed is appropriate, and we will commit to sticking to the timeline as proposed unless it is wholly unreasonable for the CMS reconsideration official to fully review and decide upon the issue in the time given.

After considering public comments, we are finalizing our 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

CMS has experience with a range of efforts designed to improve care coordination and the quality of care, and decrease the cost of care for beneficiaries, including models tested under section 1115A, most of which make certain types of data available upon request to model participants. Based on the design elements of each model, the Innovation Center may offer participants the opportunity to request different types of data, so that they can redesign their care pathways to preserve or improve quality and coordinate care for model beneficiaries. Furthermore, as described in sections II.E and II.G of this final rule, we believe it is necessary for the Innovation Center to require certain data to be reported by model participants to CMS in order to evaluate and monitor the model, including the model participant's participation in the model, which could then also be used to inform the public and other model participants regarding the impact of the model on both program spending and the quality of care.

a. Data Privacy Compliance

In § 512.275(a), we proposed that as a condition of their receipt of patient-identifiable data from CMS for purposes of the RO Model, RO participants would be required to 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 other written agreement entered into by the RO participant and CMS as a condition of the RO participant receiving such data (84 FR 34530). Such laws could include, without limitation, the privacy and security standards promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as modified, and the Health Information Technology for Economic and Clinical Health Act (HITECH). Additionally, we proposed to require RO participants contractually bind all downstream

recipients of CMS data to the same terms and conditions to which the RO participant was itself bound in its agreements with CMS as a condition of the downstream recipient's receipt of the data from the RO participant. As we noted in the proposed rule, binding RO participants and their downstream recipients to such written requirements was necessary if CMS was to protect the individually identifiable health information data that it be shared with RO participants and their downstream recipients for care redesign and other forms of quality improvement as well as care coordination purposes.

The following is a summary of the public comments received on this proposal and our responses to the comments:

Comment: A commenter expressed concern that the use of third party companies to collect and analyze data on the RO participants' behalf will cause additional burdens on RO participants to ensure that no HIPAA requirements or agreement terms and conditions violations occur with the handling of patient-identifiable data by multiple parties.

Response: The requirement that RO participants contractually bind their downstream recipients in writing to comply with applicable law and the program requirements in the RO participants' agreements with CMS is necessary to protect the individually identifiable health information data. Furthermore, in the case of covered entities and their business associates, the privacy and security requirements promulgated under HIPAA, as modified, and HITECH would have applied to such parties regardless of what these program regulations provide – we merely highlighted the applicability of these and other legal mandates. Therefore, in light of our program interests and the various already applicable laws, we are finalizing this policy with references to the existing privacy and security requirements under HIPAA, as modified, and HITECH.

Comment: A commenter recommended that CMS add an additional requirement to this Model such that data related to cancer staging information be stored as discrete data in the EHR or specialty-focused health IT record, and made available to external systems through a FHIR® (Fast Healthcare Interoperability Resources)-based application programming interface.

Response: We appreciate this commenter's suggestion. We believe that the requirement that RO participants comply with all applicable laws relating to patient-identifiable data is sufficient and that adding additional requirements as suggested by the commenter at this time may present a logical outgrowth problem as well as a burden for the RO participants. However, we will take this recommendation under consideration for future rulemaking.

After considering public comments, we are finalizing 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. Although this language was included in the proposed rule's preamble text, it was inadvertently left out of the regulatory text.

b. RO Participant Public Release of Patient De-Identified Information

We did not propose to restrict RO participants' ability to publicly release patient de-identified information that references the RO participant's participation in the RO Model. In the proposed rule, we stated our belief that such information could potentially be included in press releases, journal articles, research articles, descriptive articles, external reports, and statistical/analytical materials describing the RO participant's participation and patient results in the RO Model if such information has been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b) (84 FR 34530). Those requirements define the data elements that would need to be removed to qualify as de-identified under that regulatory scheme.

However, in order to ensure external stakeholders understand that information the RO participant releases represents their own content and opinions, and does not reflect the input or opinions of CMS, we proposed to require the RO participant to include a disclaimer on the first page of any such publicly released document, the content of which materially and substantially references or relies upon the RO participant's participation in the RO Model. We proposed to codify such a disclaimer at § 512.120(c)(2) (providing "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 & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.") We proposed to require the use of this disclaimer so that the public, and RO beneficiaries in particular, are not misled into believing that RO participants are speaking on behalf of the agency.

The following is a summary of the public comment received on this proposal and our response to the comment:

Comment: We received a comment supporting our proposal to require RO participants to include a disclaimer on all descriptive model materials and activities.

Response: We thank you for your support.

After considering the public comment received on this proposal, we are finalizing this proposal without modification at § 512.275(b).

c. Data Submitted by RO Participants

In addition to the quality measures and clinical data discussed in section III.C.8 of the proposed rule (84 FR 34514 through 34522) and this final rule, we proposed that RO participants supply and/or confirm a limited amount of summary information to CMS. This information includes the RO participant's TIN in the case of a freestanding radiation therapy center and PGP,

or CCN in the case of an HOPD. We proposed to require RO participants supply and/or confirm the NPIs for the physicians who bill for RT services using the applicable TINs. In the proposed rule, we also proposed that RO participants may be required to provide information on the number of Medicare and non-Medicare patients treated with radiation during their participation in the Model. We proposed to require RO participants' submission of additional administrative data upon a request from CMS, such as the RO participant's costs to provide care (such as the acquisition cost of a linear accelerator) and how frequently the radiation machine is used on an average day; current EHR vendor(s); and accreditation status. We proposed to elicit this through annual web-based surveys. We stated in the proposed rule that we would use the data requested under the RO Model to monitor and assess participants' office activities, benchmarks, and track to participant compliance with applicable laws and program requirements. 84 FR 34530.

The following is a summary of the public comments received on this proposal and our responses to these comments:

Comment: A commenter expressed support of requiring RO participants' submission of their accreditation status.

Response: We thank this commenter for supporting this proposed policy.

Comment: A few commenters requested that comprehensive radiation oncology accreditation standards be used to ensure that the quality and compliance standards are met. One of these commenters argued that utilizing such accreditation programs as a part of CMS' monitoring and assessment to efforts to ensure compliance with legal and model agreement requirements would ensure that facilities demonstrate their systems, personnel, policies and procedures meet standards for high-quality patient care. That commenter also requested that the accreditation requirement take effect in 2024, allowing for a phase-in/transition period so that all

RO Participants could prepare and complete the RO Model review process. This commenter further requested that accreditation be used in lieu of the monitoring requirements.

Response: We agree 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. As noted earlier in this final rule, the Model must include a set of quality measures to qualify as a MIPS APM and an Advanced APM, and as such, accreditation is not able to replace the RO quality measures without compromising the Model's qualification as a MIPS APM and Advanced APM. In addition, we do not believe that accreditation provides a full picture of quality care delivery in radiation oncology. Although we are not using accreditation status as a proxy for quality, as stated in section III.C.13.c we may at some point use an optional web-based survey to gather data from participants on administrative data points, including their accreditation status, indicating the importance of this information to understanding participants' activities. To add clarity to this policy, CMS will not use the submission of accreditation status information in lieu of the quality and compliance reporting requirements. We are finalizing this policy with modification that in response to a request made by CMS, RO participants may volunteer to submit administrative data related to their accreditation status.

Comment: 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.

Response: We thank these commenters for their feedback on our proposed annual survey. We disagree with the commenter that the additional administrative data does not have a direct relation to the RO Model. As stated in the proposed rule at 84 FR 34530, the data requested will be used to better understand participants' office activities, benchmarks, and to track participant compliance with the RO Model requirements. We agree with the commenter that the data could contain proprietary information and note that we will handle the data in accordance with applicable laws, including but not limited to FOIA. In light of these commenters' concerns, we are modifying the proposal such that if additional administrative data is requested, the RO participants' submission of such administrative data will be optional.

After considering public comments, we are finalizing this proposal with 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 (30) days prior to the start of each PY, we proposed to provide RO participants with updated participant-specific professional episode payment and technical episode payment amounts for each included cancer type. RO participants, to the extent allowed by HIPAA and other applicable law, could reuse individually identifiable claims data that they request from CMS for care coordination or quality improvement work in their assessment of CMS' calculation of their participant-specific episode payment amounts and/or amounts included in the reconciliation calculations used to determine the reconciliation payment amount or repayment amount, as applicable. To seek such care coordination and quality improvement data, we proposed that RO participants should use a Participant Data Request and Attestation (DRA) form, if appropriate for that RO participant's situation, which will be available on the Radiation

Oncology Administrative Portal (ROAP). Throughout the Model performance period, RO participants may request to continue to receive these data until the final reconciliation and final true-up process has been completed if they continue to use such data for care coordination and quality improvement purposes. At the conclusion of this process, the RO participant would be required to maintain or destroy all data in its possession in accordance with the DRA and applicable law.

We proposed that the RO participant may reuse original or derivative data without prior written authorization from us for clinical treatment, care management and coordination, quality improvement activities, and provider incentive design and implementation, but would not be permitted to disseminate individually identifiable original or derived information from the files specified in the Model DRA to 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 Participant 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.

When using or disclosing PHI or personally identifiable information (PII) obtained from files specified in the DRA, we proposed that the RO participant would be required to make "reasonable efforts to limit" the information to the "minimum necessary" as defined by 45 CFR 164.502(b) and 164.514(d) to accomplish the intended purpose of the use, disclosure or request. The RO participant would be required to further limit its disclosure of such information to what is permitted by applicable law, including the regulations promulgated under the regulations

promulgated under the HIPAA and HITECH laws at 45 CFR part 160 and subparts A and E of part 164, and the types of disclosures that the Innovation Center itself would be permitted to make under the "routine uses" in the applicable systems of records notices listed in the DRA. The RO participant may link individually identifiable information specified in the DRA (including directly or indirectly identifiable data) or derivative data to other sources of individually identifiable health information, such as other medical records available to the participant and its individual practitioner. The RO participant would be authorized to disseminate such data that has been linked to other sources of individually identifiable health information provided such data has been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b).

We solicited public comment on our proposal. The following is a summary of the public comment received on this proposal and our response:

Comment: A commenter requested that CMS provide RO participants with data on a monthly basis, as this commenter believed this is the standard in other APMs. Some commenters requested that the participant-specific professional episode payment and participant-specific technical episode payment amounts for each included cancer type be provided to RO participants 90 to 180 days prior to the start of each PY. These commenters believed that 30 days in advance is inadequate to analyze the data and take appropriate action with participant partners on a timely basis.

Response: We understand these commenters' concerns, yet there are a number of reasons why CMS is unable to provide participant-specific professional episode payment and participant-specific technical episode payment amounts and these amounts 90 to 180 days prior to the start of each PY. First, certain pricing components used to determine the participant-specific

professional episode payment and technical payment amounts are derived from current Medicare rates, which are not published until November before the start of the PY for which they would apply (see section III.C.6.c(1)). Instead, as explained in section III.C.6.c(1) of this final rule, CMS will provide each RO participant its case mix and historical experience adjustments for both the PC and TC, rather than their participant-specific professional and technical episode payment amounts, because exact figures for the participant-specific professional and technical episode payment amounts will not be known to CMS prior to the start of the PY for which they would apply. Furthermore, we disagree with the commenter that it is standard practice in other APMs to provide participants with data on a monthly basis. The data provided to model participants varies across APMs and many factors contribute to the feasibility of providing such data (for example, such as scope of the model). At this time, given the scope of this Model, we believe it is impracticable to provide RO participants with data on a monthly basis. Therefore, we are finalizing with the modification that we 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).

f. Access to Share Beneficiary Identifiable Data

As discussed earlier in this final rule, in advance of each PY and any other time deemed necessary by us, we will offer the RO participant an opportunity to request certain data and reports through a standardized DRA, if appropriate to that RO participant's situation. The data and reports provided to the RO participant in response to a DRA will not include any beneficiary-level claims data regarding utilization of substance use disorder services unless the requestor provides a 42 CFR part 2-compliant authorization from each individual about whom they seek such data. While the proffered DRA form was drafted with the assumption that most

RO participants seeking claims data will do so under the HIPAA Privacy Rule provisions governing "health care operations" disclosures under 45 CFR 164.506(c)(4), in offering RO participants the opportunity to use that form to request beneficiary-identifiable claims data, we do not represent that the RO participant or any of its individual practitioners has met all applicable HIPAA requirements for requesting data under 45 CFR 164.506(c)(4). The RO participant and its individual practitioners should consult their own counsel to make those determinations prior to requesting data using the DRA form.

Agreeing to the terms of the DRA, the RO participant, at a minimum, will agree to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use of or access to it. The safeguards will be required to provide a level and scope of security that is not less than the level and scope of security requirements established for federal agencies by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix I--Responsibilities for Protecting and Managing Federal Information Resources (available at https://www.whitehouse.gov/omb/information-for-agencies/circulars/) as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems" (available at http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf); and, NIST Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (available at http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf). We proposed that 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 will be strictly prohibited. Further, the RO participant would be required to

agree that the data specified in the DRA will 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 a law. At the conclusion of the RO Model and reconciliation process, the RO participant would be required to maintain or destroy all CMS data and any individually identifiable derivative in its possession as provided by the DRA and any other applicable written agreements with CMS.

The following is a summary of the public comment received on section III.13.f of the proposed rule and our response:

Comment: A commenter requested that beneficiaries be informed, prior to participating in the RO Model, that CMS proposes to collect quality, clinical, and administrative data and would share with RO participants certain de-identified beneficiary data, and how it will be used by CMS and RO participants.

Response: For information relating to the data that CMS proposes to collect from RO participants, please see sections III.C.8, III.C.8.c (quality measures) and III.C.8.e (clinical data elements) of this rule. We are finalizing as proposed that RO participants will be required to provide beneficiaries with the beneficiary notification letter during the initial treatment planning session which will detail, among other things, the RO beneficiary's right to refuse having his or her Medicare claims data shared with the RO participant for care coordination and quality improvement purposes under § 512.225(a)(2). Beneficiaries who do not wish to have their claims data shared with the RO participant for care coordination and quality improvement purposes under the Model would be able to notify their respective RO participant; in such cases the RO participant must provide notification in writing to CMS within 30 days of when the beneficiary notifies the RO participant.

After considering public comments, we are finalizing our 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. We are codifying these policies at our regulation at § 512.275(a)-(b).

14. Monitoring and Compliance

We proposed at 84 FR 34531 that the general provisions relating to monitoring and compliance in section II.I of this rule would apply to the RO Model. Specifically, RO participants would be required to cooperate with the model monitoring and evaluation activities in accordance with § 512.130, comply with the government's right to audit, inspect, investigate, and evaluate any documents or other evidence regarding implementation of the RO Model under § 512.135(a), and to retain and provide the government with access to records in accordance with §§ 512.135(b) and (c). Additionally, CMS would conduct model monitoring activities with respect to the RO Model in accordance with § 512.150(b). In the proposed rule we discussed our belief that the general provisions relating to monitoring and compliance would be appropriate for the RO Model, because we must closely monitor the implementation and outcomes of the RO Model throughout its duration. The purpose of monitoring would be to ensure that the Model is implemented safely and appropriately; that RO participants comply with the terms and conditions of this rule; and to protect RO beneficiaries from potential harms that may result from the activities of an RO participant.

Consistent with § 512.150(b), we 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; site visits; monitoring quality outcomes and clinical data, if applicable; and tracking patient complaints and appeals. We also discussed in the proposed rule (84 FR 34531 through 34532) that we anticipated using the most recent claims data available to track utilization as described in section III.C.7 of this final rule, and beneficiary outcomes under the Model. More specifically, we proposed to track utilization of certain types of treatments, beneficiary hospitalization and emergency department use, and fractionation (numbers of treatments) against historical treatment patterns for each participant. In the proposed rule, we discussed our belief that this type of monitoring was important because as RO participants transition from receiving FFS payment to receiving new (episode-based) payment, and we noted that we want to ensure to the greatest extent possible that the Model is effective and that RO Model beneficiaries continue to receive high-quality and medically appropriate care.

Additionally, we explained in the proposed rule that we may employ longer-term analytic strategies to confirm our ongoing analyses and detect subtler or hard-to-determine changes in care delivery and beneficiary outcomes. Some determinations of beneficiary outcomes or changes in treatment delivery patterns may not be able to be built into ongoing claims analytic efforts and may require longer-term study. This work may involve pairing clinical data with claims data to identify specific issues by cancer type.

The following is a summary of the public comments received on this proposal and our responses to the comments:

Comment: A commenter expressed support of the proposed monitoring activities. Another commenter expressed support of our proposal to monitor longer-term analytic strategies to confirm ongoing analyses.

Response: We thank these commenters for their support.

Comment: A commenter requested that CMS clearly define the monitoring activities and the effect the RO Model will have on beneficiaries. This commenter has also requested details on how CMS will ensure patient stakeholder groups have access to resulting data as well as how patient advocate groups will be able to provide input on what is and is not working from the patient perspective.

Response: We believe that the RO Model will improve quality of care for RO beneficiaries receiving treatment from RO participants, and we believe that the monitoring activities as described in section III.C.14 will help us to understand whether there are any unintended consequences. As it relates to beneficiaries, we will closely monitor beneficiary and patient complaints and survey responses to determine what is or is not working during the test of the Model and to mitigate unforeseen adverse impact on RO beneficiaries. With respect to patient stakeholder groups having access to resulting data, while we did not propose to share specific data from our monitoring and oversight of the Model with patient stakeholder groups, we will consider that in future rulemaking. Additionally, as discussed in section III.C.13.b, we finalized our proposal to not restrict RO participants' ability to publicly release patient de-identified information that references the RO participant's participation in the RO Model. Thus, RO participants may share with patient stakeholder groups the information CMS shares with the RO participants based on monitoring and oversight of their performance. Therefore, patient stakeholder groups may have access to such resulting data that is released by RO participants.

We welcome input from patient advocate groups on the patient perspective on the RO Model at any time.

We note that an Annual Evaluation Report will be publicly released for each year of the RO Model, as is required for all Innovation Center models by section 1115A(b)(4). The independent evaluation will rigorously assess the impact of the RO Model on quality, expenditures, utilization, RO beneficiary and RO participant experiences with RT service use, and quality of care, as well as on costs to RO beneficiaries and to Medicare. Detailed methodologies and data sources used to create these estimates will be included in each Annual Evaluation Report (additional information on the Evaluation can be found in section III.C.16).

Comment: A commenter expressed concern that this Model will cause a shift in treatment to modalities that treat tumors with large doses of radiation over a shorter time frame, and that providers and suppliers will rapidly transition to stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) without having the proper staff or necessary equipment to safely perform such procedures. This commenter has requested that CMS implement a program to track beneficiary outcomes both in terms of survival and toxicity to avoid unintended consequences. The commenter recommended that providers and suppliers track and report this outcomes data via a Medicare Certified Quality Clinical Data Registry (QCDR) like the Registry for Performance and Clinical Outcomes in Radiology (RPCR).

Response: We thank the commenter for this comment and appreciate their concern. CMS will take these suggestions into consideration. At this time, we believe that the Model is designed in a way that we will be able to adequately monitor RO beneficiary outcomes and treatment delivery patterns to assess whether there are unintended consequences without needing

to use a Medicare QCDR. Please see section III.C.14.b for more information relating to the monitoring activities.

Comment: A commenter requested clarification regarding onsite quality and clinical element data audits.

Response: To clarify, we may utilize onsite audits, conducted by a contractor, of quality and clinical data elements to monitor RO Participants for model compliance. Audits of quality and clinical data may also be used to ensure that the Model is effective and that RO Model beneficiaries continue receiving high-quality and medically appropriate care. Site visits may be used to better understand how RO participants manage services, use evidence-based care, and practice patient-centered care. Site visit activities may include, but are not limited to, interviewing RO participant(s) and staff, reviewing records, and observing treatments.

a. Monitoring for Utilization/Costs and Quality of Care

We proposed to monitor RO participants for compliance with RO Model requirements. We anticipated monitoring to detect possible attempts to manipulate the system through patient recruitment and billing practices. The pricing methodology requires certain assumptions about patient characteristics, such as diagnoses, age, and stage of disease, based on the historical case mix of the individual participants. It also assigns payments by cancer type. Because of these features, participants could attempt to manipulate patient recruitment in order to maximize revenue (for example, cherry-picking, lemon-dropping, or shifting patients to a site of service for which the participant bills Medicare that is not in a CBSA randomly selected for participation). As explained in the proposed rule, we 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. We also intended to monitor

patient and provider and supplier characteristics, such as variations in size, profit status, and episode utilization patterns, over time to detect changes that might suggest attempts at such manipulation.

To allow us to conduct this monitoring, we proposed that RO participants would report data on program activities and beneficiaries consistent with the data collection policies in section III.C.8 of this rule. These data would be analyzed by CMS or our designee for quality, consistency, and completeness; further information on this analysis would be provided to RO participants in a time and manner specified by CMS prior to collection of this data. We would use existing authority to audit claims and services, to use the Quality Improvement Organization (QIO) to assess for quality issues, to investigate allegations of patient harm, and to monitor the impact of the RO Model quality metrics. We noted in the proposed rule that we may monitor participants to detect issues with beneficiary experience of care, access to care, or quality of care. We also indicated that we may monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns.

We solicited public comment on our proposal. The following is a summary of the public comments received on this proposal and our responses to the comments:

Comment: A commenter indicated that discriminatory practices and attempts to game the system must be prevented and eliminated.

Response: As we discussed in the proposed rule and this final rule, we are aware that RO participants might manipulate patient recruitment to maximize revenue. For that reason, we explained that we would be monitoring compliance with RO Model-specific billing guidelines and adherence to LCDs, as well as our intention to monitor patient and provider and supplier characteristics over time to detect changes that might suggest attempts at such manipulation. We

believe that the monitoring and compliance requirements will mitigate gaming and discriminatory practices by RO participants.

Comment: A commenter appreciated the decision that CMS share the planned clinical data elements and reporting standards with EHR vendors and radiation oncology specialty societies, and requested that CMS also share this information with oncology clinical pathways developers.

Response: We plan to share the clinical data elements and the reporting process publicly via the RO Model website (see sections III.C.8 and III.C.8.e of this final rule). We appreciate the suggestion specific to pathway developers and will take this into consideration.

Comment: Two commenters asked CMS to provide specifics on how it will monitor and intervene on potential unintended consequences of the Model.

Response: As we previously stated, data submitted by RO participants will be analyzed by CMS or our designee for quality, consistency, and completeness. Further information on this analysis will be provided to RO participants in a time and manner specified by CMS prior to collection of this data. We will use existing authority to audit claims and services, to use the QIO to assess for quality issues, to use our authority to investigate allegations of patient harm, and to monitor the impact of the RO Model quality metrics. We may monitor RO participants to detect issues with beneficiary experience of care, access to care, or quality of care. We may monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns. Should unforeseen consequences arise during the Model test, we will take appropriate measures, including those outlined in § 512.160 or modifying the regulatory requirements for compliance, to mitigate such consequences.

b. Monitoring for Model Compliance

We had proposed to require all participants to annually attest in a form and manner specified by CMS that they will use CEHRT throughout such PY in a manner sufficient to meet the requirements as set forth in 42 CFR 414.1415(a)(1)(i), and as stated in the proposed rule at 84 FR 34522 through 34524. In addition, we proposed that each Technical participant and Dual participant be required to attest annually that it actively participates in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). This attestation would be required to ensure compliance with this RO Model requirement. CMS may change these attestation intervals throughout the Model upon advanced written notice to the RO participants. We proposed to codify these RO Model requirements at § 512.220(a)(3). We noted that CMS may monitor the accuracy of such attestations and that false attestations will be punishable under applicable federal law, including but not limited to the remedial action set forth in §512.160(b).

In addition, we proposed to 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, and as stated in the proposed rule at 84 FR 34581 through 34582. We proposed to codify at § 512.220(a)(2) our 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 documents 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, as stated in the proposed rule at 84 FR 34585 through 34586.

The following is a summary of the public comments received on this proposal and our responses to these comments:

Comment: A commenter expressed support of the required medical record documentation regarding the goals of care, the treatment intent, the beneficiary's inclusion in the RO Model, and the cost-sharing responsibilities. This commenter urged CMS to develop and consumer test language for providers and suppliers to use in discussing these complex issues.

Response: We appreciate the commenter's support and suggestion. We will consider developing guidance materials that RO participants may use to ensure adherence to the Model requirements. Should such materials be developed, the RO participants will be notified and those materials will be made available on the RO Model website at https://innovation.cms.gov/initiatives/radiation-oncology-model/.

Comment: A commenter expressed concern that the Innovation Center would not have the resources to effectively monitor the number of proposed RO participants.

Response: We will be utilizing a contractor to effectively monitor the activities of the RO participants.

Comment: A couple of commenters expressed frustration with the EHR data reporting requirements and asserted that these requirements would be administratively burdensome for RO participants.

Response: We appreciate the commenters' concerns; however, we disagree with these commenters' argument that such reporting requirements are excessively burdensome. Many of these requirements are already being captured by RT providers and RT suppliers prior to the implementation of this Model as part of the Quality Payment Program, accreditation, licensing, and delivery of high-quality care. Furthermore, these seven medical record documentations are critical for high-quality care and necessary for evaluation of this Model. Therefore, we are finalizing this policy as proposed.

Comment: A couple of commenters requested that the EHR / medical record documentation requirements be eliminated from the Model requirements. These commenters indicated that these data elements are not always captured in discrete fields.

Response: We will not be eliminating these documentation requirements from the Model as they are a necessary component of the Model. As stated earlier in this rule's comments and responses, we believe that delaying the start date for the Model, and therefore the collection of clinical data elements, until January 1, 2021, and publishing the final rule several months before the Model performance period, will allow participants time to become comfortable with other aspects of the Model and develop best practices to facilitate their data collection and work with EHR vendors to seek additional EHR support. As such, we are finalizing the requirement that RO participants document the seven medical record documentations set forth in section III.C.14.b with the modification that this requirement begin in PY1 instead of at the start of the Model.

Comment: A commenter expressed support for the PSO participation requirement.

Response: We thank the commenter for this support.

Comment: A few commenters were concerned with the proposed requirement of attesting annually to active participation in a radiation oncology-specific PSO. These commenters requested clarity on the PSO requirement and asked whether participation in any PSO could meet the compliance requirement as one of these commenters noted that there are fees associated with joining a PSO. There were also concerns with the time and resources it takes to join a PSO.

Response: After reviewing these comments, we are finalizing this proposed policy with modification. RO participants will annually attest to whether they actively participate in a patient safety organization, but we will no longer require that the participant be in a radiation oncology-specific PSO. Instead, RO participants will be in compliance so long as they annually attest to active participation with any PSO. We believe that this modification will alleviate the commenter's concern of paying additional fees to participate with a radiation oncology-specific PSO when an RO participant is already participating in a non-radiation oncology-specific PSO. We are also removing the text "PSO provider service agreement" and replacing it with "for example, by maintaining a contractual or similar relationship with a PSO for the receipt and review of patient safety work product" for alignment with the terminology used by AHRQ. Additionally, the PSO requirement will be effective beginning in PY1. For those RO participants that are not in a PSO, they can use the time period from the publication of this final rule until the attestation period near the end of PY1 to initiate participation with a PSO.

Comment: A commenter recommended that we collect data on participation in the Radiation Oncology Incident Learning System (RO-ILS).

Response: We thank this commenter for the suggestion. At this time, we will not be modifying our proposed monitoring policies to include data collection on participation in the RO-ILS because we believe that our monitoring policies as finalized are appropriate for the monitoring and evaluation of this Model.

Comment: A commenter thanked CMS for recognizing the importance of nationally recognized, evidence-based clinical practice guidelines. This commenter has noted that CMS can determine guideline adherence through the use of various HIT systems and real-time clinical decision support applications which can be integrated into electronic health record (EHR) systems. A couple of commenters requested clarification on the requirement to discuss goals of care with each Medicare beneficiary as the treatment intent is not always provided as a data field in oncologist's information systems.

Response: We appreciate the commenter bringing HIT systems and real-time clinical decision support applications to our attention, and we note that we do not believe that these systems are necessary at this point. We also appreciate the commenters' requests for clarification on the requirement to discuss goals of care with each RO beneficiary. To add clarity, we are committed to supporting the efforts of RO participants to work with their EHR vendors to facilitate this change to capture the seven activities required under the Model. We believe that publishing the final rule several months before the Model performance period will allow RO participants and EHR vendors to prepare for participation in the Model. Therefore, we are finalizing our monitoring policies related to the use of nationally recognized, evidence-based clinical practice guidelines as proposed.

Comment: A commenter requested that CMS provide a list of approved, nationally recognized, evidence-based clinical treatment guidelines to RO participants.

Response: We do not believe that it is necessary for us to provide such a list as radiation oncologists have the knowledge and ability to determine what nationally recognized, evidence-based clinical treatment guidelines are applicable to their patient population.

Comment: A commenter requested clarification on how clinical decision support will be assessed and documented if it is not common in radiation oncology software. Specifically, this commenter expressed concerns with documenting adherence to nationally recognized, evidence-based treatment guidelines or rationale for departure from those guidelines.

Response: We believe that publishing the final rule more than 60 days prior to the start date will provide RO participants with time to facilitate medical record software updates to include appropriate fields to comply with the data submission and monitoring requirements of the Model.

Comment: A commenter supported the qualified peer review requirement as being consistent with the CMS "Patients over Paperwork" initiative.

Response: We thank the commenter for this support.

Comment: Some commenters expressed concerns with the peer review requirements as being onerous for RO participants, particularly single practitioners and those practicing in underserved areas (that is, rural and some urban settings). These commenters asked for either the elimination of or a phased-in approach for the peer review requirements. A commenter requested that there be an exemption to those small/rural practices that show good-faith in trying to comply.

Response: We understand commenters' concerns with the proposed policy on peer review as this currently may not be a common practice among certain RT providers and RT suppliers, but this is common practice for larger RT providers and RT suppliers and those

seeking accreditation. After considering comments received, we are finalizing with modification the peer review requirement. The peer review requirements will be finalized as proposed with reporting to begin in PY1. A good faith exemption for those small/rural practices would require future rulemaking with a public comment period. We will take your request for an exemption for small/rural practices under consideration and proceed with future rulemaking should it become necessary during the test of this Model. However, we believe that the use of CBSAs as the geographic unit of selection minimizes the number of rural providers and suppliers that will be selected in the Model. We have also finalized an option for low-volume RT providers and RT suppliers to opt out of the Model as described in section III.C.3.c of this final rule and codified at § 512.210(c).

Comment: A commenter has inquired how TNM staging will be used by CMS, and specifically asked whether it would be used in the AJCC staging system. Additionally, this commenter has requested clarification on how CMS will handle cancer types that do not have a TNM staging system.

Response: We appreciate the importance of staging in the diagnosis, prognosis, and treatment of cancer. The four quality measures for the RO Model beginning in PY1 and continuing thereafter, as described in section III.C.8.b of this rule, do not rely on staging data. As we review which clinical data elements are appropriate for inclusion in the RO Model, we will consider staging data if these elements are determined to meet RO Model goals of eliminating unnecessary or low-value care, developing accurate episode prices, or developing new radiation oncology-specific quality measures.

After considering public comments, we are finalizing our proposed policies on monitoring for Model compliance with the modifications, as previously discussed, related to

active participation in a PSO (the PSO requirement will be effective beginning in PY1, but RO participants are not required to be in a radiation oncology-specific PSO) and peer review (will begin in PY1). We are codifying these policies at §§ 512.150 and 512.220.

c. Performance Feedback

We proposed to provide detailed and actionable information regarding RO participant performance related to the RO Model. We stated in the proposed rule that we intend to leverage the clinical data to be collected through the RO Model secure data portal, quality measure results reported by RO participants, claims data, and compliance monitoring data to provide information to participants on their adherence to evidence-based practice guidelines, quality and patient experience measures, and other quality initiatives. We discussed our belief that these reports can drive important conversations and support quality improvement progress. The design of and frequency with which these reports would be provided to participants would be determined in conjunction with the RO Model implementation and monitoring contractor.

We solicited public comment on our proposal. We received no comments on this proposal and therefore are finalizing this policy as proposed.

d. Remedial Action for Non-Compliance

We refer readers to section II.I of this final rule for our proposals regarding remedial action.

15. Beneficiary Protections

We proposed to require Professional participants and Dual participants to notify RO beneficiaries that the RO participant was participating in this RO Model by providing written notice to each RO beneficiary during the RO beneficiary's initial treatment planning session. In the proposed rule, we noted that we intended to provide a notification template that RO

participants may personalize with their contact information and logo, which would explain that the RO participant is participating in the RO Model and would include information regarding RO beneficiary cost-sharing responsibilities and an RO beneficiary's right to refuse having his or her data shared under § 512.225(a)(2). Beneficiaries who do not wish to have their claims data shared for care coordination and quality improvement purposes under the Model would be able to notify their respective RO participant. In such cases, the RO participant must notify in writing CMS within 30 days of when the RO beneficiary notifies the RO participant.

We discussed in our proposed rule our belief that it will be important that RO participants provide RO beneficiaries with a standardized, CMS-developed RO beneficiary notice in order to limit the potential for fraud and abuse, including patient steering. The required RO Model beneficiary notice would be exempt from the provision at § 512.120(c)(2), and discussed in section II.D.3 of this rule, that requires a standard disclaimer statement on all descriptive model materials. In the proposed rule, we discussed our belief that the disclaimer statement should not apply to the RO Model beneficiary notice, because RO participants would be required to use standardized language developed by CMS. We proposed for these policies to be in § 512.225(c).

The beneficiary notice would include, along with other pertinent information, how to contact CMS with questions. Specifically, if beneficiaries have any questions or concern with their physicians, we stated in the proposed rule that we encouraged them to telephonically contact the CMS using 1–800–MEDICARE, or their local Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs) (local BFCC-QIO contact information can be located here: https://www.qioprogram.org/locate-your-qio).

We solicited public comment on the beneficiary protections. In this section of this rule, we summarize and respond to the public comments received on this proposal.

Comment: A commenter requested that CMS make a concerted public effort toward educating all beneficiaries who may be impacted by the Model about the unique coinsurance requirements inherent to the Model's design.

Response: As required by § 512.225(a)(3) of this final rule, RO participants must notify all RO beneficiaries to whom they furnish included RT services regarding their cost-sharing responsibilities. Such notice will be furnished through the beneficiary notification letter provided by the RO participant during the initial treatment planning session and may be discussed prior in accordance with § 512.225(a)-(c) of this final rule. The beneficiary notification requirement will begin in PY1.

Comment: We received some comments on the beneficiary notification letter. These commenters requested that we eliminate the requirement for the RO participant to notify the beneficiaries as such notification is administratively burdensome. A commenter also expressed concerns with the timing of the beneficiary notification letter. A commenter requested that CMS provide this notice within the *Medicare & You* annual publication as well as on the Medicare.gov website. Another commenter requested that if we finalize the notification letter as proposed then to draft the notice with simple language at less than a 6$^{th}$ grade reading level.

Response: After considering comments, we are finalizing as proposed that we will draft the beneficiary notification template that RO participants may personalize with their contact information and logo, which will explain that the RO participant is participating in the RO Model and will include information regarding RO beneficiary cost-sharing responsibilities and an RO beneficiary's right to refuse having his or her data shared under § 512.225(a)(2). We believe that having a template with only minimal modifications (RO participant contact information, logo, and date) will not lead to potentially inaccurate information being delivered to beneficiaries.

Further, after considering comments regarding administrative burden, we are finalizing as proposed that RO participants provide this written notice to each beneficiary during the initial treatment planning session. We do not believe that a written notice that has minimal modification by the RO participant is an administrative burden on RO participants. Additionally, we believe that this notice serves an important function to ensure that beneficiaries are aware of the Model and how they may be impacted by it, as well as allowing them to choose a non-participant health care provider should they wish.

We appreciate the comment about having additional sources for the beneficiary notification such as the Medicare.gov website, and we will consider ways to provide RO beneficiaries with details about the RO Model. We recognize that the *Medicare & You* publication has included language about model tests in the past. However, that publication cannot provide beneficiaries with the specific details and parameters for every model test. Therefore, we will consider other ways to provide RO beneficiaries with details about the RO Model. Additionally, as we draft the beneficiary notification letter, we will ensure that the language used is simple to provide beneficiaries with the necessary information to convey that they are receiving treatment from an RO participant.

Comment: A commenter supported the proposal that CMS draft the beneficiary notification letter template.

Response: We appreciate this commenter's support.

Comment: A commenter noted that the RO Model references patient navigators in its discussion of the Oncology Care Model, but there is an absence of provisions calling for the inclusion of such within the RO Model. This commenter believes that the episodic nature of radiation oncology coupled with the potential number of health care provider touchpoints for

patients in the RO Model augments the importance of patient navigators in ensuring an effective continuum of care for patients receiving RT. This commenter voiced a strong recommendation to include a prominent role for patient navigators in the RO Model.

Response: We thank this commenter for highlighting the important role patient navigators have. To the extent that an RO participant wishes to include patient navigators in the care team, this will be permissible, but at this time, we will not be formally incorporating a requirement that RO participants include patient navigators in the care of RO beneficiaries. We do not believe that there is a demonstrated need for patient navigation at this time in radiation oncology, particularly as many radiation oncology patients who also receive chemotherapy typically receive care management services from their medical oncologist. However, after the Model is implemented, we will assess the need for patient navigators and, if needed, make modifications to the RO Model through future rulemaking.

Comment: A commenter has expressed concerns that the proposed RO Model will create a burden on patients, such as increasing the need for those patients to drive farther to obtain the same quality of care.

Response: We do not agree with the commenter's assertion that the Model will increase the need for beneficiaries to drive farther. We believe that providing site-neutral, more predictable or foreseeable payments to RO participants will help patients because we anticipate that the Model will lead to lower costs overall while maintaining or improving quality of care. The RO beneficiaries receiving care from RO participants will maintain the same protections as those beneficiaries outside of the Model, including the right to choose their health care providers.

After considering public comments, we are finalizing our proposed provisions on beneficiary protections with the modification of non-substantive changes to the proposed

provisions at § 512.225 in this final rule to improve readability. The beneficiary notification requirement will begin in PY1. Specifically, we are codifying the beneficiary notification requirement at § 512.225. Furthermore, we are codifying at § 512.225(a)(1) that starting in PY1, Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services that the RO participant is participating in the RO Model. We are codifying at § 512.225(a)(2) that starting in PY1, Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services that the RO beneficiary has the opportunity to decline claims data sharing for care coordination and quality improvement purposes; and that if an RO beneficiary declines claims data sharing for care coordination and quality improvement purposes, then the RO participant must inform CMS within 30 days of receiving notification from the RO beneficiary that the beneficiary is declining to have their claims data shared in that manner. We are codifying at § 512.225(a)(3) that starting in PY1, Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services of the RO beneficiary's cost-sharing responsibilities.

16. Evaluation

As stated in the proposed rule, an evaluation of the RO Model would be required to be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center (84 FR 34533).

As stated in the proposed rule our evaluation would focus primarily on the question: do the changes that comprise the RO Model result in improved quality or reduced spending for those beneficiaries receiving RT services during the model period? Conversely, if the RO Model has no effect we would expect that Medicare spending per episode or quality measures for beneficiaries associated with those episodes do not differ between RT providers and suppliers in

CBSAs selected as Participants in the Model compared to those in the comparison group. We will also analyze other data to understand how the Model is successful in achieving improved quality and reduced expenditures. These analyses may include 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 and supplier experience of care. The evaluation would inform the Secretary and policymakers about the impact of the model relative to the current Medicare fee structure for RT services, assessing the impacts on beneficiaries, health care providers, markets, and the Medicare program. The evaluation would take into account other models and any changes in Medicare payment policy during the Model performance period (84 FR 34533).

In addition to assessing the impact of the Model in achieving improved quality and reduced Medicare expenditures, we stated in the proposed rule that the evaluation is likely to address secondary questions to provide context for answers to the primary question. As stated in the proposed rule, these questions include (but will not be limited to): 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 Innovation Center models or CMS/non-CMS initiatives and how could they impact the evaluation findings (84 FR 34533)?

As stated in the proposed rule, CMS anticipated that the evaluation will include a difference-in-differences[80] or similar analytic approach to estimate model effects (84 FR 34533). Where it is available, baseline data for the participants would be obtained for at least one year prior to model implementation. Data would also be collected during model implementation for both participant and comparison groups. The evaluation 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.

The evaluation would use a multilevel approach. We would conduct analyses at the CBSA-level, participant-level, and the beneficiary-level. The CBSAs and RT providers and RT suppliers contained within CBSA geographic areas selected for participation, as discussed in section III.C.3.d, will have been randomly assigned for the duration of the evaluation, allowing us to use scientifically rigorous methods for evaluating the effect of the Model.

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[80] Difference-in-difference is a statistical technique that compares the intervention (in this case, the RO participant) and comparison (in this case, the Comparison group) groups during the period before the RO Model goes into effect (pre-intervention) and the period during and after the RO Model goes into effect (post-intervention) and uses the difference between intervention and comparison in both periods to estimate the effect of the intervention. A comparison group that is similar to the intervention group is used to help measure the size of the intervention effect by providing a comparison (or 'counterfactual') to what would have happened to the intervention group had the intervention not occurred. This helps the evaluation distinguish between changes occurring for reasons unrelated to the Model when estimating the changes that occurred because of the Model.

We referred readers to section II.E of the proposed rule for our proposed policy on RO participant cooperation with the RO Model's evaluation and monitoring policies. We solicited public comment on our proposed approach related to the evaluation of the RO Model. In this section of the rule, we summarize and respond to the public comments received on this proposal.

Comment: A few commenters expressed concern about possible unforeseen circumstances and unintended consequences as a result of the Model. A couple of these commenters urged us to evaluate model effects on quality of care and patient access and were concerned the RO Model may impact these outcomes negatively. A commenter suggested we did not have sufficient evidence to proceed with the Model. A different commenter offered support for the proposed evaluation and highlighted the importance of patient experience measures with regards to cancer care.

Response: We appreciate and share the commenters' interest in outcomes related to the Model. In designing the Model and planning the Model's evaluation, CMS considers access to care and quality of care to be outcomes that must be examined. We have a monitoring plan for tracking, and an evaluation plan to assess, the Model's impact on these outcomes. We believe collecting and analyzing measures of quality and access to care will help assess the Model's impact on beneficiaries' outcomes and experience during RO episodes. We have detailed the methodology used to create the episodes, set payment rates, and the random selection of

Participants in the NPRM, using national FFS Medicare claims. We are finalizing the evaluation and monitoring methods as proposed.

Comment: A commenter encouraged the agency to make it a priority to minimize provider and supplier burden resulting from this Model.

Response: We agree that burden on RO participants should be minimized to the extent possible, and we kept this in mind in the design of the RO Model, including the evaluation. We included features in the Model such as RO participants continuing to submit claims through the existing FFS claims process, and identifying RO participants by ZIP Code (rather than CBSA) to limit burden. We have been mindful to minimize RO participant burden in the design of the evaluation (such as relying on secondary data sources such as FFS claims), but there will be some additional data collection necessary to fully evaluate the Model and conduct all impact estimates.

Comment: A couple of commenters expressed concern that the Model as proposed may lack sufficient data to evaluate the effects of including PBT centers.

Response: We focused the evaluation design on the impacts of the Model at the population level for overall spending and quality across all RT services furnished and not the effects on one potential modality compared to another. While some future sub-analyses may include differences in costs and quality by modality, we will make no impact estimates on cost nor quality where we do not have suitable sample size of RO participants or RO episodes, understanding that any differences we may observe are observational and not causative.

After considering public comments, we are finalizing our proposals on evaluation as proposed.

17. Termination of the RO Model

In the proposed rule, we stated that the general provisions relating to termination of the Model by CMS in section II.J of the proposed rule would apply to the RO Model. We received no comments on the termination of the RO Model. As explained in section II.J. of this final rule, we are finalizing our 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

We stated in the proposed rule (84 FR 34533 through 34535) that the RO Model would leverage existing Innovation Center work and initiatives, broadening that experience to RT providers and RT suppliers, a professional population that is not currently the focus of other models tested by the Innovation Center. In the proposed rule, we discussed our belief that the RO Model would be compatible with other CMS models and programs that also provide health care entities with opportunities to improve care and reduce spending. We expected that there would be situations where a Medicare beneficiary in an RO Model episode would also be assigned to, or engage with, another payment model being tested by CMS. Overlap could also occur among providers and suppliers at the individual or organization level; for example, a physician or organization could be participating in multiple models tested by the Innovation Center. We stated that we believe that the RO Model would be compatible with other CMS initiatives that provide opportunities to improve care and reduce spending, especially population-based models, though we recognize the design of some models being tested by the Innovation Center under its section 1115A authority could create unforeseen challenges at the organization, clinician, or beneficiary level. We stated in the proposed rule that we do 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 1115A of the Act or the Shared Savings Program under section 1899 of the Act. We stated in the proposed rule that if, in the future, we determined that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking. In this section of this rule, we summarize and respond to the public comments received on the proposal in section III.C.18.a.

Comment: A few commenters generally agreed with CMS' approach not to propose to adjust the RO Model's prospective episode payments to reflect payments made under any of the existing models being tested under section 1115A of the Act or under the Shared Savings Program. They also agreed that other models and programs should be responsible for factoring RO Model payments into their reconciliation calculations.

Response: We appreciate the commenters' support.

Comment: Some commenters requested more information and clearer guidance from CMS on overlap between the RO Model and other CMS initiatives, including all models tested under section 1115A, the Shared Savings Program, and the Quality Payment Program. One of these commenters stated that without details of how CMS proposes to resolve overlaps, providers and suppliers are unable to accurately forecast how the models may impact future revenues, and they requested that, in the future, CMS needs to provide more specific guidance during the proposal phase, so stakeholders can comment on any potential issues prior to implementation. Another commenter encouraged CMS to provide additional clarity on payment adjustment changes and overlap between the RO model and Quality Payment Program, and stated that such clarity will greatly help them develop forecasting models that can in turn help better support their

patient care operations. Another commenter stated that the lack of clarity on model overlap continues to be an issue, and that they have long encouraged CMS to be more deliberate and specific in providing Innovation Center model participants with clear guidance on how scenarios in which Innovation Center models overlap will be treated. This commenter further stated that such clarity is not only beneficial for those providers and suppliers that will be required to participate under the RO Model but, importantly, for those providers and suppliers participating in the other models identified by CMS in the proposed rule. Another commenter agreed with CMS' acknowledgement that accounting resolution will be needed for overlap between the RO Model and other initiatives, but they believe that it is not clear how this accounting resolution would be handled, and specifically requested that CMS clarify how the overlap of the RO Model with other models and programs would be operationalized through program accounting, so that providers and suppliers that participate in multiple initiatives have a clear understanding of the process. Another commenter requested specific clarification on how CMS will resolve the separation of radiation oncologists from overlapping initiatives, for example, the MIPS adjustment earned in previous years and OCM inclusion up to the start date of the RO Model.

Response: We appreciate the commenters' comments, feedback, and suggestions regarding overlap between the RO Model and other CMS initiatives. We will take all of these suggestions into consideration as we implement the RO Model. As stated in the proposed rule, if, in the future, we determine that RO Model payment adjustments are necessary to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Shared Savings Program under section 1899 of the Act, we will propose overlap policies for the RO Model through notice and comment rulemaking. Further, we are not including further explanation in this final rule regarding overlap policies for the RO Model, because we are not

putting in place any overlap accounting policies for this Model at this time. As explained previously, the financial methodology and accounting policies under the applicable model tested under section 1115A of the Act or the Shared Savings Program will govern the way in which RO payments are factored into reconciliation calculations under that initiative.

Comment: A few commenters expressed concern that CMS does not have a clear overlap policy that is applied across all programs and models. One of these commenters stated that it is very important for CMS to consider model overlap in the design of new APMs, and they recommended that the goal of CMS models should be to provide APM participants with adequate flexibility to manage overlap based on their unique market situation and fundamentally change care delivery and improve population health, rather than seeking opportunities to leverage market dynamics to reduce costs. This commenter also expressed concern that the proposed models do not place sufficient emphasis on population health and encouraging providers and suppliers to keep patients from getting to later disease stages in the first place.

Another commenter stated that CMS must consider how models will interact with one another and what this means for participation in different models. This commenter recommended that CMS should focus on supporting providers and suppliers currently not participating in an APM and encouraging these providers and suppliers to participate, rather than requiring some providers and suppliers to participate, in a second model, especially without sufficient clarity on how these models may interact. The commenter also supported CMS' goal to transition providers and suppliers to risk-bearing programs and believed CMS will most effectively achieve this goal by focusing on providers and suppliers not currently participating. Another commenter stated concern that the lack of a strict overlap structure undermines the financial integrity of early adopters in high-risk Advanced APM models, as the absence of an established overlap

framework effectively creates a disincentive for providers and suppliers to voluntarily bear heightened risk for a total population. The commenter further stated that providers and suppliers are not equipped with enough information to evaluate the potential effect of specialty and other episode payment models on global payments and total cost of care, and there is a finite opportunity for these organizations to reduce costs while maintaining access and quality. To address these concerns, this commenter recommended a hierarchical approach to CMS' and the Innovation Center's model overlap, in which precedence is given to population health risk-bearing entities. The commenter also suggested that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy.

Response: We thank the commenters for their comments and suggestions regarding a larger CMS overlap policy. We appreciate this feedback, and will consider all of these recommendations moving forward, in the event that a broader overlap policy is developed for CMS. As stated in the proposed rule, we do not envision that the prospective episode payments made under the RO Model will need to be adjusted to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Shared Savings Program under section 1899 of the Act, but as stated in the proposed rule, if we determine in the future that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking.

b. Accountable Care Organizations (ACOs)

In the proposed rule, we discussed our belief that there would be potential overlap between the RO Model and ACO initiatives. ACO initiatives include a shared savings component. As a result, providers and suppliers that participate in an ACO are generally

prohibited from participating in other CMS models or initiatives involving shared savings.[81] We believed there would be potential for overlap between the RO Model and ACO initiatives but, 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, we 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.

While shared savings payments made under an ACO initiative have the potential to overlap with discounts and withholds in the RO Model, as we explained in the proposed rule it is difficult to determine the level of potential overlap at this time. It is also difficult to determine how many ACO-aligned beneficiaries will require RT services or if those beneficiaries would seek care from an RO participant. Given that the RO Model is expected to reduce Medicare spending in aggregate, we anticipated that in most cases payments under the RO Model would be less than what Medicare would have paid outside the Model. However, we also noted that it would be possible for RO participants to receive higher Medicare payments under the Model than they did historically, for example, if they have certain experience adjustments. While we expected overall payments for RT services to be lower than they would be absent the Model, we wanted to ensure that a significant proportion of the RO Model discounts, which represent Medicare savings, would not be paid out to ACOs as shared savings.

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[81] The statutory limitation under section 1899(b)(4) of the Social Security Act, only applies to providers and suppliers that participate in Shared Savings Program ACOs. As a policy matter, CMS has elected to impose a similar restriction on some participants in other ACO initiatives through the participation agreements for the various models.

Due to these factors, in the proposed rule we stated that we intended to continue to review the potential overlap with the ACO initiatives as the RO Model is launched. If substantial overlap occurs, we would consider adjusting the RO Model payments through future rulemaking to ensure Medicare retains the discount amount. ACO initiatives could also consider accounting for RO Model overlap in their own reconciliation calculations. Any changes to the payment calculations under these ACO initiatives that might be necessary to account for overlap with the RO Model would need to be made using the relevant procedures for the applicable ACO initiative. For example, if the Next Generation ACO Model makes any changes to their current payment methodologies to account for the RO Model, it would update their governing documentation as necessary, and would provide information to their participants through their typical channels of communication.

In this section of this rule, we summarize and respond to the public comments received on this proposal.

Comment: A few commenters recommended that CMS not negatively adjust ACO shared savings calculations to account for discounts embedded in RO Model payments.

Response: At this time, we are not planning to negatively adjust ACO financial calculations to account for the RO discount. ACO financial calculations rely on Medicare Part A and Part B claims data as well as non-claims-based payments that are individually identifiable final payments made under a demonstration, pilot, or time limited program and paid from the Medicare Trust Funds. Under the Shared Savings Program, use of a regional growth rate should ultimately account for changes in payment due to the RO Model, in cases where overlap occurs between the RO Model and Shared Savings Program ACOs. The application of a regional growth rate under the Shared Savings Program would account for changes in payment due to the

RO Model because the historical benchmark calculated for an ACO would be updated for each performance year of the agreement period using a blend of the national growth rate and a regional growth rate based on the actual Medicare FFS experience in counties where the ACO's beneficiaries reside. Thus, the use of this regional growth rate will naturally update the historical benchmarks of ACOs to account for the effects on spending resulting from implementation of other value-based payment models, including the RO Model, in those counties. For ACO initiatives other than the Shared Savings Program, CMS will determine whether an adjustment to the initiative's calculations is necessary based, for example, on the extent of health care practitioner or beneficiary overlap between that initiative and the RO Model. We intend to continue to review the potential overlap with ACO initiatives as the RO Model is launched. If CMS determines that adjustment to the calculations used in any of these other ACO initiatives is necessary to account for overlap with the RO Model, CMS would make changes to the governing documentation for that ACO initiative, as necessary, and would provide information to the participants in that ACO initiative through its typical channels of communication at that time in the future. Similarly, we will consider adjusting the RO Model payments through future rulemaking if necessary to ensure Medicare retains the discount amount. However, for the reasons as previously described, we are not currently applying any adjustments to the RO Model payments or ACO financial calculations at this time.

Comment: A few commenters recommended that CMS finalize a policy to exclude beneficiaries aligned to an ACO who receive included RT services from attribution to an RO participant under the RO Model. One of these commenters requested that CMS "provide an exemption for practices that are already contracted with ACOs to provide a four percent or greater discount." This commenter believes that "two percent to four percent should not

automatically be withheld up front under the assumption that there were errors in billing" and that "this practice is unfair to those that work diligently to bill with accuracy and effectively under ethical billing practices." Another commenter suggested that CMS should exclude all beneficiaries aligned to ACOs from attribution to participants in any other payment models to reduce duplicative care coordination efforts and create a clear, transparent and understandable policy across all models tested under section 1115A of the Act.

Response: We appreciate the commenters' feedback. We did not propose to exclude RT practices participating in ACOs from the RO Model, and we are finalizing our proposed policy to allow ACO-aligned beneficiaries to be attributed to practices participating in the RO Model for the following reasons. First, we believe that excluding beneficiaries that have been aligned to an ACO from the RO Model would be operationally challenging for RO participants who will be billing prospective RO Model payments and may not be aware in real time that the beneficiaries are aligned to an ACO. Further, we believe the incentives under the RO Model and the ACO initiatives are aligned appropriately to support high-quality care, and to the extent that RO participants provide more efficient care to ACO-aligned beneficiaries, this could benefit the performance of the ACO and provide higher-quality care to Medicare beneficiaries with cancer who receive RT services.

c. Oncology Care Model (OCM)

OCM seeks to provide higher quality, more highly coordinated oncology care at the same or lower cost to Medicare. 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. Because OCM and the RO Model both involve care for patients with a cancer

diagnosis who receive RT services, we stated in the proposed rule that we expect that there will be beneficiaries who would be in both OCM episodes and the RO Model episodes.

Under OCM, physician practices may receive a performance-based payment (PBP) for episodes of care surrounding chemotherapy administration to cancer patients. OCM is an episode payment model that incentivizes care coordination and management and seeks to improve care and reduce costs for cancer patients receiving chemotherapy. Given the significant cost of RT, OCM episodes that include RT services receive a risk adjustment when calculating episode benchmarks, with the goal of mitigating incentives to shift these services outside the episode (for example, by delaying the provision of RT services until after the 6-month episode ends).

As we explained in the proposed rule, practices participating in OCM receive a monthly payment per OCM beneficiary to support enhanced services such as patient navigation and care planning. Practices may also earn a PBP for reductions in the total cost of care compared to episodes' target amount, with the amount of PBP being adjusted by the practice's performance on quality measures. OCM offers participating practices the option of requesting a two-sided risk arrangement, in which episode expenditures that exceed the target amount or the target amount plus the minimum threshold for OCM recoupment (depending on the specific two-sided risk arrangement requested) would be recouped by CMS from the practice. OCM requires participating practices who have not earned a PBP by the initial reconciliation of the model's fourth performance period to move to a two-sided risk arrangement or terminate their participation in the model.

As we proposed in section III.C.7 of the proposed rule and are finalizing in section III.C.7 of this final rule, the RO Model will include prospective episode payments for RT

services furnished during a 90-day episode of care. The RO Model is not a total cost of care model and includes only 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.

Conversely, OCM 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 PBP or recoupment. We stated in the proposed rule that when the RO Model episode occurs completely before or completely after the OCM episode, then the RT services that are part of that RO Model episode would not be included in the OCM episode, and the OCM reconciliation calculations would be unaffected. 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, we stated in the proposed rule that we 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, we 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. In this case, the prorated portion of the payment under the RO Model, based on the number of days of overlap with the OCM episode, would be included in the OCM episode's expenditures as well as the prorated

portion of the RO Model discount and withhold amounts, again based on the number of days of overlap with the OCM episode. We stated that 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.

In those cases where the RO Model episode occurs entirely within or partially before or after the OCM episode, for the purpose of calculating OCM episode costs, we stated in the proposed rule that we would assume that all withholds are eventually paid to the RO Participant under the RO Model, and that there are no payments to recoup. We stated that we believe a process to allocate exact amounts paid to the participants with different reconciliation timelines between the two models would be operationally complex.

We stated in the proposed rule that we intend to continue to review the potential overlap with OCM if the RO Model is finalized, including whether there are implications for OCM's prediction model for setting risk-adjusted target episode prices, which include receipt of RT services. We further stated that since prospective episode payments made under the RO Model would not be affected by OCM, OCM would account for RO Model overlap in its reconciliation calculations, and OCM participants would be notified and provided with further information through OCM's typical channels of communication. In this section of this rule, we summarize and respond to the public comments received on this proposal.

Comment: Many commenters agreed with CMS' proposed approach for accounting for overlap between OCM and the RO Model. Some commenters requested additional details regarding the proration methodology, and a commenter specifically requested further clarification regarding how prorated payments will be determined and how prorated payments will be distributed to providers and suppliers. One commenter requested that CMS clarify and

reconsider how the RO Model will overlap with the OCM in a manner that allows for full and fair participation in both models. This commenter suggested that it would be more appropriate and fairer to RT providers and RT suppliers participating in both models to use the final discounted amount of the RO Model payment as the payment to the RO participant for purposes of the OCM reconciliation calculation. This commenter stated that RO participants would receive no financial credit under the RO Model for adjusting their spending to make do with lower payment under the discounts, so there is no double-counting of savings if that discount is also included in the OCM calculation. The commenter also stated that there is no guarantee that RO participants will earn the withhold amounts back after reconciliation under the RO Model; and that even if they do, it likely will not be without the RO participant incurring other costs to comply with quality reporting requirements. Therefore, this commenter suggested that the fairer and more accurate approach would be to deduct the discount amount from the OCM reconciliation calculation, and to deduct the amount of withholding that is not regained through quality performance.

Response: We appreciate the commenters' support for the proposed approach to account for overlap between the OCM and RO Model. We anticipate that roughly 30 percent of OCM practices that provide RT services will participate in the RO Model. Since 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, and therefore have the potential to affect a participating practice's PBP or recoupment. We proposed a proration approach to account for changes in OCM episode expenditures due to RO Model overlap, and to ensure there is no double counting of savings or double payment of the withhold amounts between the two models.

Regarding the comments about the proration methodology, we refer readers to our description of the OCM proration methodology set forth in the proposed rule, where we described how, in cases where the RO episode occurs partially within an OCM episode and partially before or after the OCM episode, we proposed to allocate the RO Model payments for RT services and the RO Model discount and withhold amounts to the OCM episode's expenditures on a prorated basis, based on the number of days of overlap. As we discussed in the proposed rule, including the RO discount and withhold amounts (on a prorated basis for cases where the RO episode occurs partially within an OCM episode and partially before or after the OCM episode) in the calculation of OCM episode expenditures would ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models. For cases where the RO episode occurs entirely within or partially before or after the OCM episode, for the purpose of calculating OCM episode costs, we stated that we would assume that all withholds are eventually paid to the RO participant under the RO Model, and that there are no payments to recoup. As we discussed in the proposed rule, we believe 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. Further detail about how OCM will account for RO Model overlap in its reconciliation calculations will be provided to OCM practices through OCM's typical communication channels. Of note, any RO episode payments that are prorated as part of the OCM reconciliation calculations will not be distributed to the RO participant or OCM participant; rather, these amounts will be included in the OCM reconciliation calculations that determine the amount of any OCM PBP or OCM recoupment. RO episode payments would not change as a result of any overlap with an OCM episode.

We believe the proposed approach to handling the RO Model discount and withholds in the OCM reconciliation calculation is fair to participants in both models and allows for full participation in both models, while also preventing us from double-counting and double-paying savings to Medicare. Of note, RO participants receive the same RO payment amount regardless of how many RT services are delivered; thus, RO participants may keep the savings that accrue for RO episodes where payment under Medicare FFS would have been less than the RO participant-specific episode payment. Since the RO participant would retain these savings, we continue to believe that the best way to ensure that Medicare savings (captured through the RO Model discount) are not paid out through the OCM reconciliation is by adding the RO Model discounts and withholds to the RO participant-specific episode payments included in the OCM reconciliation calculations. Additionally, we are not able to synchronize the timing of the OCM and RO Model reconciliations such that we could incorporate the amount of the quality withhold that is paid to the RO participant during reconciliation.

Comment: A few commenters requested that CMS not make changes to the OCM target price setting methodology based on RO Model payments.

Response: We noted in the proposed rule that overlap with the RO Model may have implications for the appropriateness of OCM's prediction model for setting risk-adjusted target prices. We are continuing to consider whether any potential changes to OCM's prediction model would be needed, and we appreciate this input from the commenters. If we make changes to the OCM prediction model, OCM practices would be notified through OCM's typical communication channels.

Comment: A few commenters requested clarity and guidance from CMS about whether the RO Model and OCM payments are paid separately or bundled together.

Response: The RO Model and OCM are separate and distinct payment models and any model payments will be paid separately and not bundled together. Furthermore, as stated in the proposed rule, a practice participating in the RO Model will receive the same prospective episode payment for RT services, regardless of its participation in OCM, because the RO Model makes prospective payments for only the RT services provided during an RO episode.

Comment: A commenter suggested the OCM participants should be exempt from the RO Model. A couple of commenters suggested that OCM participants should not be required to participate in the RO Model until their performance under OCM has been completed.

Response: We appreciate the commenter's suggestion about excluding OCM participants from the RO Model. However, we disagree with the commenters' recommendation that OCM participants should be exempt from the RO Model, and with the recommendation that OCM participants not be required to participate in the RO Model until performance under OCM has concluded. We believe that it is important to allow eligible health care providers to participate in both models because both models involve care for patients with a cancer diagnosis. We also believe that participation in both models could benefit beneficiaries in both the RO Model and OCM by aligning payment incentives across both models. We did not propose to exclude OCM participants from the RO Model as we believe that this approach would curtail the number, and potentially alter the composition, of RT providers and RT suppliers available to participate in the RO Model, which could affect our ability to detect an impact of the RO Model. Further, by not excluding voluntary OCM participants, we could avoid a possible selection effect in the RO Model.

After review of public comments and for the reasons discussed, we are finalizing our proposed approach for addressing overlap between OCM and the RO Model as proposed.

d. Bundled Payments for Care Improvement (BPCI) Advanced

As we explained in the proposed rule, the BPCI Advanced Model is testing a new iteration of bundled payments for 34 clinical episodes (30 inpatient and 3 outpatient, and 1 multi-setting).[82] The BPCI Advanced Model is based on a total cost of care approach with certain MS-DRG exclusions. While there are no cancer episodes included in the design of the BPCI Advanced Model, a beneficiary in an RO episode could be treated by a provider or supplier that is participating in the BPCI Advanced Model for one of the 34 clinical episodes included in the BPCI Advanced Model. Since prospective episode payments made under the RO Model would not be affected by the BPCI Advanced Model, the BPCI Advanced Model would determine whether to account for RO Model overlap in its reconciliation calculations, and CMS would provide further information to the BPCI Advanced Model participants through an amendment to their participation agreement. In this section of this rule, we summarize and respond to the public comments received on this proposal.

Comment: A commenter recommended that potential RO Model overlap with the BPCI Advanced Model be addressed through a notice and public comment process, rather than through a mandatory amendment to the BPCI Advanced Model participant agreements. A commenter stated that there may be potential overlap with the BPCI Advanced Model, as a Medicare beneficiary in an RO episode could be treated by a health care provider that is participating in the BPCI Advanced Model. This commenter requested clarification in this case, on how to know which model the patient would be attributed to and how the services would be reimbursed. This commenter also recommended that CMS address the potential overlap on how patients should be

[82] Major joint replacement of the lower extremity is a multi-setting Clinical Episode category. Total Knee Arthroplasty (TKA) procedures can trigger episodes in both inpatient and outpatient settings.

attributed between the BPCI Advanced Model and the RO Model, and they requested further clarification regarding how services will be reimbursed under the RO and BPCI Advanced Models before the start date to assist hospitals in effective planning for their participation.

Response: We appreciate the commenter's concerns and suggestions. The BPCI Advanced Model payment polices are governed by participation agreements with each model participant; we cannot amend those agreements by notice and comment rulemaking. Accordingly, we are finalizing as proposed (84 FR 34535) that the BPCI Advanced Model team will determine whether and how to account for RO Model overlap in its reconciliation calculations. Regarding the commenter who requested clarification on how to know which model the patient would be attributed to and how the services would be reimbursed, as we stated in the proposed rule, a beneficiary in an RO episode could be treated by a provider or supplier that is participating in the BPCI Advanced Model, and prospective episode payments made under the RO Model would not be affected by the BPCI Advanced Model. As such, the BPCI Advanced Model would determine whether to account for RO Model overlap in its reconciliation calculations, and the BPCI Advanced Model participants will receive further information from CMS if the BPCI Advanced Model team determines to make changes to their reconciliation policy.

19. Decision Not to Include a Hardship Exemption

As discussed in the proposed rule (84 FR 34535), we did not believe that a hardship exemption for participation in the 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. This is particularly evident in PY1, where the efficiency factor in section III.C.6.e(2) of the

proposed and final rules is 0.90 for all RO participants. Accordingly, we did not propose such an exemption in the proposed rule, and will not include such an exemption in this final rule.

However, in the proposed rule, we welcomed public input on whether a possible hardship exemption for RO participants under the Model might be necessary or appropriate, and if so, how it might be designed and structured while still allowing CMS to test the Model. As we stated in the proposed rule, we intend to use the input we received on this issue to consider whether a hardship exemption might be appropriate in subsequent rulemaking for a future PY. In this section of this rule, we summarize the public comments we received.

Comment: Many commenters disagreed with CMS' decision not to include a model participation hardship exemption for RO participants. A commenter requested that CMS establish a hardship exemption process for RT providers and RT suppliers that can show they serve a patient base consisting predominantly of Medicare beneficiaries, given that these providers and suppliers would face disproportionate impact from mandatory participation in the Model and would be at a significant disadvantage compared to other participants as well as RT providers and RT suppliers not included in the Model.

Some commenters requested a hardship exemption specific to rural practices. These commenters maintained that patients living in rural areas would be disparately impacted by the mandatory requirement of the proposed RO Model, and other commenters stated that rural practices will experience undue burdens if they are required to participate in the RO Model.

A few commenters recommended that CMS provide hardship exemptions for RO participants facing public health emergencies or natural disasters, such as wild fires, earthquakes, or hurricanes, to ensure that they are not unfairly penalized due to these circumstances. These commenters stated that hardship exemptions for extreme and uncontrollable circumstances have

recently been implemented in other APMs, including the Shared Savings Program and the Comprehensive Care for Joint Replacement Model, and also in the Quality Payment Program.

We appreciate the commenters' feedback on this issue. We will consider these comments when determining whether a hardship exemption is appropriate for proposing in subsequent rulemaking for a future PY. We will continue to monitor the need for a hardship exemption under the RO Model.

## IV. End-Stage Renal Disease (ESRD) Treatment Choices Model

### A. Introduction

The purpose of this section of the final rule is to implement a new payment model called the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, referred to in this section IV of the final rule as "the Model," under the authority of the Innovation Center. The intent of the ETC Model is to test whether adjusting the current Medicare fee-for-service (FFS) payments for dialysis services will incentivize ESRD facilities and clinicians managing adult Medicare FFS beneficiaries with ESRD, referred to herein as Managing Clinicians, to work with their patients to achieve increased rates of home dialysis utilization and kidney transplantation and, as a result, improve or maintain the quality of care and reduce Medicare expenditures. Both of these modalities (home dialysis and transplantation) have support among health care providers and patients as preferable alternatives to in-center hemodialysis (HD), but the utilization rate of these services in the United States (U.S.) has been below such rates in other developed nations.[83] On July 18, 2019, we published a proposed rule in the **Federal Register** titled "Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures" (84 FR 34478) and sought public comment on the proposed ETC Model. In response, CMS received 104 comment submissions from physicians, dialysis providers, patient groups, industry groups, and others. Summaries of these comments, and our responses, are found throughout this section of the final rule.

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[83] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018. Volume 2: End-stage Renal Disease (ESRD) in the United States. Chapter 11: International Comparisons. Figures 11-15, 11-16.

In the ETC Model, CMS will adjust Medicare payments under the ESRD Prospective Payment System (PPS) to ESRD facilities and payments under the Medicare Physician Fee Schedule (PFS) to Managing Clinicians paid the ESRD Monthly Capitation Payment (MCP) selected for participation in the Model. The payment adjustments will include an upward adjustment on home dialysis and home dialysis-related claims with claim service dates during the initial three years of the ETC Model, that is, between January 1, 2021 and December 31, 2023. In addition, we will make an upward or downward performance-based adjustment on all dialysis claims and dialysis-related claims with claim service dates between July 1, 2022 and June 30, 2027, depending on the rates of home dialysis utilization, and of kidney transplant waitlisting and living donor transplants among the beneficiaries attributed to these participating ESRD facilities and Managing Clinicians. The ETC Model will test whether such payment adjustments can reduce total program expenditures and improve or maintain quality of care for Medicare beneficiaries with ESRD.

B. Background

1. Rationale for the ESRD Treatment Choices Model

As discussed in the proposed rule, beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation in order to survive, as their kidneys are no longer able to perform life-sustaining functions. In recent years, ESRD Beneficiaries have accounted for about 1 percent of the Medicare population and accounted for approximately 7 percent of total fee-for-service Medicare spending.[84] Beneficiaries with ESRD face the need for coordinating treatment for many disease complications and comorbidities, while experiencing

[84] Kirchoff SM. Medicare Coverage of End-Stage Renal Disease (ESRD). Congressional Research Service. August 16, 2018. p. 1

high rates of hospital admissions and readmissions and a mortality rate greatly exceeding that of the general Medicare population. In addition, studies during the past decade have reported higher mortality rates for dialysis patients in the U.S. compared to other countries.[85, 86]

ESRD is a uniquely burdensome condition; with uncertain survival, patient experience represents a critical dimension for assessing treatment. The substantially higher expenditures and hospitalization rates for ESRD Beneficiaries compared to the overall Medicare population, and higher mortality than in other countries indicate a population with poor clinical outcomes and potentially avoidable expenditures. We anticipate that the ETC Model will maintain or improve the quality of care for ESRD Beneficiaries and reduce expenditures for the Medicare program by creating incentives for health care providers to assist beneficiaries, together with their families and caregivers, to choose the optimal renal replacement modality for the beneficiary.

As we discussed in the proposed rule, the majority of ESRD patients receiving dialysis receive HD in an ESRD facility. At the end of 2016, 63.1 percent of all prevalent ESRD patients – meaning patients already diagnosed with ESRD – in the U.S. were receiving HD, 7.0 percent were being treated with peritoneal dialysis (PD), and 29.6 percent had a functioning kidney transplant.[87] Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used home hemodialysis (HHD).[88] PD is rarely conducted within a facility. In the proposed rule and in section IV.B.2 of this final rule, we describe how current Medicare payment rules and a lack of

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[85] Foley RN, Hakim RM. Why Is the Mortality of Dialysis Patients in the United States Much Higher than the Rest of the World? Journal of the American Society of Nephrology. 2009; 20(7):1432-1435. doi:https:doi.org/10.1681/ASN.2009030282

[86] Robinson B, Zhang J, Morgenstern H, et al. Worldwide, mortality is a high risk soon after initiation of hemodialysis. Kidney International.2014;85(1):158-165. Doi:10.1038/ki.2013.252

[87] 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

[88] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. https://www.usrds.org/2018/view/v2_01.aspx

beneficiary education result in a bias toward in-center HD, which is often not preferred by patients or practitioners. With the ETC Model, we will test whether new payment adjustments will lead to greater rates of home dialysis (both PD and HHD) and kidney transplantation. In both the proposed rule and this final rule, we provide evidence from published literature to support the projection that higher utilization rates for these specific interventions would likely reduce Medicare expenditures, while preserving or enhancing the quality of care for beneficiaries and, at the same time, enhance beneficiary choice, independence, and quality of life.

The following is a summary of the comments received on the rationale for testing the proposed ETC Model and our responses.

Comment: Several commenters stated that they support the rationale, as described in the proposed rule and previously in this final rule, for testing the ETC Model. Several commenters stated that the evidence suggests that home dialysis and transplantation are associated with lower costs and better outcomes than in-center dialysis for patients with ESRD, and that the current payment system does not encourage the use of these alternative modalities. A few commenters stated that payment adjustments like those we proposed for use in the ETC Model can impact participant behavior in supporting these alternative modalities. A few commenters stated that containment of dialysis costs is an important goal for the Model.

Response: We thank the commenters for their feedback and support.

Comment: Several commenters stated that they did not believe payment adjustments could change participant behavior to increase rates of home dialysis and transplantation. A commenter stated that any payment adjustments are unlikely to overcome barriers that currently prevent the use of home dialysis and transplantation such as socioeconomic issues, race, immunologic barriers, a lack of caregiver support, housing insecurity and home environments

that are unable to store supplies and equipment. A commenter stated that the evidence that home dialysis is associated with better outcomes and lower costs is mixed, so the payment adjustments proposed for use in the Model are unlikely to achieve the stated goals. A commenter stated that, if under current payment conditions patient preference is not driving renal replacement modality selection, then changing payment incentives will not move patient preference to the center of the decision-making process.

Response: We thank the commenters for their feedback. The purpose of the ETC Model is to test whether the payment adjustments included in the Model will reduce Medicare expenditures while improving or maintaining quality of care. CMS believes that these payment adjustments will accomplish these goals by encouraging participating Managing Clinicians and ESRD facilities to support beneficiaries choosing home dialysis and transplantation. The purpose of the Model and CMS's evaluation thereof is to determine if this is the case.

a. Home Dialysis

As we noted in the proposed rule, there are two general types of dialysis: HD, in which an artificial filter outside of the body is used to clean the blood; and PD, in which the patient's peritoneum, covering the abdominal organs, is used as the dialysis membrane. HD is conducted at an ESRD facility, usually 3 times a week, or at a patient's home, often at a greater frequency. PD most commonly occurs at the patient's home. (Although PD can be furnished within an ESRD facility, it is very rare. In providing background information for the ETC Model in the proposed rule and in this final rule, we consider PD to be exclusively a home modality.) Whether a patient selects HD or PD may depend on a number of factors, such as patient

education before dialysis initiation, social and care partner support, socioeconomic factors, and patient perceptions and preference.[89,90]

As discussed in the proposed rule, when Medicare began coverage for individuals on the basis of ESRD in 1973, more than 40 percent of dialysis patients in the U.S. were on HHD. More favorable reimbursement for outpatient dialysis and the introduction in the 1970s of continuous ambulatory peritoneal dialysis, which required less intensive training, contributed to a relative decline in HHD utilization.[91] Overall, the proportion of home dialysis patients in the U.S. declined from 1988 to 2012, with the number of home dialysis patients increasing at a slower rate relative to the total number of all dialysis patients. As cited in a U.S. Government Accountability Office (GAO) report, according to U.S. Renal Data System (USRDS) data, approximately 16 percent of the 104,000 dialysis patients in the U.S. received home dialysis in 1988; however, by 2012, the rates of HHD and PD utilization were 2 and 9 percent, respectively.[92]

Additionally, as outlined in the proposed rule, an annual analysis performed by the USRDS in 2018 compared the rates of dialysis modalities for prevalent dialysis patients in the U.S. to 63 selected countries or regions around the world. In 2016, the U.S. ranked 27th in the percentage of beneficiaries that were dialyzing at home (12 percent). For example, the U.S. rate

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[89] Stack AG. Determinants of Modality Selection among Incident US Dialysis Patients: Results from a National Study. Journal of the American Society of Nephrology. 2002; 13: 1279-1287. Doi 1046-6673/1305-1279

[90] Miskulin DC, et al. Comorbidity and Other Factors Associated With Modality Selection in Incident Dialysis Patients: The CHOICE Study. American Journal of Kidney Diseases. 2002; 39(2): 324-336. Doi 10.1053/ajkd.2002.30552

[91] Blagg CR. A Brief History of Home Hemodialysis. Annals in Renal Replacement Therapy. 1996; 3: 99-105

[92] Unites States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO-16-125). October 2015

of home dialysis is significantly below those of Hong Kong (74 percent), New Zealand (47 percent), Australia (28 percent), and Canada (25 percent).[93]

As discussed in the proposed rule, a 2011 report on home dialysis in the U.S. related the relatively low rate of home dialysis in this country to factors that included educational barriers, the monthly visit requirement for the MCP under the PFS, the need for home care partner support, as well as philosophies and business practices of dialysis providers, such as staffing allocations, lack of independence for home dialysis clinics, and business-oriented restrictions that lead to inefficient supply distribution. The report recommended consolidated, collaborative efforts to enhance patient education among nephrology practices, dialysis provider organizations, hospital systems and kidney-related organizations, as well as additional educational opportunities and training for nephrologists and dialysis staff. With regard to CMS's requirement starting in 2011 that the physician or non-physician practitioner furnish at least one in-person patient visit per month for home dialysis MCP services, the report noted that CMS allows discretion to Medicare contractors to allow payment without a visit so long as there is evidence for the provision of services throughout the month. Nevertheless, the report concluded that notwithstanding this allowance the stated policy might potentially be a disincentive for physicians to promote home dialysis. The report further commented that the low rate of home dialysis in the U.S. may result in part from patients' inability to perform self-care, and suggested providing support for home care partners. With respect to dialysis providers' business practices and philosophies, the report noted that dialysis providers differ in many ways and have different

[93] United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 11: International Comparisons. Figure F11.12

experiences that deserve attention and consideration with regard to potentially posing a barrier to the provision of home dialysis.[94]

As we noted in the proposed rule, the high rate of incident dialysis patients beginning dialysis through in-center HD in the U.S. is driven by a variety of factors including ease of initiation, physician experience and training, misinformation around other modalities, inadequate education for chronic kidney disease (CKD) beneficiaries, built-up capacity at ESRD facilities, and a lack of infrastructure to support home dialysis.[95] (Provision of home dialysis requires a system of distribution of supplies to patients, as well as allocation of staff and space within facilities for education, training, clinic visits, and supervision). One study indicated that patients' perceived knowledge about various ESRD therapies was correlated with their understanding of the advantages and disadvantages of the available treatment options.[96] As discussed in the proposed rule, researchers have reported that greater support, training, and education to nephrologists, other clinicians, and patients would increase the use of both HHD and PD. A prospective evaluation of dialysis modality eligibility among patients with CKD stages III to V enrolled in a North American cohort study showed that as many as 85 percent were medically eligible for PD.[97] However, in one study, only one-third of ESRD patients beginning maintenance dialysis were presented with PD as an option, and only 12 percent of

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[94] Golper TA, Saxena AB, Piraino B, Teitelbaum, I, Burkart, J, Finkelstein FO, Abu-Alfa A. Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. American Journal of Kidney Diseases. 2011; 58(6): 879-885.doi:10.1053/j.ajkd.2011.06.028

[95] Ghaffarri A, Kalantar-Zadeh K, Lee J, Maddux F, Moran J, Nissenson A. PD First: Peritoneal Dialysis as the Default Transition to Dialysis Therapy. Seminars in Dialysis. 2013; 26(6): 706-713. doi: 10.1111/sdi.12125

[96] Finkelstein FO, Story K, Firanek C, Barr P, et al. Perceived knowledge among patients cared for by nephrologists about chronic kidney disease and end-stage renal disease therapies. *Kidney International* 2008; 9: 1178-1184. https://doi.org/10.1038/ki.2008.376

[97] Mendelssohn DC. Mujais SK, Soroka, SD, et al. A prospective evaluation of renal replacement therapy modality eligibility. Nephrology Dialysis Transplantation. 2009; 24(2): 555-561. doi: https://doi.org/10/1093/ndt/gfn484

patients were presented with HHD as an option.[98] As shown by a national pre-ESRD education initiative, pre-dialysis education results in a 2- to 3- fold increase in the rate of patients initiating home dialysis compared with the U.S. home dialysis rate.[99] Another study reported 42 percent of patients preferring PD when the option was presented to them.[100]

Recent studies show substantial support among nephrologists and patients for dialysis treatment at home.[101, 102, 103, 104, 105] As we noted in the proposed rule, we believe that increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD Beneficiaries.

As discussed in the proposed rule, research suggests that dialyzing at home is associated with lower overall medical expenditures than dialyzing in-center. Key factors that may be related to lower expenditures include potentially lower rates of infection associated with dialysis treatment, fewer hospitalizations, cost differentials between PD and HD services and supplies,

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[98] Mehrotra R, Marsh D, Vonesh E, Peters V, Nissenson A. Patient education and access of ESRD patients to renal replacement therapies beyond in-center hemodialysis. Kidney International. 2005; 68(1):378-390

[99] Lacson E, Wang W, DeVries C, Leste K, Hakim RM, Lazarus M, Pulliam J. Effects of a Nationwide Predialysis Educational Program on Modality Choice, Vascular Access, and Patient Outcomes. American Journal of Kidney Diseases. 2011; 58(2): 235-242.doi:10.1053/j.ajkd.2011.04.015

[100] Maaroufi A, Fafin C, Mougel S, Favre G, Seitz-Polski P, Jeribi A, Vido S, Dewismi C, Albano L, Esnault V, Moranne O. Patient preferences regarding choice of end-stage renal disease treatment options. American Journal of Nephrology. 2013; 37(4): 359-369. doi: 1159/000348822

[101] Rivara MB, Mehrotra R. The Changing Landscape of Home Dialysis in the United States. Current Opinion in Nephrology and Hypertension.2014; 23(6):586-591.doi:10.1097/MNH0000000000000066

[102] Mehrotra R, Chiu YW, Kalantar-Zadeh K, Bargman J, Vonesh E. Similar Outcomes With Hemodialysis and Peritoneal Dialysis in Patients With End-Stage Renal Disease. Archives of Internal Medicine. 2011; 171(2): 110-118. Doi:10.1001/archinternmed.2010.352.

[103] Ghaffari et al. 2013

[104] Ledebo I, Ronco C. The best dialysis therapy? Results from an international survey among nephrology professionals. Nephrology Dialysis Transplantation.2008;6:403-408.doi:10.1093/ndtplus/sfn148

[105] Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. Nephrology News & Issues. September 2010; 36-44

and lower operating costs for dialysis providers for providing home dialysis.[106, 107, 108, 109, 110] (Most studies on the comparative cost and effectiveness of different dialysis modalities assess PD versus HD. As noted in the proposed rule, we believe that since the extent of in-center PD is negligible, and only approximately 2 percent of HD occurs at home, these studies are suitable for drawing conclusions regarding home versus in-center dialysis.) However, research on cost differences between in-center dialysis and home dialysis is limited to comparing costs for patients who currently dialyze at home to those who do not. As previously discussed in the proposed rule and in this final rule, there are currently barriers to dialyzing at home that may result in selection bias. Put another way, beneficiaries who currently dialyze at home may be different in some way from beneficiaries who dialyze in-center that is otherwise the cause of the observed difference in overall medical expenditures. Patients may differ in terms of age, gender, race, and clinical issues such as presence of diabetes and origin of ESRD.[111] Despite selection bias present in existing research, we stated in the proposed rule our expectation that increasing rates of home dialysis will likely decrease Medicare expenditures for ESRD Beneficiaries, and this is something we would assess as part of our evaluation of the ETC Model.

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[106] Walker R, Marshall MR, Morton RL, McFarlane P, Howard K. The cost-effectiveness of contemporary home hemodialysis modalities compared with facility hemodialysis: A systematic review of full economic evaluations. Nephrology. 2014; 19: 459-470 doi: 10.1111/nep.12269

[107] Walker R, Howard K, Morton R. Home hemodialysis: a comprehensive review of patient-centered and economic considerations. ClinicoEconomics and Outcomes Research. 2017; 9: 149-161.

[108] Howard K, Salkeld G, White S, McDonald S, Chadban S, Craig J, Cass A. The cost effectiveness of increasing kidney transplantation and home-based dialysis. Nephrology. 2009; 14: 123-132 doi: 10.1111/j.1440-1797.2008.01073.x

[109] Quinn R, Ravani P, Zhang X, Garg A, Blake P, Austin P, Zacharias JM, Johnson JF, Padeya S, Verreli M, Oliver M. Impact of Modality Choice on Rates of Hospitalization in Patients Eligible for Both Peritoneal Dialysis and Hemodialysis. Peritoneal Dialysis International. 2014; 34(1): 41-48 doi: 10.3447/pdi.2012.00257

[110] Sinnakirouchenan R, Holley, J. Peritoneal Dialysis Versus Hemodialysis: Risks, Benefits, and Access Issues. Advances in Chronic Kidney Disease. 2011; 18(6): 428-432. doi: 10.1053/j.ackd.2011.09.001

[111] United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Table 1.

In addition, as we discussed in the proposed rule, current research on patients in the U.S. and Canada indicates similar, or better, patient survival outcomes for PD compared to HD.[112, 113, 114] (As previously noted, most research on the comparative effectiveness of different dialysis modalities compares PD to HD, but—as noted in the proposed rule—we believe these studies are suitable for comparing home to in-center dialysis, given that in-center PD is negligible and only approximately 2 percent of HD is conducted at home.) The USRDS shows lower adjusted all-cause mortality rates for 2013 through 2016 for PD compared to HD.[115] Therefore, as noted in the proposed rule, we believe increased rates of PD associated with increased rates of home dialysis prompted by the proposed Model would at least maintain, and may improve, quality of care provided to ESRD Beneficiaries. While studies from several nations observe that the survival advantage for PD may be attenuated following the early years of dialysis treatment (1 to 3 years), and also that advanced age and certain comorbidities among patients are related to less favorable outcomes for PD, as we discussed in the proposed rule, a component of the Model's evaluation would be to assess the applicability of these findings to the U.S. population and Medicare beneficiaries, specifically if there is sufficient statistical power to detect meaningful

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[112] Wong B, Ravani P, Oliver MJ, Holroyd-Leduc J, Venturato L, Garg AX, Quinn RR. Comparison of Patient Survival Between Hemodialysis and Peritoneal Dialysis Among Patients Eligible for Both Modalities. American Journal of Kidney Diseases. 2018; 71(3) 344-351. doi:10.1053/j.ajkd.2017.08.028

[113] Kumar VA, Sidell MA, Jones JP, Vonesh EF. Survival of propensity matched incident peritoneal and hemodialysis patients in a United States health care system. Kidney International. 2014; 86: 1016-1022. doi:10.1038/ki.2014.224

[114] Mehrotra et al. 2011

[115] United States Renal Data System. Annual Data Report, 2018. Volume 2, Chapter 5: Mortality. Figure 5.1. Mortality rates were adjusted for age, sex, race, ethnicity, primary diagnosis and vintage.

variation.[116, 117, 118, 119, 120, 121, 122] Patient benefits of HHD and PD also can include better quality of life and greater independence.[123, 124, 125] As described in greater detail in the proposed rule and throughout section IV of this final rule, one of the aims of the ETC Model is to test whether new payment incentives would lead to greater rates of home dialysis.

The following is a summary of the comments received on the benefits of and barriers to home dialysis and our responses.

Comment: Several commenters expressed support for the association between home dialysis and improved health outcomes in comparison to in center dialysis. Commenters stated that research suggests that HHD facilitates longer, more frequent dialysis, or optimal dialysis dosing for the individual patient, which in turn leads to better health outcomes and quality of life. Commenters also stated that research suggests other benefits to home dialysis, including need for fewer medications, less frequent hospitalizations, and better quality of life. A commenter stated that there is evidence that suggests that HHD can have long term outcomes that are equal to or

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[116] Li KP, Chow KM. Peritoneal Dialysis – First Policy Made Successful: Perspectives and Actions. American Journal of Kidney Diseases. 2013; 62(5): 993-1005. doi: http://dx/doi.org/10.1053/j.ajkd.2013.03.038

[117] Yeates K, Zhu N, Vonesh E, Trpeski L, Blake P, Fenton S. Hemodialysis and peritoneal dialysis are associated with similar outcomes for end-stage renal disease treatment in Canada. Nephrology Dialysis Transplantation. 2012; 27(9): 3568-3575. doi: https://doi.org/10.1093/ndt/gfr/674

[118] Chiu YW, Jiwakanon S, Lukowsky L, Duong U, Kalantar-Zadeh, Mehrotra R. An Update on the Comparisons of Mortality Outcomes of Hemodialysis and Peritoneal Dialysis Patients. Seminars in Nephrology. 2011; 31(2): 152-158. Doi:10.1016/j.semnephrol.2011.01.004

[119] Mehrotra et al. 2011

[120] Sinnakirouchenan R, Holley JL. 2011

[121] Quinn RR, Hux JE, Oliver MJ, Austin, PC, Tonelli M, Laupacis A. Selection Bias Explains Apparent Differential Mortality between Dialysis Modalities. Journal of the American Society of Nephrology. 2011; 22(8) 1534-1542. doi: 10.1681/ASN.2010121232

[122] Weinhandl ED, Foley RN, Gilbertson DT, Arneson TJ, Snyder JJ, Collins AJ. Propensity-Matched Mortality Comparison of Incident Hemodialysis and Peritoneal Dialysis Patients. Journal of the American Society of Nephrology. 2010; 21(3): 499-506. doi: 10.1681/ASN.2009060635: 10.1681/ASN.2009060635

[123] Ghaffari et al. 2013

[124] Rivara and Mehrotra. 2014

[125] Juergensen E, Wuerth D, Finkelstein SH et al., Hemodialysis and Peritoneal Dialysis: Patients' Assessments of Their Satisfaction with Therapy and the Impact of the Therapy on their Lies. Clinical Journal of American Society of Nephrology. 2006; 1(6): 1191-1196. DOI: https://doi.org/10.2215/CJN.01220406

better than deceased donor transplants. A commenter stated that they believe home dialysis can preserve or enhance the quality of care for ESRD Beneficiaries while reducing Medicare expenditures. Another commenter stated that shifting dialysis provision from in-center dialysis to home dialysis would have positive economic effects, including decreasing costs for dialysis providers, creating economies of scale for home dialysis supplies and logistics, and increasing research and development into new home dialysis technologies.

Response: We thank the commenters for their feedback and support. If the Model increases rates of home dialysis as intended, we will assess the impact of increased rates of home dialysis on quality of care, including—to the extent possible--those particular aspects of care quality identified by commenters. The evaluation plan for the Model is discussed in section IV.C.11 of this final rule.

Comment: Multiple commenters expressed agreement with barriers to the provision of home dialysis services as previously identified in this final rule and in the proposed rule. Commenters specifically identified barriers surrounding limited patient education about and awareness of home dialysis, and lack of familiarity and comfort with prescribing home dialysis among Managing Clinicians. Commenters also identified additional factors that may prevent beneficiaries from selecting home dialysis, including: clinical, mental, and social stability; inadequate or unstable housing conditions; socioeconomic factors; and patient preference. Several commenters identified aspects of the Medicare FFS payment system that disincentivize home dialysis, including the ability for Managing Clinicians to maximize revenue through in-center dialysis over home dialysis, and Medicare requirements around MCP monthly in-person visits for home dialysis beneficiaries. A commenter stated that the requirements for an ESRD facility to become certified to provide home dialysis are burdensome and prevent some ESRD

facilities from seeking certification to begin a home dialysis program. Commenters identified system-level factors related to the supply of goods and services necessary to conduct home dialysis, including dialysis supplies in general and PD solution in particular, availability of vascular access services, and lack of new technology and innovation in the home dialysis industry. Commenters discussed a lack of access to primary care, lack of screening for CKD in a primary care setting, and lack of patient education about ESRD and dialysis options before beneficiaries initiate dialysis, as beneficiaries who have access to these services are more likely to initiate dialysis at home. Commenters stated that many of these barriers to home dialysis are outside of the control of Managing Clinicians and ESRD facilities.

Response: We thank the commenters for their feedback. CMS recognizes that there are a variety of barriers that prevent ESRD Beneficiaries from choosing home dialysis at present. ESRD facilities and Managing Clinicians are the clinical experts in dialysis provision in general, and in the clinical and non-clinical needs of individual ESRD Beneficiaries specifically. We therefore believe that ESRD facilities and Managing Clinicians are uniquely positioned to assist ESRD Beneficiaries in overcoming these barriers, given their close care relationship to and frequent interaction with ESRD Beneficiaries. Therefore, we have designed the ETC Model to test whether outcomes-based payment adjustments for ESRD facilities and Managing Clinicians can maintain or improve quality and reduce costs by increasing rates of home dialysis transplant waitlisting, and living donor transplants. The ETC Model is one piece of the Advancing American Kidney Health initiative, a larger HHS effort focused on improving care for patients with kidney disease.[126] The payment adjustments in the ETC Model test one approach to

[126] E.O. 13879 of July 10, 2019.

addressing existing disincentives to home dialysis and transplant in the current Medicare FFS payment system.

We recognize that educating patients about their renal replacement options is key to supporting modality selection. As such, we are waiving certain requirements for the Kidney Disease Education (KDE) benefit to allow Managing Clinicians who are ETC Participants additional flexibility to furnish and bill for these educational services under the Model. These waivers are detailed in section IV.C.7.b of this final rule.

In response to the commenters' concerns about system-level factors, including products and services necessary to home dialysis provision, we have designed the benchmarking and scoring methodology, described in section IV.C.5.d of this final rule, to be comparative to account for these types of system-level factors. In the initial years of the Model, participant achievement will be assessed in relation to home dialysis rates among non-participants. As such, any system-level limitations that affect home dialysis rates for ETC Participants are also reflected in the ESRD facilities and Managing Clinicians not participating in the Model that form the basis for the benchmarks.

In response to the commenters' concerns about certification requirements deterring ESRD facilities from operating home dialysis programs, we did not propose to waive Medicare certification requirements as part of this Model, in order to preserve patient health and safety. Additionally, the aggregation approach for this Model, in which all ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area are assessed as one aggregation group with respect to their performance on the home dialysis rate, alleviates the need for individual ESRD facilities to become certified to perform home dialysis.

Comment: Several commenters stated that comparing U.S. rates of home dialysis to other countries, particularly other countries with very high home dialysis rates, is inappropriate, because those countries have different demographic, socioeconomic, and health system factors that impact home dialysis utilization. Several commenters stated that other countries that are more similar to the U.S. in demography, socioeconomic status, and health system structure have home dialysis rates closer to that of the U.S.

Response: We appreciate the commenters' concerns about comparing home dialysis rates in the U.S. to home dialysis rates in other countries. We acknowledge that there are differences between the U.S. and other countries that may make direct comparisons challenging. We provided the comparison in the proposed and final rules for context but have designed the Model specifically for the U.S. market, in particular the Medicare program.

b. Kidney Transplants

As we discussed in the proposed rule, a kidney transplant involves surgically transplanting one healthy kidney from a living or deceased donor. A kidney-pancreas transplant involves simultaneously transplanting both a kidney and a pancreas, for patients who have kidney failure related to type 1 diabetes mellitus. While the kidney in a kidney transplant may come from a living or deceased donor, a kidney transplant in conjunction with a pancreas or other organ can only come from a deceased donor. As noted in the proposed rule, candidates for kidney transplant undergo a rigorous evaluation by a transplant center prior to placement on a waitlist, and once placed on the waitlist, potential recipients must maintain active status on the waitlist. The United Network for Organ Sharing (UNOS) maintains the waitlist for and conducts matching of deceased donor organs. ESRD Beneficiaries already on dialysis continue to receive regular dialysis treatments while waiting for an appropriate organ.

As cited in the proposed rule, a systematic review of studies worldwide found significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with maintenance dialysis.[127] Additionally, this review found that beneficiaries who receive transplants experience a better quality of life than those who receive treatment with chronic dialysis.[128]

As we noted in the proposed rule, per-beneficiary-per-year Medicare expenditures for beneficiaries receiving kidney or kidney-pancreas transplants are often substantially lower than for those on dialysis.[129] The average dialysis patient is admitted to the hospital nearly twice a year, often as a result of infection, and approximately 35.4 percent of dialysis patients who are discharged are re-hospitalized within 30 days of being discharged.[130] Among transplant recipients, there are lower rates of hospitalizations, emergency department visits, and readmissions.[131] As discussed in the proposed rule, while comparisons between patients on dialysis and those with functioning transplants rely on observational data, due to the ethical concerns with conducting clinical trials, the data nonetheless suggest better outcomes for ESRD patients that receive transplants.

Notwithstanding these outcomes, as we discussed in the proposed rule, only 29.6 percent of prevalent ESRD patients in the U.S. had a functioning kidney transplant and only 2.8 percent of incident ESRD patients – meaning patients new to ESRD – received a pre-emptive kidney

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[127] Tonelli M, Weibe N, Knoll G, Bello A, Browne S. Jadhav D, Klarenbach S, Gill J. Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcomes. American Journal of Transplantation. 2011; 11(10). doi: https://doi.org/10.1111/j.1600-6143.2011.03686.x

[128] Tonelli, M. et al. 2011

[129] United States Renal Data System.Annual Data Report, 2018. Volume 2. Chapter 9: Healthcare expenditures for Persons with ESRD. Figure F9.8

[130] United States Renal Data System. Annual Data Report, 2018; Volume 2, Chapter 4: Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays. Tables F4-1, F4-8

[131] United States Renal Data System. Annual Data Report, 2018: Volume 2, Chapter 4: Hospitalizations, Readmissions, Emergency Department Visits, and Observation Stays. Tables F4.1, F4.8, and F4.14

transplant in 2016.[132] A pre-emptive transplant is a kidney transplant that occurs before the patient requires dialysis. These rates are substantially below those of other developed nations. The U.S. was ranked 39th of 61 reporting countries in kidney transplants per 1,000 dialysis patients in 2016, with 39 transplants per 1,000 dialysis patients in 2016.[133] While the relatively low rate of transplantation in the U.S. may partly reflect the high numbers of dialysis patients and differences in the relative prevalence and incidence of ESRD, as we noted in the proposed rule, there are other likely contributing causes, such as differences in health care systems, the infrastructure supporting transplantation, and cultural factors.[134]

As we discussed in the proposed rule, the main barrier to kidney transplant is the supply of available organs. Medicare is undertaking regulatory efforts to increase organ supply, discussed in the proposed rule and in section IV.B.3.a of this final rule. Further, as discussed in the proposed rule, we believe there are a number of things ESRD facilities and Managing Clinicians can do to assist their beneficiaries in securing a transplant. Access to kidney transplantation can be improved by increasing referrals to the transplant waiting list, increasing rates of deceased and living kidney donation, expanding the pools of potential donors and recipients, and reducing the likelihood that potentially viable organs are discarded.[135] We noted in the proposed rule that we anticipated Managing Clinicians and ESRD facilities selected for participation in the ETC Model would address these areas of improvement through various

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[132] 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

[133] United States Renal Data System. Annual Data Report, 2018. Volume 2. Chapter 11. International Comparisons. Figure 11.16

[134] United States Renal Data System. Annual Data Report, 2018: Volume 2. Chapter 11. International Comparisons. https://www.usrds.org/2018/view/v2_11.aspx

[135] Serur D, Bingaman A, Smith B. Kidney Transplantation 2017 Breaking Down Barriers and Building Bridges. American Society of Nephrology: Kidney News Online. 2017; 9(4): kidneynews.org/kidney-news/practice-pointers/kidney-transplantation-2017-breaking-down-barriers-and-building-bridges

strategies in order to improve their rates of transplantation. As we noted in the proposed rule, these strategies could include educating beneficiaries about transplantation, coordinating care for beneficiaries as they progress through the transplant waitlist process, and assisting beneficiaries and potential donors with issues surrounding living donation, including support for paired donations and donor chains. In paired donations and donor chains, willing donors who are incompatible with their intended recipient can donate to other candidates on the transplant waitlist in return for a donation from another willing donor who is compatible with their intended recipient.[136]

After increasing during the 1990s, the volume of simultaneous pancreas and kidney transplants has either remained stable or declined slightly since the early 2000s. As we noted in the proposed rule, the reason for this decline is not clear, but is likely to be multifactorial, possibly including a decrease in patients being placed on the waiting list for this procedure, more stringent donor selection, and greater scrutiny of transplant center outcomes.[137]

As we discussed in the proposed rule, under current Medicare payment systems, an ESRD Beneficiary receiving a kidney transplant represents a loss of revenue to the ESRD facility and, to a lesser extent, the Managing Clinician. After a successful transplant occurs, the ESRD facility no longer has a care relationship with the beneficiary, as the beneficiary no longer requires maintenance dialysis. While the Managing Clinician may continue to have a care relationship with the beneficiary post-transplant, payment for physicians' services related to maintaining the health of the transplanted kidney is lower than the MCP for managing dialysis.

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[136] Segev D, Gentry S, Warren D. Kidney Paired Donation and Optimizing the Use of Live Donor Organs. JAMA. 2005;293(15):1883-1890. doi:10.1001/jama.293.15.1883

[137] Redfield RR, Scalea JR, Odoricio JS. Simultaneous pancreas and kidney transplantation: current trends and future directions. Current Opinion in Organ Transplantation. 2015; 20(1): 94-102. Doi:10.1097/MOT.0000000000000146

Whereas a Managing Clinician sees a beneficiary on dialysis and bills for the MCP each month, a post-transplant beneficiary requires fewer visits per year, and these visits are of a lower intensity. As described in greater detail in the proposed rule and throughout this section IV of this final rule, one of the aims of the ETC Model is to test whether new payment incentives would lead to greater rates of kidney transplantation.

The following is a summary of the comments received on the benefits of and barriers to transplantation and our responses.

Comment: Multiple commenters expressed support for the premise that transplantation is the best treatment option for most patients with ESRD. These commenters also stated that research shows that transplantation is associated with better health outcomes, better quality of life, and lower health care expenditures.

Response: We thank the commenters for their feedback and support.

Comment: A commenter stated that rates of transplantation in the U.S. are not directly comparable to rates of transplantation in other countries due to different population characteristics.

Response: We thank the commenter for this feedback. As stated in the proposed rule and earlier in this final rule, we acknowledge that, in addition to variations in the relative prevalence and incidence of ESRD, there are other likely contributing causes to the relatively low rate of transplantation in the U.S. relative to other countries, such as differences in health care systems, the infrastructure supporting transplantation, and cultural factors.[138] As such, while we included information about transplant rates in other countries for comparison, we did

[138] United States Renal Data System. Annual Data Report, 2018: Volume 2. Chapter 11. International Comparisons. https://www.usrds.org/2018/view/v2_11.aspx

not propose to base the design of the Model's transplant component on transplant rates in other countries. We believe that the transplant rate in the U.S. can be higher than it is now, and to that end are testing this Model in conjunction with other efforts to increase transplant rates described in section IV.B.1.a of this final rule.

Comment: Multiple commenters expressed agreement with the barriers to transplantation identified in the proposed rule (also discussed earlier in this final rule). Commenters specifically identified the limited supply of organs for transplantation as the key barrier to transplantation. Several commenters stated that there is significant variation nationally in the patient experience of transplantation, including the supply of organs and transplant center practices. A commenter stated that each transplant center sets its own guidelines for transplant waitlisting, and that some centers exclude patients who do not have financial resources or health insurance coverage beyond Medicare. A commenter described factors that patients have identified as limiting their access to transplant waitlisting, including: the complexity, intensity, and difficulty of the waitlisting process; uncertainty and lack of social, financial, and medical support; cost; and fear of loss of Medicare coverage post-transplant. A commenter stated that lack of access to primary care and early detection of kidney disease is associated with lower likelihood of receiving a transplant.

Response: We thank the commenters for their feedback. CMS recognizes that there are a variety of barriers that prevent ESRD Beneficiaries from receiving a transplant at present. As noted previously in this final rule, we believe that ESRD facilities and Managing Clinicians are uniquely positioned to assist beneficiaries in overcoming barriers to transplantation, for both deceased donor transplantation and living donor transplantation, given their close care relationship to and frequent interaction with ESRD Beneficiaries. Therefore, we have designed

the ETC Model to test whether outcomes-based payment adjustments for ESRD facilities and Managing Clinicians can maintain or improve quality and reduce costs by increasing rates of home dialysis and transplantation. As also noted previously in this final rule, the ETC Model is one piece of a larger HHS effort focused on improving care for patients with kidney disease. In particular, we recognize that other transplant providers, including transplant centers and organ procurement organizations (OPOs) are central to the supply and use of deceased donor organs. As such, we are implementing the ETC Learning Collaborative, described in section IV.C.12 of this final rule, to increase the supply and use of deceased donor organs. CMS and HHS have also undertaken other regulatory efforts to increase the supply of organs, including the proposed rule issued December 23, 2019 entitled "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization[s]" (84 FR 70628), and the proposed rule published December 20, 2019 entitled "Removing Financial Disincentives to Living Organ Donation" (84 FR 70139). The payment adjustments in the ETC Model test one approach for addressing existing disincentives to transplantation in the current Medicare FFS payment system, including to create incentives to support a beneficiary through the complexity of the transplant process. As described in greater detail in section IV.C.1 of this final rule, we are altering the PPA calculation such that ETC Participant performance will be assessed based on a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, rather than a transplant rate focused on the receipt of all kidney transplants including deceased donor transplants. We made this alteration to recognize the role that ETC Participants can currently play in getting patients on the transplant waitlist rate and in increasing the rate of living donor transplants described later on in the rule while allowing the ETC Learning Collaborative and these other

CMS and HHS rules (if finalized) time to take effect and to increase the supply of available deceased donor organs. However, as described in greater detail in section IV.C.5.c.(2) of this final rule, it is also our intent to observe the supply of deceased donor organs available for transplantation. Any change from holding ETC Participants accountable for the rate of all kidney transplants including deceased donor transplantation, rather than the rate of kidney transplant waitlisting and living donor transplantation would be proposed through notice and comment rulemaking in the future.

In the final rule, we are clarifying that when referencing kidney transplants in this final rule and the ETC Model regulations, CMS is including any kidney transplant, alone or in conjunction with any other organ, not just a kidney transplant or kidney-pancreas transplant. As discussed in more detail in section IV.C.5 of this final rule, we received a comment that urged CMS to include in the ETC Model kidney transplants in conjunction with any other organ, in addition to the kidney transplants and kidney-pancreas transplants referenced in the proposed rule. By specifying in the proposed rule that we were including kidney and kidney-pancreas transplants under the Model, it was not our intent to imply that we were excluding kidney transplants in conjunction with any other organ. Therefore, as discussed in section IV.C.5 of this final rule, we are clarifying as part of the final definition of kidney transplant that the ETC Model includes kidney transplants that occur alone or in conjunction with any other organ.

c. Addressing Care Deficits Through the ETC Model

Considering patient and clinician support for home dialysis and kidney transplant for ESRD patients, along with evidence that use of these treatment modalities could be increased with education, we proposed to implement the ETC Model to test whether adjusting Medicare payments to ESRD facilities under the ESRD PPS and to Managing Clinicians under the PFS

would increase rates of home dialysis, both HHD and PD, and kidney and kidney-pancreas transplantation.

We proposed that the ETC Model would include two types of payment adjustments: the Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). The HDPA would be a positive payment adjustment on home dialysis and home dialysis-related claims during the initial three years of the Model, to provide an up-front incentive for ETC Participants to provide additional support to beneficiaries choosing to dialyze at home. The PPA would be a positive or negative payment adjustment, which would increase over time, on dialysis and dialysis-related claims, both home and in-center, based on the ETC Participant's home dialysis rates and transplant rates during a Measurement Year in comparison to achievement and improvement benchmarks, with the aim of increasing the percent of ESRD Beneficiaries either having received a kidney transplant or receiving home dialysis over the course of the ETC Model. We proposed that the magnitude of the HDPA would decrease as the magnitude of the PPA increases, to shift from a process-based incentive approach (the HDPA) to an outcomes-based incentive approach (the PPA).

The proposed payment adjustments under the ETC Model would apply to all Medicare-certified ESRD facilities, and Managing Clinicians enrolled in Medicare located within Selected Geographic Areas. While we proposed to apply the HDPA to all ETC Participants, the PPA would not apply to certain ESRD facilities and Managing Clinicians managing low volumes of adult ESRD Medicare beneficiaries. Under our proposal, one or both of the payment adjustments under the ETC Model would apply to payments on claims for dialysis and certain dialysis-related services with through dates from January 1, 2020 through June 30, 2026, with

the goal of reducing Medicare spending, preserving or enhancing quality of care for beneficiaries, and increasing beneficiary choice regarding ESRD treatment modality.

The following is a summary of the comments received on addressing care deficits through the ETC Model, and our responses.

Comment: Multiple commenters expressed support for the goals of the proposed Model. Commenters expressed support for increasing rates of home dialysis and transplantation, on the grounds that these alternative renal replacement modalities are better for patients with ESRD than in-center dialysis. Several commenters expressed support for the proposed Model's approach to increasing home dialysis and transplantation through payment adjustments, as well as the proposed Model's geographic scope and its mandatory design. These commenters also stated that the proposed Model had the potential to: create system-wide change; support technological innovation; and facilitate research into factors that impact the provision of dialysis, clinical outcomes related to dialysis modality selection, and patient outcomes.

Response: We thank the commenters for their feedback and support of the Model's goals.

Comment: Multiple commenters stated that they supported the goals of the proposed Model, but expressed reservations about aspects of the Model's design. Several commenters stated that any payment incentives for providers and suppliers need to be balanced against patient preferences and minimizing or avoiding unintended consequences. Several commenters stated that the ETC Model, as proposed, would not address some or all of the key barriers to home dialysis and transplantation, including that the Model, as proposed, had an insufficient focus on prevention and patient education, organ availability, and the supply of trained home dialysis staff including home dialysis nurses, and did not adequately take into account the unique structure of

the dialysis market. Several commenters stated that the proposed Model would not sufficiently incentivize ETC Participants to take patient choice into account. Several commenters expressed concern that the ETC Model would harm the KCC Model because the national impact of the ETC Model would deter participation in and the evaluation of the KCC Model.

Response: We thank the commenters for their feedback and support of the Model's goals. In terms of the commenters' concerns that the Model does not address some or all of the key barriers to home dialysis and transplantation and does not sufficiently incentivize supporting patient choice, this Model is one piece of the larger HHS effort to improve care for beneficiaries with kidney disease, which also includes the KCC Model. While the ETC Model focuses primarily on modality selection, other parts of the HHS effort focus more directly on other ways to improve care for beneficiaries with kidney disease, including education and prevention, care coordination, organ supply, and technological innovation. We agree that supporting patient choice in modality selection is vital, and we believe the ETC Model will support providers and suppliers in their ability to assist beneficiaries choosing renal replacement modalities other than in-center dialysis. We address the commenters' specific comments about the interaction with the KCC Model in section IV.C.6 of this final rule, and in other sections of this final rule where particular policies are discussed.

Comment: Multiple commenters stated that they supported the goals of the proposed ETC Model but opposed the Model itself. Several commenters stated that the proposed Model had significant methodological limitations that would lead to unintended consequences and adverse patient outcomes. A commenter stated that the proposed Model would amount to a payment reduction for all dialysis providers. Several commenters stated that, as proposed, methodological flaws with the Model's design would prevent participants from being successful

in the Model. In particular, a few commenters stated that small dialysis organizations and rural ESRD facilities would be harmed due to the financial risk in the Model. Several commenters stated that rather than implement the ETC Model, CMS should focus on implementing voluntary models that incentivize dialysis providers to collaborate around care coordination, such as the CEC Model. A commenter stated that, as the current organ allocation system may change, it is inappropriate to test a model around transplantation at this time.

Response: We thank the commenters for their feedback and support of the Model's goals. We address commenters' specific comments about methodological concerns, the impact of the Model on small and rural ESRD facilities, and the organ allocation system in later sections of this final rule where particular policies are discussed.

Comment: Several commenters stated that supporting patient choice and informed decision-making are vital, and should be the focus of the proposed Model.

Response: We thank the commenters for their feedback, and we agree that supporting patient choice in modality selection is vital. We believe this Model will support beneficiaries' ability to choose renal replacement modalities other than in-center HD.

Comment: Many commenters recommended additional or alternative approaches, outside of the ETC Model, that CMS could take to improve quality of care for Medicare beneficiaries with kidney disease.

Response: We thank commenters for their feedback; however, these suggestions did not address the ETC Model and therefore are out of scope for this rulemaking. We may consider these comments in developing future policies related to beneficiaries with kidney disease.

2. The Medicare ESRD Program

In the proposed rule and in this section of the final rule, we describe current Medicare

payment rules and how they may create both positive and negative incentives for the provision of home dialysis services and kidney transplants.

a. History of the Medicare ESRD Program

Section 299I of the Social Security Amendments of 1972 (Pub. L. 92-603) extended Medicare coverage to individuals regardless of age who have permanent kidney failure, or ESRD, requiring either dialysis or kidney transplantation to sustain life, and who meet certain other eligibility requirements. Individuals who become eligible for Medicare on the basis of ESRD are eligible for all Medicare-covered items and services, not just those related to ESRD. Subsequently, the ESRD Amendments of 1978 (Pub. L. 95-292) amended Title XVIII of the Act by adding section 1881.

Section 1881 of the Act establishes Medicare payment for services furnished to individuals who have been determined to have ESRD, including 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 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. This provision also directs the Secretary of HHS to consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

Prior to 2011 and the implementation of the ESRD PPS, Medicare had a composite payment system for the costs incurred by ESRD facilities furnishing outpatient maintenance dialysis, including some routinely provided drugs, laboratory tests, and supplies, whether the

services were furnished in a facility or at home. (For a discussion of the composite payment system, please see 75 FR 49032). Under this methodology, prior to 2009, CMS differentiated between hospital-based and independent facilities for purposes of setting the payment rates. (Effective January 1, 2009, CMS discontinued the policy of separate payment rates based on this distinction, 75 FR 49034). However, the same rate applied regardless of whether the dialysis was furnished in a facility or at a beneficiary's home (75 FR 49058). The system was relatively comprehensive with respect to the renal dialysis services included as part of the composite payment, but over time a substantial portion of expenditures for renal dialysis services such as drugs and biologicals were not included under the composite payment and paid separately in accordance with the respective fee schedules or other payment methodologies (75 FR 49032). With the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), the Secretary was required to implement a payment system under which a single payment is made for renal dialysis services in lieu of any other payment.

As we described in the proposed rule, in 2008, CMS issued a final rule entitled "Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities," which was the first comprehensive revision since the outset of the Medicare ESRD program in the 1970s. The Conditions for Coverage (CfC) established by this final rule include separate, detailed provisions applicable to home dialysis services, setting substantive standards for treatment at home to ensure that the quality of care is equivalent to that for in-center patients. (73 FR 20369, 20409, April 15, 2008).

As we also noted in the proposed rule, on January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as

required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA. The ESRD PPS is discussed in detail in the following section.

b. Current Medicare Coverage of and Payment for ESRD Services

The Medicare program covers a range of services and items associated with ESRD treatment. Medicare Part A generally includes coverage of inpatient dialysis for patients admitted to a hospital or skilled nursing facility for special care, as well as inpatient services for covered kidney transplants. Medicare Part B generally includes coverage of renal dialysis services furnished by Medicare-certified outpatient facilities, including certain dialysis treatment supplies and medications, home dialysis services, support and equipment, and doctor's services during a kidney transplant. Costs for medical care for a kidney donor are covered under either Part A or B, depending on the service. To date, Medicare Part C has been available to ESRD Beneficiaries only in limited circumstances, such as when an individual already was enrolled in a Medicare Advantage (MA) plan at the time of ESRD diagnosis; however, as required under section 17006 of the 21st Century Cures Act, ESRD Beneficiaries will be allowed to enroll in MA plans starting with 2021. Medicare Part D generally provides coverage for outpatient prescription drugs not covered under Part B, including certain renal dialysis drugs with only an oral form of administration (oral-only drugs), and prescription medications for related conditions.

(1) The ESRD PPS under Medicare Part B

As we discussed in the proposed rule, under the ESRD PPS, a single per treatment payment is made to an ESRD facility for all of the renal dialysis services and items defined in section 1881(b)(14)(B) of the Act and furnished to beneficiaries for the treatment of ESRD in a facility or in a patient's home. The ESRD PPS includes patient-level adjustments for case mix,

facility-level adjustments for wage levels, low-volume facilities and rural facilities, and, when applicable, a training add-on for home and self-dialysis modalities, an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care, a transitional drug add-on payment adjustment (TDAPA), and a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES).[139] Under section 1881(b)(14)(F) of the Act, the ESRD PPS payment amounts are increased annually by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

As we noted in the proposed rule, in implementing the ESRD PPS, we have sought to create incentives for providers and suppliers to offer home dialysis instead of just dialysis at a facility. In the CY 2011 ESRD PPS final rule, we noted that in determining payment under the ESRD PPS, we took into account all costs necessary to furnish home dialysis treatments including staff, supplies, and equipment. In that rule, we described that Medicare would continue to pay, on a per treatment basis, the same base rate for both in-facility and home dialysis, as well as for all dialysis treatment modalities furnished by an ESRD facility (HD and the various forms of PD) (75 FR 49057, 49059, 49064). The CY 2011 ESRD PPS final rule also finalized a wage-adjusted add-on per treatment adjustment for home and self-dialysis training under 42 CFR 413.235(c), as CMS recognized that the ESRD PPS base rate alone does not account for the staffing costs associated with one-on-one focused home dialysis training treatments furnished by a registered nurse (75 FR 49064). CMS noted, however, that because the costs associated with the onset of dialysis adjustment and the training add-on adjustment

[139] After we published the proposed rule to implement the ETC Model, CMS established the TPNIES under the ESRD PPS as part of the CY 2020 ESRD PPS final rule (84 FR 60648). We discuss the implications of this change for the ETC Model payment adjustments in sections IV.C.4.b, and IV.C.5.e(1) of this final rule.

overlap, ESRD facilities would not receive the home dialysis training adjustment in addition to the add-on payment under the ESRD PPS for the first 4 months of dialysis for a Medicare patient (75 FR 49063, 49094).

As we noted in the proposed rule, ESRD PPS payment requirements are set forth in 42 CFR part 413, subpart H. Since the implementation of the ESRD PPS, CMS has published annual rules to make routine updates, policy changes, and clarifications. Payment to ESRD facilities under the ESRD PPS for a calendar year might also be reduced by up to two percent based on their performance under the ESRD QIP, which is authorized by section 1881(h) of the Act. Section 1881(h) of the Act requires the Secretary to select measures, establish performance standards that apply to the measures, and develop a methodology for assessing the total performance for each renal dialysis facility based on the performance standards established with respect to the measures for a performance period. CMS uses notice and comment rulemaking to make substantive updates to the ESRD PPS and ESRD QIP program requirements.

(2) The MCP

As we discussed in the proposed rule, Medicare pays for routine professional services relating to dialysis care directly to a billing physician or non-physician practitioner. When Medicare pays the physician or practitioner separately for routine dialysis-related physicians' services furnished to a dialysis patient, the payment is made under the Medicare physician fee schedule using the MCP method as specified in 42 CFR 414.314. The per-beneficiary per-month MCP is for all routine physicians' services related to the patient's renal condition. Whereas the MCP for patients dialyzing in-center varies based on the number of in-person visits the physician

has with the patient during the month, the MCP for patients dialyzing at home is the same regardless of the number of in-person visits.[140]

(3) The Kidney Disease Education Benefit

As we discussed in the proposed rule, in addition to establishing the ESRD PPS, the MIPPA, in section 152(b), amended section 1861(s)(2) of the Act by adding a new subparagraph (EE) ''kidney disease education services'' as a Medicare-covered benefit under Part B for beneficiaries with Stage 4 CKD. Medicare currently covers up to 6 1-hour sessions of KDE services, addressing the choice of treatment (such as in-center HD, home dialysis, or kidney transplant) and the management of comorbidities, among other topics (74 FR 61737, 61894).

However, utilization of KDE services has been low. As we described in the proposed rule, citing the USRDS, GAO reported that less than 2 percent of eligible Medicare beneficiaries used the KDE benefit in 2010 and 2011, the first 2 years it was available, and that use of the benefit has decreased since then.[141] According to GAO, stakeholders have attributed this low usage to the statutory restrictions on which practitioners can provide this service, and also the limitation of eligibility to the specific category of Stage 4 CKD patients. As we noted in the proposed rule, these restrictions are specified in section 1861(ggg)(1) and (2) of the Act. A "qualified person" is a physician, physician assistant, or nurse practitioner, or a provider of services located in a rural area. GAO cited literature emphasizing the importance of pre-dialysis

[140] Medicare Claims Processing Manual, Chapter 8, 140; https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf

[141] United States Government Accountability Office. 2015

education in helping patients to make informed treatment decisions, and indicating that patients who have received such education might be more likely to choose home dialysis.

c. Impacts of Medicare Payment Rules on Home Dialysis

As we discussed in the proposed rule, in the CY 2011 ESRD PPS final rule, we acknowledged concerns from commenters that the proposed ESRD PPS might contribute to decreasing rates of home dialysis. In particular, commenters stated that the single payment method would require ESRD facilities to bear the supply and equipment costs associated with home dialysis modalities, and thus make them less economically feasible. We noted in response that while home dialysis suppliers may not achieve the same economies of scale as ESRD facilities, suppliers would remain able to provide equipment and supplies to multiple ESRD facilities and be able to negotiate competitive prices with ESRD equipment and supply manufacturers (75 FR 49060). Nevertheless, we stated that we would monitor utilization of home dialysis under the ESRD PPS (75 FR 49057, 49060).

As we further discussed in the proposed rule, a May 2015 report from GAO examined the incentives for home dialysis associated with Medicare payments to ESRD facilities and physicians. Citing the USRDS, GAO found a decrease in the percentage of home dialysis patients as a percentage of all dialysis patients between 1988 and 2008, but then a slight increase to 11 percent in 2012.[142] According to GAO, the more recent increase in use of home dialysis was also reflected in CMS data for adult Medicare dialysis patients, showing an increase from 8 percent using home dialysis in January 2010 to about 10 percent as of March 2015.

[142] United States Government Accountability Office, 2015

Although this increase was generally concurrent with the phase-in of the ESRD PPS, the GAO report identified factors that might undermine incentives to encourage home dialysis. According to interviews with stakeholders, facilities' costs for increasing provision of in-center HD may be lower than for either HHD or PD. Although the average cost of an in-center HD treatment is typically higher than the average cost of a PD treatment, ESRD facilities may be able to add an in-center patient without incurring the cost of an additional dialysis machine because each machine can be used by 6 to 8 patients. In contrast, when adding a home dialysis patient, facilities generally incur costs for additional equipment specific to individual patients.[143]

Similarly, GAO received comments from physicians and physician organizations that Medicare payment may lead to a disincentive to prescribe home dialysis, because management of a home dialysis patient often occurs in a private setting and tends to be more comprehensive, while visits to multiple in-center patients may be possible in the same period of time. The GAO report noted, on the other hand, that monthly physician payments for certain patients under 65 who undergo home dialysis training may begin the first month, instead of the fourth, of dialysis, which may provide physicians with an incentive to prescribe home dialysis. In addition, the GAO report stated that Medicare makes a one-time payment for each patient who has completed home dialysis training under the physician's supervision.[144]

The GAO report concluded that interviews with stakeholders indicated potential for further growth, noting that the number and percentage of patients choosing home dialysis had increased in the recent years. The report stated that Medicare payments to facilities and physicians would need to be consistent with the goal of encouraging home dialysis when

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[143] United States Government Accountability Office, 2015

[144] United States Government Accountability Office, 2015

appropriate. A specific recommendation was to examine Medicare policies regarding monthly Medicare payments to physicians and revise them if necessary to encourage physicians to prescribe home dialysis for patients for whom it is appropriate.[145]

As discussed in the proposed rule, in the CY 2017 ESRD PPS final rule, CMS finalized an increase to the home and self-dialysis training add-on payment adjustment (81 FR 77856), to provide an increase in payment to ESRD facilities for training beneficiaries to dialyze at home.

3. CMS Efforts to Support Modality Choice

While CMS has taken steps in the past to support modality choice, the deficits in care previously described – low rates of home dialysis and kidney transplantation – remain. We noted in the proposed rule our belief that the proposed ETC Model is consistent with several different recent actions to support modality choice for ESRD Beneficiaries, which are described in the proposed rule as well as this final rule.

a. Regulatory Efforts

As discussed in the proposed rule, on September 20, 2018, we published in the **Federal Register** a proposed rule entitled "Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" (83 FR 47686). This rule was finalized without change on September 30, 2019 (84 FR 51732). This final rule, among other things, removed the requirements at 42 CFR 482.82 that required transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. CMS removed these requirements in order to address the unintended consequences that occurred as a result of the Medicare re-approval requirements, which have resulted in transplant programs

[145] United States Government Accountability Office. 2015

potentially avoiding performing transplant procedures on certain patients and many organs with perceived risk factors going unused out of fear of being penalized for outcomes that are non-compliant with § 482.82. Although CMS removed certain requirements at § 482.82, CMS emphasized that transplant programs should focus on maintaining high standards that protect patient health and safety and produce positive outcomes for transplant recipients. As we noted in this final rule, CMS will also do complaint investigations based on public or confidential reports about outcomes or adverse events. These efforts, and the survey of the other Conditions of Participation, will provide sufficient oversight to ensure that transplant programs will continue to achieve and maintain high standards of care. (84 FR 51749).

In addition, as we discussed in the proposed rule, on November 14, 2018, CMS published in the Federal Register a final rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS" (CY 2019 ESRD PPS final rule) (83 FR 56922). In that final rule, CMS adopted a new measure for the ESRD Quality Incentive Program (QIP) beginning with PY 2022, entitled the Percentage of Prevalent Patients Waitlisted (PPPW) measure, and placed that measure in the Care Coordination domain for purposes of performance scoring under the program. We stated that the adoption of this measure reflects CMS's belief that ESRD facilities should make better efforts to ensure that their patients are appropriately waitlisted for transplants (83 FR 57006). We also noted in the proposed rule that the proposed ETC Model would provide greater incentives for ESRD facilities and Managing Clinicians

participating in the Model to assist ESRD Beneficiaries with navigating the transplant process, including coordinating care to address clinical and non-clinical factors that impact eligibility for wait-listing and transplantation.

b. Alternative Payment Models

Recognizing the importance of ensuring quality coordinated care to beneficiaries with ESRD, in 2015, CMS began testing the Comprehensive ESRD Care (CEC) Model. As we noted in the proposed rule, the CEC Model is an accountable care model in which dialysis facilities, nephrologists, and other health care providers join together to form ESRD Seamless Care Organizations (ESCOs) that are responsible for the cost and quality of care for aligned beneficiaries. Although there are no specific incentives under the CEC Model relating to home dialysis, CMS evaluated whether total cost of care incentives caused an increase in the rate of home dialysis, as would be predicted by some of the literature, during the first two years of the CEC Model. To date, the evaluation has not shown any statistically significant impact on the rates of home dialysis among CEC Model participants.[146] Although the evaluation results available for the CEC Model thus far are limited, as we noted in the proposed rule, based on these preliminary findings CMS believes that more targeted, system-wide incentives may be necessary to encourage modality choices and that the agency must provide explicit incentives in order to affect behavior changes by providers and suppliers.

On July 10, 2019, CMS announced the Kidney Care Choices (KCC) Model (formerly the Comprehensive Kidney Care (CKC) Model). The KCC Model builds on the existing CEC Model, and includes incentives for coordinating care for aligned beneficiaries with CKD or

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[146] Marrufo G, et al. Comprehensive End-Stage Renal Disease Care (CEC) Model: Performance Year 2 Annual Evaluation Report. CMS Innovation Center. September 2019; innovation.cms.gov/Files/reports/cec-annrpt-py2.pdf.

ESRD and for reducing the total cost of care for these beneficiaries, as well as providing financial incentives for successful transplants. As we noted in the proposed rule, we view the KCC Model as complementary to the ETC Model, as both models incentivize a greater focus on kidney transplants. We proposed that ESRD facilities and Managing Clinicians may participate in both models, as discussed in the proposed rule and section IV.C.6 of this final rule.

C. Provisions of the Proposed Regulation

1. Proposal to Implement the ETC Model

In this section IV of the final rule, we discuss the policies that we proposed for the ETC Model, including model-specific definitions and the general framework for implementation of the ETC Model. The payment adjustments for the proposed ETC Model were designed to support increased utilization of home dialysis modalities and kidney and kidney-pancreas transplants that may, according to the literature described earlier in this section IV of the rule, be subject to barriers. Specifically, with regard to home dialysis, we acknowledged in the proposed rule the possible need for ESRD facilities to invest in new systems that ensure that appropriate equipment and supplies are available in an economical manner to support greater utilization by beneficiaries. We also recognized in the proposed rule that dialysis providers, nephrologists, and other clinicians would need to enhance education and training, both for patients and professionals, that there are barriers to patients choosing and accepting home dialysis modalities, and that the appropriateness of home dialysis as a treatment option varies among patients according to demographic and clinical characteristics, as well as personal choice.

We proposed that the duration of the payment adjustments under the ETC Model would be 6 years and 6 months, beginning on January 1, 2020, and ending on June 30, 2026. We also considered an alternate start date of April 1, 2020, to allow more time to prepare for Model

implementation. We noted in the proposed rule that, if the ETC Model were to begin April 1, 2020, all intervals within the timelines outlined in the proposed rule, including the periods of time for which claims would be subject to adjustment by the HDPA and the Measurement Years and Performance Payment Adjustment Periods used for purposes of applying the PPA, would remain the same length, but start and end dates would be adjusted to occur three months later.

We also included in the proposed rule the following proposals for the Model: (a) the method for selecting ESRD facilities and Managing Clinicians for participation; (b) the schedule and methodologies for payment adjustments under the Model, and waivers of Medicare payment requirements necessary solely to test these methodologies under the Model; (c) the performance assessment methodology for ETC Participants, including the proposed methodologies for beneficiary attribution, benchmarking and scoring, and calculating the Modality Performance Score; (d) monitoring and evaluation, including quality measure reporting; and (e) overlap with other CMS models and programs.

We proposed to codify the definitions and policies of the ETC Model at subpart C of part 512 of 42 CFR (proposed §§ 512.300 through 512.397). We discuss the proposed definitions in section IV.C.2 of this final rule and each of the proposed regulatory provisions under the applicable subject area later. Section II of this final rule provides that the general provisions codified at §§ 512.100 through 512.180 apply to both the ETC Model and the RO Model described in section III of this rule.

The following is a summary of the comments received on the proposal to implement the Model, including the proposed start date and duration of the Model, and our responses.

Comment: Many commenters opposed starting the model on January 1, 2020. Commenters stated that January 1, 2020 was too soon, and would not provide ETC Participants

sufficient advance notice to prepare for successful participation in the Model and begin working to address barriers to home dialysis and transplantation. In particular, commenters pointed to specific areas in which ETC Participants would need time to prepare, including: design and implementation of new care processes; development of new relationships with other care providers, particularly transplant providers and vascular access providers; securing supplies necessary to operate and maintain a home dialysis program; training of clinical staff, particularly home dialysis nurses; development of new health information and data systems to track and manage patients; and making decisions about participating in other CMS models and programs. Commenters also recommended delaying the start date to allow CMS to resolve outstanding concerns from the stakeholder community, and to assess the efficacy of the model design. Several commenters suggested that CMS delay the start date to no sooner than April 1, 2020, the alternative start date included in the proposed rule. Several other commenters suggested a longer delay, including suggestions of July 1, 2020, October 1, 2020, and January 1, 2021. Several commenters suggested an indefinite delay, such that the Model would not begin until CMS further consulted with stakeholders to resolve their concerns, including through a second round of notice and comment rulemaking. A commenter suggested that the Model be delayed until potential changes to the organ allocation system are resolved.

Response: We appreciate the feedback from the commenters. After reviewing the concerns raised in the comments received, we agree that implementing the ETC Model on January 1, 2020 would not allow ETC Participants sufficient time to prepare for successful participation in the Model. We appreciate the feedback from the commenters about alternative start dates for the Model that would allow ETC Participants sufficient time to prepare for the Model. We had intended to delay the ETC Model implementation date until July 1, 2020, as had

been recommended by some of the commenters, but as we were completing this final rule, the U.S. began responding to an outbreak of respiratory disease caused by a novel coronavirus, referred to as "coronavirus disease 2019" (COVID-19), which created a serious public health threat greatly impacting the U.S. health care system. The Secretary of the Department of Health and Human Services, Alex M. Azar II, declared a Public Health Emergency (PHE) on January 31, 2020, retroactively effective from January 27, 2020, to aid the nation's healthcare community in responding to the COVID-19 pandemic. On July 23, 2020, Secretary Azar renewed, effective July 25, 2020, the determination that a PHE exists.

In light of this unprecedented PHE, which continues to strain health care resources, as well as our understanding that ETC Participants may have limited capacity to meet the ETC Model requirements in 2020, we are delaying implementation until January 1, 2021 to ensure that participation in the ETC Model does not further strain the ETC Participants' capacity, potentially hindering the delivery of safe and efficient dialysis care. We believe this delayed implementation will provide ETC Participants with sufficient time to prepare for participation in the Model and adhere to Model requirements.

Since the Model will begin on January 1, 2021, rather than January 1, 2020 (that is, 12 months later than proposed), all time intervals outlined in the proposed rule, including the periods of time for which claims are adjusted for the HDPA and Measurement Years and Performance Payment Adjustment Periods for the purposes of applying the PPA, will remain the same in length, but will begin and end 12 months later than proposed. For detailed descriptions of these time periods, see sections IV.C.5.d (HDPA) and IV.C.5.a (MYs and PPA Periods) of this final rule. Also, as this final rule was published to the **Federal Register** in September, 2020,

ETC Participants have more than 90 days to prepare to participate in the Model, which we believe is sufficient.

In response to the commenters' recommendations that we delay implementation of the ETC Model until we have gone through another round of rulemaking, we have made certain changes to the policies we proposed for the Model in response to the comments we received, as discussed in subsequent sections of this final rule, and we do not believe that it is necessary to conduct an additional round of notice and comment rulemaking before finalizing the rule and implementing the ETC Model. With respect to comments recommending that CMS delay implementation of the Model until changes to the transplant system have had time to take effect, as discussed in section IV.C.5.c.(2) of this final rule, we are altering the MPS calculation such that ETC Participant performance will be assessed based on a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rather than a transplant rate focused on all kidney transplants including deceased donor transplants. We made this alteration to recognize the role that ETC Participants can currently play in getting patients on the transplant waitlist rate and in increasing the rate of donor transplants while allowing the effects from the ETC Learning Collaborative time to take effect, together with the other proposed rules addressing the transplant system (if finalized), and we do not believe that any further delays are necessary. As discussed in section IV.C.5.c.(2) of this final rule, it is our intent to observe the supply of deceased donor organs available for transplantation.

Comment: Several commenters suggested that the Model have a staggered implementation, with some components of the Model beginning right away and other components phasing in over the duration of the Model. Several commenters suggested using a "Year 0" approach, in which ETC Participants would be in the Model for one year before

payment adjustments begin. Similarly, several commenters suggested that the downward payment adjustments in the PPA be delayed for some amount of time, either until Measurement Year (MY) 3 or MY4, to give ETC Participants more time to implement changes before they would be subject to downside financial risk, and to allow other changes to the transplant system time to take effect. A commenter suggested that downward payment adjustments should begin in 2021 for large dialysis organizations (LDOs) and in 2022 for all other dialysis organizations.

Response: We do not believe it is necessary to phase-in our implementation of the Model, including the onset of downward payment adjustments. The payment adjustments under the Model already begin with the HDPA, which is an upward payment adjustment only. The Model will be ongoing for 1 year and 6 months before the PPA begins, functionally phasing-in the Model's downward payment adjustment. As discussed in section IV.C.3.a of this final rule, the size of the Model is determined based on the necessary participation and duration to detect a statistically meaningful effect. If we were to further phase-in the implementation of the downward payment adjustments, we would not have sufficient duration to evaluate the effectiveness of the payment adjustments at achieving the Model's goals. While we appreciate the commenters' recommendation that CMS adopt a "Year 0" approach, and note that CMS has taken this approach in other models, in the case of the ETC Model a "Year 0" would amount to nothing more than a delayed implementation. As discussed earlier in this section IV.C.1 of this final rule, we believe that delaying the implementation of this Model to January 1, 2021, is sufficient to address the commenters' concerns about the lead time needed prior to participation in the Model. We do not believe it is appropriate to stagger the implementation of the payment adjustments to ESRD facilities based on dialysis organization type, as a commenter suggested, as

this approach could unfairly advantage ESRD facilities owned by certain types of dialysis organizations over others.

Comment: A few commenters recommended that CMS shorten the duration of the Model test to 3 years, with two optional extension years. Commenters stated that this approach would allow for a more limited test of the Model, and would facilitate extension of the Model if the Model appears to be achieving the intended goals during the initial 3 years. Additionally, commenters suggested that the initial years of the Model be limited to a smaller portion of the country, such as 10 percent, and that CMS increase the size of the Model in future years.

Response: As discussed in the proposed rule and in section IV.C.3.a of this final rule, the geographic scope of the Model is determined based on the scope of participation necessary to detect a statistically meaningful effect. We do not anticipate that we would be able to determine whether the Model is achieving its goals after three years, particularly as we are limiting the Model to a smaller portion of the country than originally proposed, such that we could decide to extend the Model at that time.

Comment: Several commenters stated that CMS should conduct subsequent rulemaking through the duration of the Model to adapt the Model based on observations made during the operation of the Model.

Response: We agree that if it becomes apparent that changes to the Model are needed during the Model's implementation, any potential changes to the ETC Model provisions would be made through subsequent notice and comment rulemaking. As discussed in section II.J of this final rule, we note that section 1115A(b)(3)(B) of the Act requires CMS to modify or terminate the design or implementation of a model test under certain circumstances.

Comment: Several commenters recommended that CMS separate the ETC Model into two separate payment models, one focused on home dialysis and one focused on kidney transplantation. Commenters stated that this approach would account for differences in the barriers to home dialysis and transplantation and the different incentives needed to overcome those barriers. Commenters also stated that this approach would allow CMS to operate smaller model tests that would produce more actionable results.

Response: The ETC Model is designed to test whether the mechanisms included in the Model will achieve the Model's goals, through incentivizing Managing Clinicians and ESRD facilities to support modality choice. We view home dialysis and transplantation as complementary alternative renal replacement modalities, not as separate aims. Therefore, we do not see them as separable into two separate model tests. We disagree that testing two separate models would be needed to produce more actionable results, as the evaluation of the ETC Model is designed to detect an increase in either home dialysis rates, transplant rates, or both.

After considering public comments, we are finalizing our proposed provisions regarding implementation of the ETC Model, with modification to our regulation at § 512.320 to adjust the dates for application of the payment adjustments under the ETC Model. The start date for application of the ETC Model's payment adjustments has changed from applying to claims with a claim through date beginning January 1, 2020, to claims with a claim service date beginning on or after January 1, 2021. The end date for application of such payment adjustments has changed from applying to claims with a claim through date ending June 30, 2026, to claims with a claim service date ending on or before June 30, 2027. We also are modifying which date associated with the claim we are using to determine if the claim is subject to the payment adjustments under the Model. Whereas we proposed using the claim through date, which is the last day on the

billing statement for services furnished to the beneficiary, we are finalizing using the date of service on the claim, which is the date on which the service was furnished. We are making this change from using claim through date to using date of service to align with Medicare claims processing standards. While Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Therefore, in order to process payment adjustments, we will use the date of service to determine the claims subject to adjustment under the Model.

2. Definitions

We proposed at § 512.310 to define certain terms for the ETC Model. We describe these proposed definitions in context throughout the proposed rule and section IV of this final rule. In addition, we proposed that the definitions proposed in section II of the proposed rule also would apply to the ETC Model. We received comments on our proposed definitions.

After considering public comments, we are finalizing our proposed provisions on the definitions with modification, as described elsewhere in this section IV of this final rule. Specifically, we are codifying in our regulations at § 512.310 to define certain terms for the ETC Model. We have summarized the comments received and responded to them through this section IV of the final rule, where relevant.

3. ETC Participants

a. Mandatory Participation

We proposed to require all Managing Clinicians and all ESRD facilities located in Selected Geographic Areas to participate in the ETC Model. We proposed to define "selected geographic area(s)" as those Hospital Referral Regions (HRRs) selected by CMS, as described in the proposed rule and in section IV.C.3.b of this final rule, for purposes of selecting ESRD

facilities and Managing Clinicians required to participate in the ETC Model as ETC Participants. Our proposed definition of "Hospital Referral Regions (HRRs)" is described in the proposed rule and in section IV.C.3.b of this final rule.

For purposes of the ETC Model, we proposed to define "ESRD facility" as defined in 42 CFR 413.171. As we described in the proposed rule, under § 413.171, an ESRD facility is an independent facility or a hospital-based provider of services (as described in 42 CFR 413.174(b) and (c)), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in § 494.10 and meets the supervision requirements described in 42 CFR part 494, and that furnishes institutional dialysis services and supplies under 42 CFR 410.50 and 410.52. We proposed this definition because this is the definition used by Medicare for the ESRD PPS. We considered creating a definition specific to the ETC Model; however, as noted in the proposed rule, we believe that the ESRD PPS definition of ESRD facility captures all facilities that furnish renal dialysis services that we are seeking to include as participants in the ETC Model.

For purposes of the ETC Model, we proposed to define "Managing Clinician" as a Medicare-enrolled physician or non-physician practitioner who furnishes and bills the MCP for managing one or more adult ESRD Beneficiaries. In the proposed rule, we considered limiting the definition to nephrologists, or other specialists who furnish dialysis care to beneficiaries with ESRD, for purposes of the ETC Model. However, as we noted in the proposed rule, analyses of claims data revealed that a variety of clinician specialty types manage ESRD Beneficiaries and bill the MCP, including non-physician practitioners. We continue to believe that the proposed approach to defining Managing Clinicians more accurately captures the set of practitioners we

are seeking to include as participants in the ETC Model, rather than limiting the scope to self-identified nephrologists.

As proposed, the ETC Model would require the participation of ESRD facilities and Managing Clinicians in Selected Geographic Areas that might not otherwise participate in a payment model involving payment adjustments based on participants' rates of home dialysis and kidney transplants. Participation in other CMS models focused on ESRD, such as the CEC Model and the KCC Model, is optional. Interested individuals and entities must apply to such models during the applicable application period(s) to participate. To date, we have not tested an ESRD-focused payment model in which ESRD facilities and Managing Clinicians have been required to participate. We considered using a voluntary design for the ETC Model as well; however, as noted in the proposed rule, we believe that a mandatory design has advantages over a voluntary design that are necessary to test this Model, in particular. First, we believe that testing a new payment model specific to encouraging home dialysis and kidney transplants may require the engagement of an even broader set of ESRD care providers than have participated in CMS models to date, including providers and suppliers who would participate only in a mandatory ESRD payment model. As we discussed in the proposed rule, we are concerned that only a non-representative and relatively small sample of providers and suppliers, namely those that already have higher rates of home dialysis or kidney transplants relative to the national benchmarks, would participate in a voluntary model, which would not provide a robust test of the proposed payment incentives. In addition, because kidney and kidney-pancreas transplants are rare events - fewer than 4 percent of ESRD Beneficiaries received such a transplant in 2016 - we noted in the proposed rule that we would need a large number of beneficiaries to be included

in the model test and comparison groups in order to detect a change in the rate of transplantation under the ETC Model.

Second, as noted in the proposed rule, we believe that a mandatory design combined with randomized selection of a subset of geographic areas would enable CMS to better assess the effect of the Model's interventions on ETC Participants against a contemporaneous comparison group. As described in the proposed rule and elsewhere in this section IV of the final rule, we proposed to require participation by a subset of all ESRD facilities and Managing Clinicians in the U.S., selected based on whether they are located in a Selected Geographic Area. Also, we proposed to evaluate the impact of adjusting payments to Managing Clinicians and ESRD facilities by comparing the clinical and financial outcomes of ESRD facilities and Managing Clinicians located in these Selected Geographic Areas against that of ESRD facilities and Managing Clinicians located in Comparison Geographic Area(s), which we proposed to define as those HRRs that are not Selected Geographic Areas. Because both ETC Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model would be representative of the larger dialysis market, many of the stakeholders in which operate on a nationwide basis, CMS would be able to generate more generalizable results, assuming randomization creates two groups that are similar to each other. As we noted in the proposed rule, this proposed model design would therefore make it easier for CMS to evaluate the impact of the Model, as required under section 1115A(b)(4) of the Act, and to predict the impact of expanding the Model under section 1115A(c) of the Act, if authorized, while also limiting the scope of the model test to Selected Geographic Areas.

The following is a summary of the comments received on our proposed definitions for Managing Clinician and ESRD facility and our proposal to require participation in the Model by

Managing Clinicians and ESRD facilities located in Selected Geographic Areas, and our responses.

Comment: A commenter stated that, for the purposes of the ETC Model, CMS should modify the proposed definition of ESRD facility to require that a facility must either have or be in a network under common ownership with ESRD facilities that have the capacity to furnish in-center dialysis.

Response: We believe that adopting this commenter's recommendation would be equivalent to excluding ESRD facilities owned by dialysis organizations that provide home dialysis only. We do not believe that it is necessary to exclude ESRD facilities owned by dialysis organizations that provide only home dialysis services from participation in the Model. The ETC Model is designed to test the effectiveness of the Model's payment adjustments at improving or maintaining quality and reducing costs through increased provision of home dialysis and transplants throughout the dialysis market as a whole, including among ESRD facilities and dialysis organizations that currently provide only home dialysis. Excluding ESRD facilities and dialysis organizations that do not offer in-center dialysis could discourage new entrants to the dialysis market who use innovative care models that do not include in-center dialysis. Discouraging this type of innovation could limit the availability of home dialysis overall.

Comment: A commenter supported the proposal to include non-physician practitioners in the definition of Managing Clinician for the purposes of the Model, as this recognizes the care provided by other clinicians, including nurse practitioners, who manage dialysis patients.

Response: We appreciate the commenters' feedback and support.

Comment: Several commenters stated that they support CMS's proposal to require participation in the ETC Model by ESRD facilities and Managing Clinicians located in Selected Geographic Areas.

Response: We appreciate the commenters' feedback and support.

Comment: Many commenters opposed requiring ESRD facilities and Managing Clinicians to participate in the ETC Model. Several commenters asserted that requiring participation by approximately half of the country does not constitute a model test, but rather a substantive change to Medicare payment policy. Some commenters stated that this exceeds the scope of the Innovation Center's authority. Some commenters stated that, the scope and mandatory nature of the Model, coupled with the downward payment adjustments, constitute an overall payment reduction for ESRD facilities and Managing Clinicians, which will cause unintended consequences, including market consolidation, decrease in availability of services, and disruption of patient care.

Response: We do not believe that the size, scope, and duration of the Model constitute a substantive change to Medicare payment policy, as the model test is limited in duration and is not a permanent change to the Medicare program. We also believe that both section 1115A of the Act and the Secretary's existing authority to operate the Medicare program authorize the ETC Model as we have proposed and are finalizing it.

Section 1115A of the Act authorizes the Secretary to test payment and service delivery models expected to reduce Medicare costs while preserving or enhancing care quality. The statute does not require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality. Although section 1115A(b) of the Act describes a number of payment and service delivery models that the

Secretary may choose to test, the Secretary is not limited to those models. Rather, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Here, the ETC Model addresses a defined population (FFS Medicare beneficiaries with ESRD) for which there are potentially avoidable expenditures (arising from less than optimal modality selection). For the reasons described elsewhere in this final rule, we have determined that it is necessary to test this Model among varying types of ESRD facilities and Managing Clinicians that may not have chosen to voluntarily participate in another kidney care model, such as the CEC Model or KCC Model.

As noted elsewhere in this final rule, we are currently testing a number of voluntary kidney models. We have designed the ETC Model to require participation by ESRD facilities and Managing Clinicians in order to avoid the selection bias inherent to any model in which providers and suppliers may choose whether to participate. As discussed in the proposed rule and previously in this final rule, such a design will enable us to obtain a representative sample, to detect a change in the rate of transplantation under the ETC Model, and to better assess the effect of the Model's interventions on ETC Participants against a contemporaneous comparison group. Under the ETC Model, we will have tested and evaluated such a model across a wide range of ESRD facilities and Managing Clinicians. We believe it is important to gain knowledge from a variety of perspectives in considering whether and which models merit expansion (including on a nationwide basis). Thus, the ETC Model meets the criteria required for an initial model test.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of Medicare. Specifically, the Secretary has authority under both sections 1102 and 1871 of the Act to implement regulations as necessary to administer Medicare, including

testing this payment and service delivery model. We note that, while the ETC Model will be a model, and not a permanent feature of the Medicare program, the Model will test different methods for delivering and paying for services under the Medicare program, which the Secretary has the clear authority to regulate. The proposed rule went into great detail about the proposed provisions of the proposed ETC Model, enabling the public to fully understand how the proposed model was designed and could apply to affected providers and suppliers.

We also note that this is a new model, not an expansion of an existing model. As permitted by section 1115A of the Act, we are testing the ETC Model within Selected Geographic Areas. The fact that the Model will require the participation of certain ESRD facilities and Managing Clinicians does not mean it is not an initial model test. If the ETC Model is successful such that it meets the statutory requirements for expansion, and the Secretary determines that expansion is warranted, we would undertake further rulemaking to expand the duration and the scope of the Model, as required by section 1115A(c) of the Act.

We appreciate the concerns from commenters about the potential impact of the Model on patient care, the structure of the dialysis market, and the availability of dialysis services. We do not expect the Model will result in adverse results such as market consolidation, decrease in availability of services, or disruption of patient care. In contrast, CMS believes that the Model will have the opposite effects. The payment adjustments in the Model are designed to incentivize innovative care delivery methods that focus on expanding access to renal replacement therapies other than in center hemodialysis, that are associated with better clinical outcomes for patients. However, we intend to monitor the impact of the Model closely, as described in section IV.C.10.a of this final rule. In the event that adverse outcomes such as these arise, CMS would modify or terminate the Model accordingly.

Comment: Several commenters stated that previous mandatory models have been of smaller size, and a commenter stated that CMS has cancelled proposed mandatory models in the past, due to further analysis, feedback that mandatory participation would have negative impact on CMS's flexibility to design and test other models, and the possibility of reduction of participation in other voluntary models. Several commenters asserted that the use of mandatory models undermines the creation of and participation in voluntary models.

Response: CMS believes that it is important to test both the mandatory ETC Model and the voluntary KCC Model at the same time, as both of these models test different frameworks. The solicitation for applicants for the KCC Model for PY 1 was completed on January 22, 2020. CMS is satisfied with the number of applications that were submitted. We believe that we will have sufficient participation to be able to test the different options in the KCC Model. Though previous mandatory models tested by the Innovation Center may have been smaller or cancelled in the past, we believe that requiring participation by ESRD facilities and Managing Clinicians in the ETC Model is necessary to achieve the level of model participation needed to detect changes in the rates of dialysis modality choice and for the power calculations discussed in this section of this final rule. As discussed in section IV.C.3.b of this final rule, we are decreasing the size of the Model. This decrease from 50% of HRRs in the country to 30% of HRRs in the country brings the size of the Model more in line with other mandatory models.

Comment: A commenter stated that they agree that the Innovation Center has the authority to proceed with mandatory initiatives, and they support the testing of mandatory models established through the rulemaking process.

Response: We appreciate this feedback and support from the commenter.

Comment: Several commenters stated that CMS should test this model on a voluntary basis. A commenter stated that ESRD facilities and Managing Clinicians located in Comparison Geographic Areas should be allowed to opt in to the ETC Model.

Response: We appreciate this feedback. However, as stated previously in this final rule, we considered using a voluntary design for the Model, but we concluded that we do not believe we can adequately test this Model on a voluntary or opt in basis. Specifically, we do not believe that if the Model were voluntary we would have a sufficient number and diversity of ESRD facilities and Managing Clinicians to conduct a robust test. Additionally, allowing ESRD facilities and Managing Clinicians located in Comparison Geographic Areas to opt-in to the ETC Model could skew the model test through selection effects. We assume that only ESRD facilities and Managing Clinicians who already have high rates of home dialysis and transplantation would opt in to participation. This behavior would produce the appearance of artificially high performance among ETC Participants, because any observed increase in performance could be due to selection effects rather than change in performance related to the Model's payment adjustments. This behavior would also remove high performers from the benchmarking group, which would lower benchmarks for ETC Participants, and therefore not provide as great an incentive for ETC Participants to improve their performance under the Model.

After considering public comments, we are finalizing the provisions regarding mandatory participation in the Model in our regulations at § 512.325(a) as proposed. We are also finalizing the definition of Selected Geographic Area(s) in our regulations at § 512.310, as proposed, with a technical change to capitalize "Selected Geographic Area(s)" in the final rule, rather than use "selected geographic area(s)" as we did in the proposed rule. In addition, we are finalizing the definitions of ESRD facility in our regulations at § 512.310, as proposed. We are finalizing the

definition of Managing Clinician in our regulation at § 512.310 with modification. Specifically, we made a technical change to capitalize "Managing Clinician" in the final rule. Additionally, we have added new language to our regulation to clarify that Managing Clinicians will be identified by an National Provider Identifier (NPI), because an NPI uniquely identifies individual clinicians regardless of the location the Managing Clinician furnishes a particular service, which is necessary for purposes of attributing services to each individual Managing Clinician, as described further in section IV.C.5.b.(2).(b) of this final rule.

b. Selected Geographic Areas

We proposed to use an ESRD facility's or Managing Clinician's location in Selected Geographic Areas, randomly selected by CMS, as the mechanism for selecting ETC Participants. We stated in the proposed rule that we believe that geographic areas provide the best means to establish the group of providers and suppliers selected for participation in the Model and the group of providers and suppliers not selected for participation in the Model to answer the primary evaluation questions described in the proposed rule and section IV.C.11 of this final rule. Specifically, by using geographic areas as the unit for randomized selection, we will be able to study the impact of the Model on program costs and quality of care, both overall and between ESRD facilities and Managing Clinicians selected for participation in the Model and those ESRD facilities and Managing Clinicians not selected for participation in the Model.

To improve the statistical power of the Model's evaluation, we noted in the proposed rule our aim of including in the Model approximately 50 percent of adult ESRD Beneficiaries. To achieve this goal, we proposed to assign all geographic areas, specifically HRRs, into one of two categories: Selected Geographic Areas (those geographic areas for which ESRD facilities and Managing Clinicians located in the area would be selected for participation in the ETC Model

and would be subject to the Model's Medicare payment adjustments for ESRD care); and Comparison Geographic Areas (those geographic areas for which ESRD facilities and Managing Clinicians located in the area would not be selected for participation in the ETC Model and thus would be subject to customary Medicare payment for ESRD care). Given the national scope of the major stakeholders in the dialysis market and the magnitude of the payment adjustments proposed for this Model, as stated in the proposed rule, we believe a broad geographic distribution of participants would be necessary to effectively test the impact of the proposed payment adjustments.

We proposed to use HRRs as the geographic unit of selection for selecting ETC Participants. An HRR is a unit of analysis created by the Dartmouth Atlas Project to distinguish the referral patterns to tertiary care for Medicare beneficiaries, and is composed of groups of zip codes. The Dartmouth Atlas Project data source is publicly available at https://www.dartmouthatlas.org/. Therefore, we proposed to define the term "HRRs" to mean the regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at https://www.dartmouthatlas.org.

With 306 HRRs in the U.S., we noted in the proposed rule that we believe there will be a sufficient number of HRRs to support random selection and improve statistical power of the proposed Model's evaluation. As noted in the proposed rule, we conducted power calculations for the outcomes of home dialysis and kidney and kidney-pancreas transplant utilization. For home dialysis, the CMS Office of the Actuary (OACT) forecasted an average increase of 1.5 percentage points per year. With a current home dialysis rate of 8.6 percent,[147] this represents an

[147] 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

increase of 18 percent. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need few HRRs included in the intervention group. However, for transplants, which are rare events, a substantial number of HRRs would be needed to detect changes. OACT did not assume any change in its main projections but estimated that an additional 2,360 transplants would occur over the course of the proposed Model due to a lower discard rate for deceased donor organs. With 20,161 transplants currently conducted on an annual basis,[148] this represents an 11.7 percent increase over 5 years. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need approximately 153 HRRs in the intervention group, which represents 50 percent of the 306 HRRs in the US. As noted in the proposed rule, we believe random selection with a large sample of units, such as the 306 HRRs, would safeguard against uneven distributions of factors among Selected Geographic Areas and Comparison Geographic Areas, such as urban or rural markets, dominance of for-profit dialysis organizations, and dense population areas with greater access to transplant centers.

In the proposed rule, we considered using Core Based Statistical Areas (CBSAs) or Metropolitan Statistical Areas (MSAs) as the geographic unit of selection. However, as we noted in the proposed rule, neither CBSAs nor MSAs include rural areas and, due to the nature of dialysis treatment, we believe inclusion of rural providers and suppliers is vital to testing the Model. Specifically, as a significant proportion of beneficiaries receiving dialysis live in rural areas and receive dialysis treatment from providers and suppliers located in rural areas, we believe using a geographic unit of selection that does not include rural areas would limit the generalizability of the model findings to this population.

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[148] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 6: Transplantation. https://www.usrds.org/2018/view/v2_06.aspx

In the proposed rule, we also considered using counties or states as the geographic unit of selection. However, as noted in the proposed rule, we determined that counties would be too small and therefore too operationally challenging to use for this purpose, both due to the high number of counties and the relatively small size of counties such that a substantial number of Managing Clinicians practice in multiple counties. We also determined that states would be too heterogeneous in population size, and that using states could confound the evaluation of the Model due to potential variation in state-level regulations relating to ESRD care. Additionally, the use of counties or states could introduce confounding spillover effects, such as where ESRD Beneficiaries receive care from a Managing Clinician in a county or state selected for the Model and dialyze in a county or state not selected for the Model, thus mitigating the effect of the Model's incentives on the beneficiary's overall care. As we noted in the proposed rule, HRRs are derived from Medicare data based on hospital referral patterns, which are correlated with dialysis and transplant referral patterns and which would therefore mitigate potential spillover effects of this nature.

We proposed to establish the Selected Geographic Areas by selecting a random sample of 50 percent of HRRs in all 50 states and the District of Columbia, stratified by region. Regional stratification would use the four Census-defined geographic regions: Northeast, South, Midwest, and West. Information about Census-defined geographic regions is available at https://www2.census.gov/geo/pdfs/maps-data/maps/reference/usus_regdiv.pdf.[149] As proposed, the stratification would control for regional patterns in practice variation. If an HRR spans two or more Census-defined geographic regions, the HRR would be assigned to the region in which

[149] This URL has been updated relative to the URL included in the proposed rule.

the HRR's associated state is located. For example, the Rapid City HRR centered in Rapid City, South Dakota, contains zip codes located in South Dakota and Nebraska, which are in the Midwest Census Region, and zip codes located in Montana and Wyoming, which are in the West Census Region. For the purposes of the regional stratification, we would consider the Rapid City HRR and all zip codes therein to be in the Midwest region, as its affiliated state, South Dakota, is in the Midwest region.

We proposed that the U.S. Territories, as that term is defined in section II of the proposed rule and of this final rule, would be excluded from selection, as HRRs are not constructed to include these areas.

In addition, outside of the randomization, we proposed that all HRRs for which at least 20 percent of the component zip codes are located in Maryland would be selected for participation in the ETC Model, in conjunction with the Maryland Total Cost of Care (TCOC) Model currently being tested in Maryland. These HRRs would not be included in the randomization process previously described. We stated in the proposed rule that CMS believes that the automatic inclusion of ESRD facilities and Managing Clinicians in these HRRs as participants in the ETC Model would be necessary because, while the Maryland TCOC Model includes incentives to lower the Medicare TCOC in the state, including state accountability for meeting certain Medicare TCOC targets, as well as global budget payments that hold Maryland hospitals accountable for the Medicare TCOC, there currently is no direct mechanism to lower the cost of care for ESRD Beneficiaries specifically under the Maryland TCOC Model. As noted in the proposed rule, we believe that adding Maryland-based ESRD facilities and Managing Clinicians as participants in the ETC Model will assist the state of Maryland and hospitals

located in that state to meet the Medicare TCOC targets established under the Maryland TCOC Model.

We proposed that all HRRs that are not Selected Geographic Areas would be referred to as "Comparison Geographic Area(s)." We proposed that Comparison Geographic Areas would be used for the purposes of constructing performance benchmarks (as discussed in the proposed rule and in section IV.C.5.d of this final rule), and for the Model evaluation (as discussed in the proposed rule and in section IV.C.11 of this final rule).

The following is a summary of the comments received on Selected Geographic Areas, including the size and scope of the Model, geographic units used for Selected Geographic Areas, and the inclusion or exclusion of certain geographic areas in the Model, and our responses.

Comment: Multiple commenters opposed our proposal to require participation in the ETC Model by ESRD facilities and Managing Clinicians located in 50 percent of the 306 HRRs in the country because doing so would require significant change to the infrastructure of ETC Participants and to the care delivery system nationally. Commenters stated that the change in payments under the Model implemented over the proposed geographic area within the timeframe proposed for the Model could lead to unintended consequences and disruption in care, and several commenters stated that this would harm smaller health care providers, in particular. A commenter stated that this national impact would undermine the integrity of the model test.

Response: We appreciate the feedback from commenters raising concerns around the impact of the proposed scope of the model test on health care providers and beneficiaries. We acknowledge that the scope and timeframe for implementing the Model will require changes on the part of ETC Participants, which may take time to implement. As discussed previously in this final rule, we believe we have addressed commenters' concerns regarding the time needed to

make these changes by delaying the Model start date to January 1, 2021. We further believe we have addressed the commenters' concerns regarding the potential for unintended consequences through the benchmarking and scoring methodology (described in section IV.C.5.d of this final rule) and have addressed the commenters' concerns regarding smaller health care providers through the low volume exclusions from the PPA (described in section IV.C.5.f of this final rule). We do not believe that the scope of the ETC Model harms the integrity of the model test. Rather, as discussed in the proposed rule and previously in this final rule, we designed the Model based on power calculations about the scope of participation necessary for CMS to be able to evaluate whether the Model increased the rate of transplants. However, as described in section IV.C.5 of this final rule, we have modified the Model to assess ETC Participant performance on the transplant rate, which includes both the transplant waitlist rate and living donor transplant rate. As such, we have revised the scope of the Model based on power calculations about the level of participation necessary for CMS to be able to evaluate whether the Model increased the rate of transplant waitlisting, living donor transplants, and the rate of home dialysis, as described in section IV.C.5 of this final rule. We discuss our plan for conducting the Model's evaluation in section IV.C.11 of this final rule.

Comment: Several commenters stated that implementing the Model with this proposed geographic scope would constitute a permanent change in Medicare policy, rather than a model test.

Response: We disagree that this Model would constitute a permanent change in Medicare policy. Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving or improving care quality. The ETC

Model would be a model tested under this authority, and not a permanent feature of the Medicare program.

Comment: Several commenters expressed concern that requiring participation by ESRD facilities and Managing Clinicians located in 50 percent of the 306 HRRs in the U.S. is beyond the level of participation necessary to evaluate the Model. Several commenters suggested reducing the geographic scope of the Model to 20 percent, 25 percent, or no larger than 25 percent of HRRs in the country. Several commenters suggested starting the Model with a smaller geographic scope, and increasing the scope in subsequent years if the Model is successful.

Response: We appreciate the commenters' feedback. In response to comments, and because we will now evaluate changes to transplant waitlisting, including beneficiaries who receive living donor transplantation we conducted a revised power calculation. We performed the revised power calculation to determine the minimum sample size of ETC Participants and Managing Clinicians and ESRD facilities located in Comparison Geographic Areas necessary to produce robust and reliable results. Our assumptions included a two percentage point increase to the transplant waitlist rate, which is currently 16%. To detect an effect size of this magnitude with 80 percent power and an alpha of 0.05, we would need approximately 30 percent of the 306 HRRs in the US to minimize the risk of false positive and false negative results. This number of HRRs will also be sufficient to detect a one and one-half percent change in home dialysis. As a result, we are finalizing our proposal to require participation in the Model by ESRD facilities and Managing Clinicians located in 30 percent of the HRRs in the country.

Comment: A few commenters noted that the proposed geographic scope of the Model may lead to a spillover effect for ESRD facilities located in the Comparison Geographic Areas

given that ownership of ESRD facilities can span across HRRs in Selected Geographic Areas and Comparison Geographic Areas.

Response: We share the commenters' concern that the impact of the model test may extend to the Model's Comparison Geographic Areas through common facility ownership and this may influence our evaluation of the Model. We plan to examine the variation in the outcome measures prior to and during the model intervention for facilities with common ownership, and if necessary, consider modifications to the Model in future notice-and-comment rulemaking.

Comment: A commenter supported randomizing geographic areas to select ETC Participants. Several commenters opposed randomization of geographic areas as the mechanism for selecting ETC Participants. Several commenters noted that the method proposed for randomization would not sufficiently account for non-random differences between HRRs or ESRD facilities. A few commenters suggested that CMS use covariate-based constrained randomization for purposes of selecting model participants because the commenters claimed that this approach would ensure comparability across treatment and control groups and allow for a smaller model.

Response: We appreciate the comments on the proposed randomization method. As we noted in the proposed rule and previously in this final rule, our proposal to stratify by region would help control for regional patterns in practice variation. We also believe that stratification will help ensure that ETC Participants are geographically dispersed across the country and do not find it necessary to use covariate-based constrained randomization for purposes of selecting model participants, as suggested by some of the commenters. In addition, with the evaluation approach that will be used, we can account for known, measurable differences between ETC

Participants in Selected Geographic Areas and those ESRD facilities and Managing Clinicians located in the Comparison Geographic Areas through rigorous statistical methods. Specifically, as we outlined in the proposed rule, the evaluator would match Managing Clinicians and ESRD facilities located in Comparison Geographic Areas with Managing Clinicians and ESRD facilities that are located in Selected Geographic Areas (that is, ETC Participants) using propensity scores or other accepted statistical techniques.

Comment: Several commenters stated that randomization cannot ensure that 50 percent of ESRD Beneficiaries are included in the Model.

Response: While the aim stated in the proposed rule was to include approximately 50 percent of adult beneficiaries with ESRD in the Model, as described in the proposed rule, our determination regarding the size of the geographic area necessary to test the Model is based around the number of HRRs in which ESRD facilities and Managing Clinicians would be required to participate in the Model, not the proportion of individual beneficiaries included in the model test. The same holds true for this final rule; our determination regarding the size of the geographic area necessary to test the Model is based around the number of HRRs in which ESRD facilities and Managing Clinicians are required to participate in the Model, rather than the proportion of individual beneficiaries included in the model test. We are therefore finalizing the randomization method, as proposed.

Comment: A commenter stated that CMS should select regions where home dialysis and transplant rates are particularly low to focus resources on areas with the most need.

Response: As stated in the proposed rule and previously in this final rule, the intent of the model test is to determine whether adjusting the current Medicare FFS payments for dialysis and dialysis-related services would incentivize ESRD facilities and Managing Clinicians to work

with their patients to achieve increased rates of home dialysis utilization and kidney transplantation and, as a result, reduce Medicare expenditures while improving or maintaining quality of care. If we were to select ETC Participants from only those geographic areas that had particularly high or particularly low rates of home dialysis or transplants, as the commenter suggested, we would not be able to determine if the Model's payment adjustments would have the same effect nationally.

Comment: Several commenters opposed the use of geographic areas to select model participants. These commenters stated that, due to the national nature of the dialysis market, selecting ESRD facilities for participation based on their location could change the nature of the dialysis market for the entire country or create unintended consequences for the dialysis market nationally. In particular, commenters stated that the Model could make national dialysis companies provide different levels of care to patients in Selected Geographic Areas than in Comparison Geographic Areas and delay the implementation of best practices nationally, or divert resources from Comparison Geographic Areas to Selected Geographic Areas.

Response: We appreciate the feedback from commenters about the national nature of segments of the dialysis market and how this may interact with our proposal to select ETC Participants based on geographic areas. We acknowledge the possibility that national dialysis providers will behave differently, in terms of resource allocation or adoption of best practices in Selected Geographic Areas versus Comparison Geographic Areas, or that they will adopt best practices nationally resulting in broader changes to dialysis provision. However, we believe that, for dialysis providers that operate nationally, either outcome would be true regardless of what mechanism we use to select ESRD facilities for model participation. As described in section

IV.C.10.a of this final rule, we will monitor for unintended consequences that arise as a result of the Model.

Comment: Several commenters recommended that CMS should select individual participants, rather than selecting participants based on geographic location.

Response: We did not propose selecting individual participants because we believe that this approach would not work for this Model. A design feature of the Model is aligning the incentives for key dialysis providers, namely Managing Clinicians and ESRD facilities, to support beneficiaries in choosing alternative renal replacement modalities. Managing Clinicians refer ESRD Beneficiaries to multiple ESRD facilities, and ESRD facilities furnish dialysis to beneficiaries under the care of multiple Managing Clinicians. By selecting ETC Participants based on location, we are increasing the likelihood that, for any given ESRD Beneficiary, both the beneficiary's Managing Clinician and ESRD facility are participants in the Model.

Comment: Several commenters recommended that CMS release the Selected Geographic Areas with the proposed rule to allow for public comment or for potential model participants to have sufficient time to prepare for participation. A commenter stated that while they understand that CMS has withheld information about Selected Geographic Areas to assure that CMS receives stakeholder feedback from the entire nation, ETC Participants should have no fewer than 90 days' notice prior to implementation to prepare for participation in the Model.

Response: We appreciate the commenters' suggestions about releasing information about Selected Geographic Areas in advance of the start of the Model, and the need for ETC Participants to have sufficient time to prepare for participation in the Model. We did not provide information about the specific Selected Geographic Areas in the proposed rule because, as the commenters noted, we wanted to ensure that we received feedback from the public generally, not

just those stakeholders located in Selected Geographic Areas. CMS is posting a list of Selected Geographic Areas on the Innovation Center website concurrent with the release of this final rule, thus notifying the public and ETC Participants of the Selected Geographic Areas more than 90 days in advance of the start of the Model on January 1, 2021.

Comment: Commenters expressed concerns about how the method for randomly selecting participating HRRs will interact with the benchmarking methodology using data from Comparison Geographic Areas. Commenters stated that random selection does not address other covariates that impact home dialysis and transplant rates, including current rates of home dialysis and transplantation, urbanicity, population density, percentage of dual-eligible beneficiaries, and the availability of transplant centers. Commenters stated that, if balance on these covariates is not observed, model participants could be unfairly compared to ESRD facilities and Managing Clinicians located in Comparison Geographic Areas that face different factors that contribute to home dialysis and transplant rates.

Response: We appreciate the commenters' concern that underlying regional variation in home dialysis and transplant rates may mean that ETC Participants and ESRD facilities and Managing Clinicians located in Comparison Geographic Areas will face varying factors that affect their rates of home dialysis and transplants. However, as we noted in the proposed rule and earlier in this final rule, our proposal to stratify by region would help control for regional patterns in practice variation. We also believe that inclusion of improvement scoring in the scoring methodology, described in the proposed rule and in section IV.C.5.d. of this final rule, which awards points based on an ETC Participant's improvement against its own past performance, will help compensate for any underlying regional variation in these factors.

Comment: Several commenters stated that, due to the national nature of the dialysis market, large dialysis companies will have ESRD facilities located in both Selected Geographic Areas and in the Comparison Geographic Areas used for benchmarking under the ETC Model. These commenters stated that dialysis companies could face incentives to either not improve on or not maintain current home dialysis and transplant performance in ESRD facilities located in Comparison Geographic Areas to attempt to keep benchmarks low, to improve relative performance for their ESRD facilities located in Selected Geographic Areas.

Response: We appreciate the feedback from commenters about the potential for dialysis organizations operating in both Selected Geographic Areas and Comparison Geographic Areas to manipulate the Model's benchmarks. However, we believe that the achievement benchmarking methodology, described in the proposed rule and in section IV.C.5.d of this final rule, mitigates this risk. First, the proposed achievement benchmarks would use only data from home dialysis and transplant rates among ESRD facilities and Managing Clinicians located in Comparison Geographic Areas. Because we will construct these benchmarks using 12 months of data beginning 18 months before the start of the MY and ending 6 months before the start of the MY, the time periods for determining achievement benchmarks for MY1 and MY2 occurred primarily before the proposal or finalization of the rule to implement the Model. For MY3, the proposed achievement benchmarks would include 6 months of data from before the Model and 6 months of data after the Model began. Only in MY4 would all data used to construct the achievement benchmarks be from after the Model began. It would therefore be difficult for dialysis organizations to alter their past performance in order to manipulate these achievement benchmarks for the initial years of the Model. Additionally, we stated in the proposed rule that it is our intent to increase achievement benchmarks above the rates observed in Comparison

Geographic Areas for future MYs through subsequent rulemaking. For these subsequent MYs, we are considering an approach under which achievement benchmarks would not be tied to performance in Comparison Geographic Areas, so there would not be an opportunity for LDOs to manipulate the achievement benchmarks by changing their performance in Comparison Geographic Areas if this approach is finalized.

Comment: Several commenters stated that HRRs may not be reflective of how dialysis care is delivered, how organ transplants are allocated, or referral patterns between Managing Clinicians and ESRD facilities. Commenters pointed out that HRRs are designed to capture patterns of care in hospitals for Medicare beneficiaries, but may not be reflective of other segments of the health care market, including dialysis services. These commenters further stated that, as a result of this misalignment, using HRRs may have unintended consequences. A commenter stated that the misalignment between dialysis company markets and HRRs could create a situation where ESRD facilities owned by a dialysis organization with a centralized home dialysis facility are selected to participate in the Model but the affiliated home dialysis facility is not selected to participate, which would not accurately reflect the provision of home dialysis by that company in that area. Other commenters stated that beneficiaries or ETC Participants may move between HRRs, or may seek or provide care in multiple HRRs.

Response: We appreciate commenters' concerns about the relationship between the geographic distribution of providers and suppliers involved in the provision of services to ESRD Beneficiaries and the geographic unit of selection used in the ETC Model. Providing care to ESRD Beneficiaries involves multiple parts of the health care system – including ESRD facilities and dialysis organizations, as well as Managing Clinicians and the practices in which they operate – each of which furnishes care in a unique geographic area or set of geographic areas.

Because there are so many overlapping geographies served by these providers and suppliers, it is unlikely that there is one type of geographic unit that would align perfectly, such that no dialysis organization market is in both Selected Geographic Areas and Comparison Geographic Areas, or that no Managing Clinician sees patients in both Selected Geographic Areas and Comparison Geographic Areas. We continue to believe that HRRs are the most appropriate geographic unit of selection for the Model, for the reasons described in the proposed rule and elsewhere in this section of the final rule. Also, we believe that the aggregation methodology used in assessing ETC Participant performance (described in section IV.C.5.c.(4) of this final rule) addresses concerns about individual ETC Participant performance assessment in relation to geography. We acknowledge that ETC Participants may move between HRRs or provide care in multiple HRRs, and we do not believe that this harms the model test. It is commonplace for participants to move into and out of Innovation Center models on occasion, and this movement generally does not harm model evaluations. As to the movement of ESRD Beneficiaries, because the level at which performance is being assessed is the ETC Participant, not the beneficiary, and attribution of ESRD Beneficiaries to ETC Participants occurs in units of one month, we do not believe that beneficiaries moving between HRRs will impact the model test.

Comment: Several commenters suggested using different geographic units to select ETC Participants, including CBSAs. A commenter supported using CBSAs instead of HRRs because CBSAs are well understood by health care providers. Other commenters opposed using CBSAs instead of HRRs for several reasons, including that CBSAs are smaller than HRRs and would therefore exacerbate divisions of participants and beneficiaries because the likelihood of a beneficiary being attributed to a participating ESRD facility and non-participating Managing Clinician (and vice versa) would increase, and that CBSAs do not include rural counties and

CMS did not propose a method for associating rural counties with CBSAs. Others suggested alternative geographic units for selecting ETC Participants. A commenter suggested that CMS use regions that align with market areas for other payers, such as Medicare Advantage plans and other private payers, to prevent ETC Participants from having to ask other clinicians (such as primary care providers.) to provide different levels of care to ESRD patients based on participation in the Model. That commenter also suggested that CMS use a variety of geographic units to select participants similar to the method used in the design of the Civil Justice Reform Act experiments in the 1990s, in particular that CMS select participants in those states that have expressed interest in and wish to implement regulatory changes in conjunction with the Model, as states play a regulatory role in the provision of dialysis care. A commenter suggested using the ESRD Networks as the geographic units to select ETC Participants, as the ESRD Networks have longstanding relationships with dialysis and transplant programs, personnel, and patients, and could support participants to achieve the goals of the Model. A commenter suggested incorporating Donation Service Areas (DSAs) into the geographic unit selection process.

Response: We appreciate the feedback from commenters about the use of alternative geographic units to select ETC Participants. We acknowledge that there are a variety of types of geographic units we could use to select ETC Participants, and that there are benefits and challenges associated with each option. We continue to believe that HRRs are the most appropriate unit of geographic selection for this Model, for the reasons described in the proposed rule and elsewhere in this section of the final rule.

Comment: A commenter supported our proposal to select for participation all HRRs for which at least 20 percent of the component zip codes are located in Maryland, outside of the randomization, in conjunction with the Maryland TCOC Model currently being tested in

Maryland. A commenter opposed including these Maryland HRRs, or any other states participating in Innovation Center models, outside of the randomization, as states are large geographic units and the commenter opposes the size of the Model.

Response: We appreciate the feedback from commenters about the inclusion of HRRs predominantly located in Maryland. We do not believe that including these HRRs outside of the randomization harms the randomization, or represents a significant increase in the size of the Model. We are therefore finalizing this policy as proposed.

Comment: Several commenters stated that they support the proposed exclusion of the U.S. Territories from the Selected Geographic Areas under the ETC Model.

Response: We appreciate the feedback and support from the commenters.

After considering public comments, we are finalizing our proposed provisions on Selected Geographic Areas in our regulations at § 512.325(b), with modification. We are modifying the proportion of HRRs randomly selected for inclusion in the Model as Selected Geographic Areas from 50 percent to 30 percent. We are finalizing the definition of Selected Geographic Area(s) as proposed with the technical change to capitalize the term "Selected Geographic Area(s)" in the final rule. We are also finalizing as proposed the definition of hospital referral regions (HRRs), and we are clarifying that we will use the 2017 HRRs for the duration of the ETC Model. HRRs are recalculated periodically to reflect changes in patterns of care over time. At the time of publication of the proposed rule, the 2017 HRRs are the most current available. We are also finalizing as proposed the definition of Comparison Geographic Area(s), with the technical change to capitalize the term "Comparison Geographic Area(s)" in the final rule. We are codifying these definitions in our regulations at § 512.310.

c. Participant Selection for the ETC Model

We proposed to define "ETC Participant" as an ESRD facility or Managing Clinician that is required to participate in the ETC Model pursuant to § 512.325(a), which describes the selection of model participants based on their location within a Selected Geographic Area, as described in the proposed rule and previously in this final rule. In addition, we noted in the proposed rule that the definition of "model participant," as defined in section II of this final rule, would include an ETC Participant.

The following is a summary of the comments received on providers and suppliers included as ETC Participants and our responses.

Comment: Several commenters stated that the ETC Model should include transplant providers as participants, including transplant centers, transplant physicians, transplant surgeons, OPOs, donor hospitals, and other transplant providers in order to achieve the Model's focus on increasing rates of kidney transplantation. Commenters asserted that transplant providers hold more control over the transplant process than Managing Clinicians and ESRD facilities, so including them in the Model's payment adjustments would be necessary for or would increase the likelihood of Model success.

Response: We appreciate the suggestions from commenters about including transplant providers in the Model. We agree that transplant providers are central to increasing transplant rates. However, we do not believe that it is necessary to include transplant providers as participants receiving payment adjustments in this Model. First, the ETC Model is designed to test the effectiveness of a particular set of policy interventions, namely adjusting certain Medicare payments for Managing Clinicians and ESRD facilities to increase rates of home dialysis and kidney transplants. As noted previously in this final rule, we selected Managing Clinicians and ESRD facilities as participants in this Model because we believe these two groups

of health care providers have the most direct relationship with ESRD Beneficiaries. Second, CMS and HHS are undertaking other activities targeting the availability of organs for transplantation. These efforts include the ETC Learning Collaborative described in section IV.C.12 of this final rule, which includes transplant centers and OPOs. As previously noted, HHS published a proposed rule in the **Federal Register** on the December 23, 2019, entitled "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization[s]" (84 FR 70628). This proposed rule would, among other things, update the OPO Conditions for Coverage to support higher donation rates and reduce discard rates of viable organs. The Health Resources and Services Administration (HRSA) also published a proposed rule in the **Federal Register** on December 20, 2019, entitled "Removing Financial Disincentives to Living Organ Donation" (84 FR 70139) to remove financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors to include lost wages and childcare and elder-care expenses incurred by a primary care giver. We believe that the increased volume of beneficiaries on the transplant waitlist driven by the payment adjustments in the ETC Model, together with the increased organ availability from other HHS and CMS efforts and the ETC Learning Collaborative, will serve as an incentive for transplant providers to support increasing rates of transplantation. As discussed in section IV.C.5.c.(2) of this final rule, it is our intent to observe organ availability.

After considering public comments, we are finalizing our proposed definition of ETC Participant without modification, and codifying this definition in our regulations at § 512.310.

(1) ESRD Facilities

We proposed that all Medicare-certified ESRD facilities located in a Selected Geographic Area would be required to participate in the ETC Model. We proposed to determine ESRD facility location based on the zip code of the practice location address listed in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). We considered using the zip code of the mailing address listed in PECOS. However, we concluded that mailing address is a less reliable indicator of where a facility is physically located than the practice location address, as facilities may receive mail at a different location than where they are physically located.

The following is a summary of the comments received on required participation for all ESRD facilities located in Selected Geographic Areas and our responses.

Comment: Several commenters suggested that CMS exclude certain ESRD facilities from selection for participation in the ETC Model. In particular, these commenters stated that ESRD facilities owned by small dialysis organizations would face substantial hardship and financial risk if selected for participation. Several of these commenters specifically recommended that ESRD facilities owned in whole or in part by a dialysis organization owning 35 or fewer ESRD facilities should be excluded from the Model, while another commenter recommended that ESRD facilities owned by these smaller dialysis organizations be allowed to opt in to the Model on a voluntary basis. A commenter recommended that CMS exclude dialysis organizations with fewer than 100 patients in a market area. A commenter suggested that no more than 25 percent of a dialysis organization's ESRD facilities should be included in the Model, while another commenter suggested that any health care provider that would have more than 10 percent of all of their treatments subject to the Model's payment adjustments should be excluded from the Model. A commenter recommended that ESRD facilities that decide that it is

not logical or possible for them to offer home dialysis should be allowed to opt out of participation in the Model.

Response: The Model was designed to test the proposed payment adjustments for all types of ESRD facilities nationally, including those owned by both large and small dialysis organizations. To determine if payment adjustments can achieve the Model's goals of increasing rates of home dialysis utilization and kidney transplantation and, as a result, improving or maintaining the quality of care while reducing Medicare expenditures among all types of ESRD facilities, we need to test the model with ESRD facilities owned by all types of dialysis organizations. Additionally, while we include all ESRD facilities in the HDPA, as described in the proposed rule and in section IV.C.5.e.(1) of this final rule, the Model excludes certain ESRD facilities that fall below the low volume threshold from the application of the PPA. We believe that this approach balances the need to include all types of ESRD facilities in the model test with the need to increase statistical reliability and to exclude low-volume ESRD facilities from the PPA, which is the only downside financial risk included in the Model. We do not believe that it is appropriate to allow ESRD facilities to opt in or out of the Model for the purposes of the model test, as this would exacerbate potential selection effects.

Comment: Several commenters recommended that CMS adopt requirements around what types of dialysis an ESRD facility, or its parent dialysis organization, must provide in order to be selected for participation in the Model. Some commenters stated that only ESRD facilities that are currently certified to provide home dialysis should be selected for participation, to preserve the quality of care associated with centralization of home dialysis, to avoid unintended adverse outcomes, and/or to avoid penalizing ESRD facilities that cannot become certified to provide home dialysis in a timely manner. Several commenters stated that the Model should

exclude from participation those ESRD facilities that are owned by dialysis organizations that own only ESRD facilities that provide home dialysis or that provide home dialysis only in a Selected Geographic Area to avoid "cherry picking" by home dialysis-only organizations, resulting in unfair comparisons in the PPA benchmarking methodology.

Response: We do not believe that it is necessary to exclude ESRD facilities that do not currently provide home dialysis services from the Model, nor do we believe that it is necessary to exclude ESRD facilities owned by dialysis organizations that provide only home dialysis. The ETC Model is designed to test the effectiveness of the Model's payment adjustments at improving or maintaining quality and reducing costs through increased provision of home dialysis and transplants on the dialysis market as a whole, including ESRD facilities new to the provision of home dialysis, as well as new entrants to the dialysis market who offer innovative approaches to dialysis provision that do not include in-center dialysis. Excluding these ESRD facilities from the model test could limit the Model's ability to increase provision of home dialysis services by these dialysis providers by discouraging new entrants to the market who may employ innovative approaches to home dialysis.

After considering public comments, we are finalizing our proposal in our regulation at § 512.325(a) to require all Medicare-certified ESRD facilities located in a Selected Geographic Area to participate in the Model, without modification.

(2) Managing Clinicians

We proposed that all Medicare-enrolled Managing Clinicians located in a Selected Geographic Area would be required to participate in the ETC Model. We proposed identifying the Managing Clinician's location based on the zip code of the practice location address listed in PECOS. If a Managing Clinician has multiple practice location addresses listed in PECOS, we

proposed to use the practice location through which the Managing Clinician bills the plurality of his or her MCP claims. In the proposed rule, we considered using the zip code of the mailing address listed in PECOS. However, as noted in the proposed rule, we determined that mailing address is a less reliable indicator of where a clinician physically practices than the practice location address, as clinicians may receive mail at a different location from where they physically practice.

The following is a summary of the comments received on required participation for all Managing Clinicians located in Selected Geographic Areas and our responses.

Comment: A commenter asked for clarification as to whether individual Managing Clinicians would be selected for participation based on their location or if practices with Managing Clinicians would be selected for participation based on their location.

Response: Managing Clinicians will be selected individually based on their location and not the practice location. However, as described in the proposed rule and in section IV.C.5.c.(4) of this final rule, the performance of Managing Clinicians that bill through the same practice TIN will be aggregated to the practice level for purposes of determining the PPA.

Comment: A commenter recommended that CMS not determine a Managing Clinician's location based on where he or she provides the plurality of his or her MCP claims. The commenter stated that this could create misalignment between incentives for Managing Clinicians and ESRD facilities if a Managing Clinician has patients who dialyze at ESRD facilities that are ETC Participants as well as at ESRD facilities located in Comparison Geographic Areas, and therefore CMS should select Managing Clinicians based on the location where dialysis services are provided to their patients.

Response: We recognize that Managing Clinicians provide dialysis management services included in the MCP to ESRD Beneficiaries that dialyze at multiple ESRD facilities, and that in some cases, this may mean that a Managing Clinician may have ESRD Beneficiaries who dialyze at ESRD facilities that are ETC Participants and ESRD Beneficiaries that dialyze at ESRD facilities located in Comparison Geographic Areas. However, selecting Managing Clinicians based on where their attributed beneficiaries dialyze would not solve this issue, as a Managing Clinician could still provide dialysis management services to ESRD Beneficiaries who dialyze at ESRD facilities that are ETC Participants and at ESRD facilities that are located in Comparison Geographic Areas. Also, we believe that the commenter's suggested selection method would be more complex, and would make it more difficult for Managing Clinicians to understand whether they are ETC Participants in real time, as beneficiary attribution occurs after each MY has ended.

After considering public comments, we are finalizing our proposal in our regulation at § 512.325(a) to require all Medicare-enrolled Managing Clinicians located in a Selected Geographic Area to participate in the ETC Model, without modification.

4. Home Dialysis Payment Adjustment

We proposed to positively adjust payments for home dialysis and home dialysis-related services billed by ETC Participants for claims with claim through dates during the first three CYs of the ETC Model (CY 2021 – CY 2023). We stated that the HDPA would provide an up-front positive incentive for ETC Participants to support ESRD Beneficiaries in choosing home dialysis. The HDPA would complement the PPA, described in the proposed rule and section IV.C.5 of this final rule, which under our proposal would begin in mid-CY 2021 and increase in magnitude over the duration of the Model; as such we proposed that the HDPA would decrease

over time as the magnitude of the PPA increases. There would be two types of HDPAs: the Clinician HDPA and the Facility HDPA. We proposed to define the "Clinician HDPA" as the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant for the Managing Clinician's home dialysis claims, as described in § 512.345 (Payments Subject to the Clinician HDPA) and § 512.350 (Schedule of Home Dialysis Payment Adjustments). We proposed to define the "Facility HDPA" as the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate (discussed in section IV.B of this final rule) for an ESRD facility that is an ETC Participant for the ESRD facility's home dialysis claims, as described in § 512.340 (Payments Subject to the Facility HDPA) and § 512.350 (Schedule of Home Dialysis Payment Adjustments). We proposed to define the "HDPA" as either the Facility HDPA or the Clinician HDPA. As we noted in the proposed rule, we do not believe that an analogous payment adjustment is necessary for increasing kidney transplant rates during the initial years of the ETC Model. Rather, instead of creating a payment adjustment, we proposed to implement the ETC Learning Collaborative that focuses on disseminating best practices to increase the supply of deceased donor kidneys available for transplant. For a description of the learning collaborative, see section IV.C.12 of this final rule.

The following is a summary of the comments received on the HDPA and our responses.

Comment: A commenter expressed support for the proposed HDPA because it would enable the increased use of home dialysis for appropriate ESRD Beneficiaries. Another commenter expressed concern that, while CMS recognized that the initial transition period onto dialysis is important for supporting ESRD Beneficiaries in selecting home dialysis, the proposed HDPA is tied to claims submitted for home dialysis, and would thus provide the largest benefit to ESRD facilities and Managing Clinicians that already have the infrastructure in place to

support increased use of home dialysis. A commenter expressed opposition to providing the HDPA to ESRD facilities, given that, in the commenter's view, ESRD facilities already have an incentive to furnish home dialysis services over in-center dialysis services. According to the commenter, the profit margin for home dialysis is generally higher than or equal to in-center dialysis for ESRD facilities, but the returns on capital are substantially higher when providing home dialysis services, as fewer fixed assets are required to furnish home dialysis services than in-center dialysis.

Response: We thank the commenters for their feedback. CMS recognizes that by tying the HDPA to home dialysis and home dialysis-related claims, ETC Participants who furnish higher numbers of home dialysis and home dialysis-related services at the outset of the Model will receive more HDPA payments under the Model. However, this does not detract from the incentives to increase rates of home dialysis created by the HDPA, particularly in combination with the PPA, and CMS believes the proposed HDPA is an appropriate means to incentivize the increased provision of home dialysis and home dialysis-related services while also rewarding those who are already furnishing high rates of home dialysis and home dialysis-related services. CMS disagrees with the commenter's suggestion to eliminate the Facility HDPA. The commenter's statement that ESRD facilities currently have a greater incentive to provide home dialysis over in-center dialysis is directly contradicted by the data on relative rates of in-center and home dialysis described in the proposed rule and previously in this final rule. The overwhelming majority of ESRD Beneficiaries, including ESRD Beneficiaries for whom Medicare is a secondary payer, currently receive in-center dialysis rather than home dialysis.

Comment: A commenter recommended that CMS apply the HDPA to payments for devices and procedures related to creation of vascular access for dialysis, and reduce payments

for interventions, such as angioplasty and stenting, which are performed when a vascular means of access becomes clogged.

Response: It is not clear whether the commenter was suggesting that CMS adjust payments for vascular access device and procedures to supplement or supplant our proposed payment adjustments to claims for home dialysis and home dialysis-related services. Either way, if ETC Participants use devices and procedures related to creating vascular access for dialysis, and the ESRD Beneficiaries who acquire vascular access then receive home dialysis or home dialysis-related services, Medicare payments for those home dialysis and home dialysis-related services will be adjusted by the HDPA. Moreover, vascular access, while an important consideration for beneficiaries on dialysis, is not the focus of this Model.

Comment: A commenter opined that the payment adjustments proposed for the ETC Model are reminiscent of the "bonus-and-penalty payment methodology" used in the Premier Hospital Quality Incentive Demonstration ("Premier"), launched by CMS in 2003, which the commenter described as unsophisticated compared to more recent payment methodologies used in Innovation Center models. The commenter further noted that Premier did not yield improved patient outcomes.

Response: CMS disagrees with the commenter's comparison between Premier and the ETC Model. In Premier, CMS offered high achieving participants either a 1 percent or 2 percent positive adjustment on certain claims, and did not incorporate downside risk. While the HDPA may resemble the Premier payment adjustment, under the ETC Model the HDPA will be applied concurrently with the PPA, which provides both upward and downward adjustments to certain payments, and at a notably larger magnitude than the payment adjustments under Premier.

After considering public comments, we are finalizing our general proposal regarding the HDPA, as proposed. We are also finalizing the proposed definitions for the Home Dialysis Payment Adjustment (HDPA), Clinician Home Dialysis Payment Adjustment (Clinician HDPA), and Facility Home Dialysis Payment Adjustment (Facility HDPA) in our regulation at § 512.300 without modification, other than the technical change to capitalize every word of each of these terms (for example, in the proposed rule, we proposed to define "Home dialysis payment adjustment," but in this final rule we are defining the term "Home Dialysis Payment Adjustment").

a. Payments Subject to the HDPA

We proposed that the HDPA would apply to all ETC Participants for those payments described in the proposed rule and in sections IV.C.4.b and IV.C.4.c of this final rule, according to the schedule described in the proposed rule and section IV.C.4.d of this final rule. We solicited comment on our proposal to apply the HDPA with respect to all ETC Participants, without exceptions.

We also proposed that the HDPA would apply to claims where Medicare is the secondary payer for coverage under section 1862(b)(1)(C) of the Act. We explained that when a beneficiary eligible for coverage under an employee group health plan becomes eligible for Medicare because he or she has developed ESRD, there is a 30-month coordination period during which the beneficiary's group health plan remains the primary payer if the beneficiary was previously insured. During this time, Medicare is the secondary payer for these beneficiaries. We proposed to apply the HDPA to Medicare as secondary payer claims because the initial transition period onto dialysis is important for supporting beneficiaries in selecting home dialysis, as beneficiaries who begin dialysis at home are more likely to remain on a home

modality. As we noted in the proposed rule, the HDPA would adjust the Medicare payment rate for the initial claim, and then the standard Medicare Secondary Payer calculation and payment rules would apply, possibly leading to an adjustment to the Medicare Secondary Payer amount. We sought comment on the proposal to apply the HDPA to Medicare as secondary payer claims.

The following is a summary of the comments received on payments subject to the HDPA and our proposal to apply the HDPA to claims where Medicare is a secondary payer, and our responses.

Comment: A commenter expressed support for CMS's proposal to apply the HDPA to all ETC Participants, reasoning that the HDPA incentivizes an increase in home dialysis rates, which aligns with the Model's goals. Another commenter recommended that CMS apply the HDPA to all ESRD providers.

Response: We thank the commenters for their feedback. We agree that CMS's proposal to apply the HDPA to all ETC Participants aligns with the Model's goals by incentivizing an increase in home dialysis rates, which we expect to improve or maintain quality while reducing costs. Regarding the commenter's recommendation that CMS apply the HDPA to all ESRD providers, we are finalizing our proposal to apply the HDPA only to ETC Participants to allow us to compare the rates of home dialysis between ETC Participants (who are subject to the HDPA) and ESRD facilities and Managing Clinicians located in Comparison Geographic Areas (who are not subject to the HDPA) for purposes of evaluating whether the HDPA statistically impacts the provision of home dialysis.

Comment: A commenter expressed strong support for CMS's proposal to apply the HDPA to claims where Medicare is the secondary payer.

Response: We thank the commenter for the feedback and support.

After considering public comments, we are finalizing our general proposals regarding payments subject to the HDPA, without modification.

b. Facility HDPA

For ESRD facilities that are ETC Participants, we proposed to adjust Medicare payments under the ESRD PPS for home dialysis services by the HDPA according to the schedule described in the proposed rule and section IV.C.4.d of this final rule. As noted in the proposed rule and previously in this final rule, under the ESRD PPS, a single per treatment payment is made to an ESRD facility for all renal dialysis services, which includes home dialysis services, furnished to beneficiaries. This payment is subject to a number of adjustments, including patient-level adjustments, facility-level adjustments, and, when applicable, a training adjustment add-on for home and self-dialysis modalities, an outlier payment, and the TDAPA. We explained in the proposed rule that, at that time, the formula for determining the final ESRD PPS per treatment payment amount was as follows:

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

We proposed to apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate on claims submitted for home dialysis services. For purposes of the ETC Model, we proposed to define the "Adjusted ESRD PPS per Treatment Base Rate" as the per treatment payment amount as defined in 42 CFR 413.230, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA amount. We stated in the proposed rule that the proposed formula for determining the final ESRD PPS per treatment payment amount with the Facility HDPA would be as follows:

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

In the proposed rule, we considered adjusting the full ESRD PPS per treatment payment amount by the Facility HDPA, including any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA. However, we concluded that adjusting these additional payment amounts was not necessary to create the financial incentives we seek to test under the proposed ETC Model. We sought comment on our proposed definition of Adjusted ESRD PPS per Treatment Base Rate, and the implications of excluding from the definition the adjustments and payment amounts previously listed, such that those amounts would not be adjusted by the Facility HDPA under the ETC Model.

As discussed previously in section IV.B.1 of this final rule, after we published the proposed rule for the ETC Model, CMS established a new payment adjustment under the ESRD PPS called the TPNIES, which could apply to certain claims as soon as CY 2021. The TPNIES is part of the calculation of the ESRD PPS per treatment payment amount under 42 CFR 413.230 and, like the TDAPA, is applied after the facility-level and patient-level adjustments. We discuss the implications of this change for the Facility HDPA later in this section of the final rule.

In the proposed rule, we proposed in § 512.340 to apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate on claim lines with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, and with condition codes 74, 75, 76, or 80, when the claim is submitted by an ESRD facility that is an ETC Participant with a claim through date during a CY subject to adjustment, as described in the proposed rule and section IV.C.4.d of this final rule, where the beneficiary is age 18 or older during the entire month of the

claim. We explained that facility code 7 (the second digit of Type of Bill) paired with type of care code 2 (the third digit of Type of Bill), indicates that the claim occurred at a clinic or hospital-based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. We stated in the proposed rule that condition codes 74 and 75 indicate billing for a patient who received dialysis services at home, and condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. Condition code 76 indicates billing for a patient who dialyzed at home but received back-up dialysis in a facility. We noted in the proposed rule that, taken together, we believed these condition codes capture home dialysis services furnished by ESRD facilities, and therefore were the codes we proposed to use to identify those payments subject to the Facility HDPA. We sought comment on this proposed provision.

As further described in the proposed rule and in section IV.C.7.a of this final rule, we also proposed that the Facility HDPA would not affect beneficiary cost sharing. Beneficiary cost sharing instead would be based on the amount that would have been paid under the ESRD PPS absent the Facility HDPA.

The following is a summary of the comments received on the Facility HDPA and our responses.

Comment: Many commenters recommended that CMS adjust the home and self-dialysis training add-on payment adjustment under the ESRD PPS by the Facility HDPA. One such commenter opined that the training add-on payment adjustment is directly related to the Model's goal of shifting beneficiaries to home dialysis modalities. A commenter recommended that CMS adjust the TDAPA by the Facility HDPA, asserting that new renal dialysis drugs and biological products pending FDA approval that could be furnished to beneficiaries receiving home dialysis

services may be found to better support implementation of home dialysis delivery services. A commenter expressed support for CMS's proposal to exclude the outlier payment from the definition of the Adjusted ESRD PPS per Treatment Base Rate.

Response: We thank the commenters for their feedback. As we stated in the proposed rule, we believe adjusting the training add-on payment adjustment amount and the TDAPA amount by the Facility HDPA is not necessary to create the financial incentives we seek to test under the ETC Model. Regarding the commenter's suggestion that CMS apply the Facility HDPA to the training add-on payment adjustment, while we agree with the commenter that beneficiary training is necessary prior to initiating home dialysis, CMS believes that adjusting the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA for claims submitted for home dialysis will provide a sufficient financial incentive to shift beneficiaries to home dialysis. Regarding the commenter's suggestion that CMS should apply the Facility HDPA to the TDAPA, the commenter discussed drugs for which drug sponsors are seeking FDA approval. CMS does not find it appropriate to change its proposed application of the Facility HDPA in anticipation of certain renal dialysis drugs that may or may not be approved by the FDA. Further, even if these drugs were already approved or become approved by the FDA during the Model, that would not change CMS's position, as the Model is not focused on drug innovation or designed to encourage pharmaceutical companies to create and release more drugs. Rather, the Model is designed to increase rates of home dialysis and transplantation.

While we are not modifying the proposed application of the Facility HDPA, we are updating the formula for calculating the final ESRD PPS per treatment payment amount with the Facility HDPA to reflect the addition of the TPNIES. Because CMS would apply the TPNIES in the calculation of the per treatment payment amount after the application of the patient-level

adjustments and facility-level adjustments, in the same manner as the TDAPA, the TPNIES does not alter the proposed application of the Facility HDPA. We had proposed to apply the Facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate, meaning the per treatment payment amount as defined in 42 CFR 413.230, including patient-level adjustments and facility-level adjustments and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA amount. To take into account the TPNIES payment adjustment that could apply beginning in CY2021, we are finalizing the formula for determining the final ESRD PPS per treatment payment amount with the Facility HDPA, with the TPNIES as follows:

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

Comment: A commenter expressed general support for CMS's proposed approach for identifying home dialysis services for the purposes of applying the Facility HDPA, but recommended that CMS also apply the Facility HDPA to claims with condition code 73. The commenter asserted that for beneficiaries who qualify for Medicare based on ESRD diagnosis, CMS considers Medicare coverage to begin when a beneficiary participates in a home dialysis training program offered by a Medicare-approved training facility, and ESRD facilities report such home dialysis training using condition code 73 on claims. Other commenters similarly suggested that CMS apply the Facility HDPA to claims for home dialysis-related services with condition code 73.

Response: We thank the commenters for their feedback. CMS understands that condition code 73 relates to training a beneficiary on home dialysis, and that one way CMS determines the start of Medicare coverage for an ESRD Beneficiary is when an ESRD facility bills Medicare using condition code 73 for that beneficiary. However, under the ETC Model, CMS seeks to

adjust payments for and incentivize the provision of home dialysis services, and not home dialysis training *per se*. CMS recognizes that training is necessary for a beneficiary to succeed in home dialysis; however, adjusting payments for claims that include condition code 73 may encourage impermissible "gaming" wherein ETC Participants train all beneficiaries on home dialysis, regardless of whether the ETC Participant believes home dialysis is the most appropriate modality for the beneficiary. In such a case, CMS would be compensating ETC Participants for simply training beneficiaries, rather than for starting and maintaining trained Beneficiaries on home dialysis. Further, any home dialysis claim submitted for an ESRD Beneficiary after the claim containing condition code 73 would be adjusted by the Facility HDPA, providing a robust enough incentive to ETC Participants to increase the provision of home dialysis services.

Comment: A commenter expressed support for CMS's proposal that the Facility HDPA would not affect beneficiary cost sharing.

Response: We thank the commenter for the feedback and support.

After considering public comments, we are finalizing our proposed provisions on payments subject to the Facility HDPA with modification. Specifically, we are codifying in our regulation at § 512.340 that we will adjust the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA for claim lines with Type of Bill 072X and with condition codes 74 or 76 where the claim is submitted by an ESRD facility that is an ETC Participant with a claim service date during a calendar year subject to adjustment as described in §512.350, where the beneficiary is at least 18 years old before the first day of the month. We are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable MY. Whereas we proposed using the claim through date, we are finalizing using the date of service on

the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim date of service to identify the MY in which the service was furnished. In addition, while we had proposed to apply the Facility HDPA only to claims for which the beneficiary was at least 18 years old for the entire month of the claim, in the final rule, we are changing the language to state that the beneficiary must be at least 18 years of age "before the first day of the month," which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). While we proposed to apply the Facility HDPA to claims with condition code 75, we have since learned that this condition code is no longer valid and therefore will be removed for the final rule. Additionally, in this final rule, we will not apply the Facility HDPA to claims with condition code 80, as we had proposed, because condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. As described in greater detail in section IV.C.5.b.(1) of this final rule, we are excluding beneficiaries who reside in or receive dialysis services in a SNF or nursing facility from attribution to ETC Participants for purposes of calculating the PPA. We will exclude home dialysis claims for these beneficiaries from the application of the Facility HDPA for the same reason. We are finalizing the definition of Adjusted ESRD PPS per Treatment Base Rate in our regulation at § 512.310 with one modification to reflect that the Adjusted ESRD PPS per Treatment Base Rate calculation excludes any applicable TPNIES amount, with a technical change to capitalize every word in the term "Adjusted ESRD PPS per Treatment Base Rate."

c. Clinician HDPA

For Managing Clinicians that are ETC Participants, we proposed to adjust the MCP by the Clinician HDPA when billed for home dialysis services. We proposed to define the "MCP" 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 as specified in 42 CFR 414.314. We considered adjusting all Managing Clinician claims for services furnished to ESRD Beneficiaries, including those not for dialysis management services. However, as described in the proposed rule, we concluded that adjusting claims for services other than dialysis management was not necessary to create the financial incentives we seek to test under the ETC Model.

We proposed to specify in our regulation at § 512.345 that we would adjust the amount otherwise paid under Part B with respect to MCP claims by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant. MCP claims would be identified by claim lines with CPT® codes 90965 or 90966. We would adjust MCP claims with a claim through date during a CY subject to adjustment, as described in the proposed rule and section IV.C.4.d of this final rule, where the beneficiary is 18 years or older for the entire month of the claim. CPT® code 90965 is for ESRD-related services for home dialysis per full month for patients 12-19 years of age. CPT® code 90966 is for ESRD-related services for home dialysis per full month for patients 20 years of age and older. These two codes are used to bill the MCP for patients age 18 and older who dialyze at home, and therefore are the codes we proposed to use to identify those payments subject to the HDPA. As noted in the proposed rule and previously in this final rule, we proposed to adjust the amount otherwise paid under Part B by the Clinician HDPA so that beneficiary cost sharing would not be affected by the application

of the Clinician HDPA. The Clinician HDPA would apply only to the amount otherwise paid for the MCP absent the Clinician HDPA.

The following is a summary of the comments received on the Clinician HDPA and our responses.

Comment: Two commenters expressed support for our proposal that the Managing Clinician HDPA would not affect beneficiary cost sharing. One such commenter reasoned that beneficiaries included in the Model should not be financially harmed or experience perverse incentives to obtain care not resulting in optimal patient health outcomes. Another commenter expressed concern that CMS did not explain in the proposed rule how the HDPA would impact beneficiary co-insurance.

Response: We thank the commenters for their feedback. As we noted in the proposed rule, the Clinician HDPA is applied to the Part B paid amount. Beneficiary cost sharing (for example, beneficiary coinsurance) is not subject to the HDPA adjustment.

Comment: A commenter suggested that, during the Model, CMS increase the payment amount for physicians' services for patients in training for self-dialysis.

Response: We thank the commenter for this feedback. CMS disagrees with the commenter's suggestion that CMS increase the PFS payment amount for services furnished to patients in training for self-dialysis, as (1) the Model uses percentages for its payment adjustments to give each ETC Participant a percentage (rather than flat-dollar) increase or decrease in payment, and (2) CMS has modified its proposal to include self-dialysis services for purposes of calculating the home dialysis rate, as described in section IV.C.5.c.(1) of this final rule.

After considering public comments, we are finalizing our proposals on the application of the Clinician HDPA to MCP claims with modifications. Specifically, we are codifying in our regulation at § 512.345 that we will adjust the amount that is otherwise paid under Medicare Part B with respect to MCP claims, identified by claim lines with CPT® codes 90965 or 90966, by the Clinician HDPA when the claim is submitted by a Managing Clinician who is an ETC Participant and with a claim service date during a calendar year subject to adjustment described in § 512.350, where the beneficiary is at least 18 years old before the first day of the month. As noted elsewhere, we are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable MY. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim date of service to identify the MY in which the service was furnished. In addition, while we had proposed to apply the Clinician HDPA only to claims for which the beneficiary was at least 18 years old for the entire month of the claim, in the final rule, we are changing the language to state that the beneficiary must be at least 18 years "before the first day of the month," which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). Finally, we are finalizing the definition of Monthly capitation payment (MCP), as proposed, in our regulation at § 512.310.

d. HDPA Schedule and Magnitude

We proposed to specify in our regulations at § 512.350 that the magnitude of the HDPA would decrease over the years of the ETC Model test, as the magnitude of the PPA increases. In

this way, we would transition from providing additional financial incentives to support the provision of home dialysis through the HDPA in the initial three CYs of the ETC Model, to holding ETC Participants accountable for attaining the outcomes that the Model is designed to achieve via the PPA. In the proposed rule, we considered alternative durations of the HDPA, including limiting the HDPA to one year such that there would be no overlap between the HPDA and the PPA, or extending the HDPA for the entire duration of the Model. However, we did not elect to propose these approaches in the proposed rule. We explained that if the HDPA applied for only the first year of the Model, there would be a six-month gap between the end of the HDPA (December 31, 2020) and the start of the first PPA period (July 1, 2021), during which there would be no model-related payment adjustment. If the HDPA applied for the duration of the Model, there would be two sets of incentives in effect: a process-based incentive from the HDPA and an outcomes-based incentive from the home dialysis component of the PPA. As we explained in the proposed rule, while we believe that the time-limited overlap between the two payment adjustments is acceptable to smoothly transition ETC Participants from process-based incentives to outcomes-based incentives, we do not believe this structure is beneficial to the Model test over the long term.

We proposed the payment adjustment schedule in Table 11:

**TABLE 11: PROPOSED HDPA SCHEDULE**

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

Under this proposed schedule, the HDPA would no longer apply to claims submitted by ETC Participants with claim through dates on or after January 1, 2023. We sought input from the public about the proposed magnitude and duration of the proposed HDPA.

The following is a summary of the comments received on the proposed HDPA schedule and magnitude and our responses.

Comment: Several commenters recommended that we continue to apply the HDPA beyond the first 3 years of the Model, and some suggested that we continue to apply the HDPA for the entire duration of the Model. A commenter recommended that the period during which the HDPA is applied be increased from 3 years to 4 years. Several commenters expressed concern regarding the proposal to reduce the magnitude of the HDPA after the first year, and otherwise taper down the magnitude of the HDPA over the course of the first three years of the Model. Commenters also expressed concern regarding the proposal to apply the HDPA during only the first three years of the Model. Several commenters expressed concern that building up the infrastructure necessary to increase the provision of home dialysis will take time, and that it would be more appropriate to apply the HDPA to claims submitted by ETC Participants for more years of the Model. Some commenters explained that the sources of delay and difficulty in establishing or building upon a home dialysis program include: capital investments; hiring staff, particularly dialysis nurses who are in short supply across the nation; receiving local zoning and building permits; and obtaining federal and state regulatory approval. Commenters expressed concern that going through the required processes and obtaining the appropriate equipment and staffing can easily take a year or more, at which time the magnitude of the HDPA will have already decreased.

Response: Regarding the comments recommending that CMS extend the duration of time during which the HDPA would be applied, CMS indicated in the proposed rule that applying the HDPA for the duration of the Model would create an overlap between a payment adjustment that is process-based, the HDPA, and another that is outcomes-based, the PPA, that would not be beneficial to the Model test over the long-term. Applying the HDPA for another year would similarly not be beneficial to the Model over the long-term. The Model is designed to more heavily emphasize, in the beginning of the Model, the process of building up necessary infrastructure to provide more home dialysis services, and to more heavily emphasize, in later years of the Model, the outcomes of increased home dialysis and transplants. CMS recognizes that building the necessary infrastructure will take time, and that is why CMS proposed to apply the HDPA for the first three years of the Model. CMS believes that three years is more than enough time to take all necessary steps to increase utilization of home dialysis.

Comment: A commenter recommended that CMS wait to apply the HDPA to claims submitted by an ETC Participant until after a patient has been on home dialysis for three months. The same commenter expressed concern that ETC Participants will start patients on home dialysis who will not do well on home dialysis so that the ETC Participants could potentially receive a short-term increase in payment via the application of the HDPA.

Response: While CMS appreciates the commenter's suggestion that CMS wait to apply the HDPA to claims submitted by an ETC Participant until the beneficiary has been on home dialysis for 3 months, CMS believes it is important to apply the HDPA sooner so as to better position ETC Participants to immediately begin making investments to increase the provision of home dialysis to beneficiaries for whom this modality is clinically appropriate. CMS also appreciates the commenter's concern over the possibility of ETC Participants gaming the HDPA

when the HDPA applies immediately and not after a particular ESRD Beneficiary has been on home dialysis for a certain amount of time, but CMS believes the overall payment methodology under the Model eliminates a gaming incentive of this nature. Part of the calculation for the PPA derives from the ETC Participant showing improvement in its home dialysis rate in a given year. An ETC Participant will need to increase its beneficiary population receiving home dialysis in a sustainable fashion for its data to reflect an improvement, creating an incentive for ETC Participants to identify suitable candidates for home dialysis and to keep such candidates on home dialysis over the course of months and years, as appropriate.

Comment: Some commenters expressed general support for the magnitude of the HDPA as proposed. A few commenters expressed agreement with the idea that payment incentives have a role in achieving higher value care for kidney patients. One such commenter noted that rates of PD have increased due to aligning the reimbursement for in-center dialysis with home-based modalities. Similarly, another such commenter noted that ESRD facilities have proven remarkably responsive to policy changes that are tied to payment adjustments, such as the ESRD PPS and ESRD QIP initiatives. That same commenter expressed a belief that the payment adjustments under the ETC Model are far milder than the ESRD PPS and QIP initiatives, and expressed confidence that Managing Clinicians and ESRD facilities that are ETC Participants will quickly adopt new treatment and process innovations to maximize their performance within the Model.

Response: We thank the commenters for the feedback and support. We also appreciate the comment regarding the increase in the provision of PD, but note that the ESRD PPS base payment rate is modality neutral, and that the identified increase in rates of PD could be

explained by a higher profit margin for providing PD over HD, and not because the Medicare payment is higher.

Comment: A commenter expressed support for the proposed magnitude of the HDPA, but expressed concern that the uptake of home dialysis may be slower than CMS anticipates, and thus suggested that CMS consider implementing a performance benchmark that an ETC Participant must reach before CMS lowers the magnitude of that ETC Participant's HDPA. The same commenter also recommended that the duration of the HDPA should be different for LDOs versus non-LDOs, such that the HDPA would apply to claims submitted by non-LDOs for a longer period of time than for claims submitted by LDOs, or that the magnitude of the HDPA applied to claims submitted by non-LDOs would taper down more slowly than it would for the LDOs. Several commenters expressed concern that the Facility HDPA and Clinician HDPA adjustments are too low to adequately incentivize behavioral change.

Response: We appreciate the commenters' feedback. CMS does not believe it would be beneficial to the Model to require a performance benchmark for an ETC Participant to reach before CMS decreases the magnitude of the Participant's HDPA, as the intent of the HDPA is to incentivize investments in home dialysis in the early years of the Model. In later years, such incentives would be created by the application of the PPA. CMS also disagrees with the recommendation that CMS differentiate the duration or magnitude of the HDPA between LDOs and non-LDOs, as such a distinction fails to consider differences in current home dialysis service provision across LDOs and non-LDOs. CMS believes that the HDPA and PPA, in combination, provide an equally strong incentive to LDOs and non-LDOs alike toward establishing or building out home dialysis programs. Further, to the extent that the HDPA will result in a greater revenue increase to LDOs over non-LDOs early in the Model, such a disparity is appropriate given the

larger volume of patients that LDOs, by definition, serve. An ESRD facility furnishing services to a larger volume of patients will require a larger investment in infrastructure compared to an ESRD facility furnishing services to a smaller volume of patients. CMS further believes that the magnitude of the Facility HDPA and Clinician HDPA, especially when coupled with the respective PPAs, are adequate to incentivize ETC Participants to create or build out their home dialysis programs.

Comment: Many commenters noted that establishing a home dialysis program or building upon an existing program requires hiring and training staff, particularly dialysis nurses, who several commenters noted are in short supply; securing additional space and equipment; establishing training protocols for patients; undergoing a survey and certification process (depending on the State); obtaining zoning and building permits; and obtaining federal and State regulatory approval. Commenters stated that the magnitude of the HDPA is not large enough to cover these significant up-front costs. Other commenters expressed concern that the HDPA would prove inadequate to help small and independent ESRD facilities increase their provision of home dialysis, as such facilities often have low margins and fewer resources than LDOs. A commenter expressed concern that the HDPA would favor chain ESRD facilities with several ESRD facilities within close proximity who can hire one dialysis nurse to cover multiple ESRD facilities, and will lead smaller health care providers to sell their facility to large chain ESRD facilities, causing further consolidation. Still other commenters expressed concern that CMS did not attempt to quantify the investment required by ESRD facilities and Managing Clinicians to establish or build upon home dialysis programs, which those commenters believed should have informed the proposed magnitude and duration of the HDPA. A commenter expressed concern

that CMS did not indicate, in the proposed rule, that the HDPA as proposed would be adequate to allow ETC Participants to increase their capacity to provide home dialysis services.

Response: CMS believes that providing positive payment adjustments via the HDPA over the first three years of the Model will provide sufficient time for ETC Participants to build out infrastructure to establish or build upon home dialysis programs. CMS recognizes that market realities impose significant barriers to increasing capacity to offer home dialysis programs, which is exactly why CMS proposed to apply the HDPA. While CMS cannot easily affect the supply of dialysis nurses or the number of vendors in the home dialysis market, it can provide ETC Participants with positive payment adjustments through the HDPA to help overcome these market obstacles. Regarding the commenter's concern about chain ESRD facilities that have several clinics in close proximity being able to hire one nurse to cover multiple ESRD facilities, such ESRD facilities would have that advantage regardless of the payment adjustments made under this Model. The ETC payment methodology does not create or increase this advantage that chain ESRD facilities have over others. Moreover, we believe that non-chain ESRD facilities can innovate their business practices to overcome the identified advantage that chain ESRD facilities currently have. For example, non-chain ESRD facilities could hire a part-time nurse rather than a full-time nurse, or collaborate with other nearby non-chain ESRD facilities to contract with a nurse to mimic the approach that the commenter anticipates chain ESRD facilities will take. Regarding the comments expressing concern that CMS did not quantify the investment required by ESRD facilities and Managing Clinicians to establish or build upon home dialysis programs, CMS could not have adequately quantified such investments for all ETC Participants. ESRD facilities and Managing Clinicians are heterogeneous, and costs will differ greatly among ESRD facilities and Managing Clinicians.

Regional differences in cost, differing patient population sizes, differing relationships with community partners, and differences in margins, funding, and business models make it impossible for CMS to accurately identify the cost of creating or building upon a home dialysis program for each ESRD facility or Managing Clinician. The HDPA will provide ETC Participants with upfront revenue that the ETC Participant can use to increase provision of home dialysis.

Comment: Several commenters expressed concern that the Clinician HDPA, as proposed, is too small in amount to effectively address the current gap in reimbursement between providing in-center dialysis compared to home dialysis. Several commenters expressed concern that even with the 3 percent HDPA, Managing Clinicians are still paid more under current Medicare rules for providing four or more in-center dialysis treatments a month than for providing home dialysis in a month. Noting that CMS acknowledged in the proposed rule that current Medicare payment rates and mechanisms may create a disincentive to prescribe and furnish home dialysis, the commenters suggested the HDPA for Managing Clinicians should be set at a magnitude such that the Clinician HDPA plus the MCP for home dialysis exceeds the current MCP for four or more in-center dialysis visits in a given month. The same commenters recommended that following the end of the proposed HDPA period, CMS should include a payment adjustment to the MCP that equalizes the MCP for home dialysis and the MCP for four or more in-center visits. A commenter stated that the proposed Clinician HDPA of 3 percent still leaves the payment amount for home dialysis services below the in-center MCP payment for four or more visits during a month.

Response: CMS recognizes that for physicians, the MCP for in-center dialysis is currently higher than the MCP for home dialysis. However, CMS firmly believes that moving

beneficiaries to home dialysis will ultimately be cost saving for ETC Participants by the end of the model period and that the Clinician HDPA adjustments, as proposed, are sufficiently large to encourage ETC Participants create or build out home dialysis programs to realize those long term savings. The infrastructure and equipment necessary for providing home dialysis may be expensive up-front, but once the infrastructure and equipment have been acquired, home dialysis will be less costly for the ETC Participant to provide compared to providing four or more in-center dialysis sessions. Even though the Clinician HDPA is not large enough to make payment for providing home dialysis equal to or higher than payment for providing four or more in-center dialysis sessions, it is large enough to sufficiently lessen the up-front costs of establishing or building out home dialysis capability and allow the ETC Participant to realize the benefits associated with moving appropriate ESRD Beneficiaries away from in-center services to home dialysis. For ETC Participants, these benefits may include: reduced labor costs and capital depreciation associated with reduced provision of in-center services; the capacity to increase the total number of patients served at any given time and overall given that fewer patients will use in-center space, which can only accommodate so many patients at any one time, allowing the ETC Participant to more rapidly expand the patient population it serves; and generally decreased operating costs in the medium- and long-run. For ESRD Beneficiaries, the benefits may include reduced or eliminated commuting to ESRD facilities for treatment, greater involvement in the ESRD Beneficiary's own treatment, and generally greater autonomy.

Comment: Several commenters recommended that the HDPA be increased in magnitude. Some of these commenters recommended that the magnitude of the HDPA be increased significantly. Some commenters suggested certain specific amounts for the HDPA. A few commenters recommended that the magnitude of the HDPA be increased to 3-5 percent. Other

commenters suggested that the magnitude of the HDPA stay at 3 percent for all three years it is applied, or that it remain at 3 percent for the duration of the Model. Another commenter recommended that the HDPA be maintained at 3 percent for all three years, but alternatively suggested that the magnitude of the HDPA start at 1 percent in year one, increase to 2 percent in year 2, and to 3 percent in year three. Another commenter more generally suggested that the HDPA be established at a set amount for every year of the Model and not be tapered down in magnitude, as proposed. Some commenters expressed concern that the HDPA would be too small to make an impact on home dialysis rates when combined with the PPA, given that the PPA could impose a large downward adjustment on certain payments for ETC Participants.

Response: CMS does not believe the magnitude of the HDPA needs to be increased. Increasing the HDPA by any amount, including maintaining the HDPA at 3 percent for two additional years or for the duration of the Model, would serve to undermine the Model's emphasis on improving outcomes. CMS believes that the proposed magnitude of the HDPA will be adequate to make an impact on home dialysis rates notwithstanding the PPA, and that increasing the magnitude of the HDPA beyond what was proposed would undercut the focus on outcomes under the Model.

After considering public comments, we are finalizing our proposed provisions on the HDPA schedule and magnitude, with one modification. Specifically, in order to accommodate the start date for the payment adjustments under the ETC Model finalized in our regulations at § 512.320, we are codifying in our regulations at § 512.350 that CMS adjusts the payments specified in § 512.340 by the Facility HDPA and that CMS adjusts the payments specified in § 512.345 by the Clinician HDPA according to the schedule in Table 11.a:

**TABLE 11.a: HDPA SCHEDULE**

| | Calendar Year 2021 | Calendar Year 2022 | Calendar Year 2023 |
|---|---|---|---|
| Magnitude of Payment Adjustment | +3% | +2% | +1% |

5. Performance Payment Adjustment

We proposed to adjust payment for claims for dialysis services and dialysis-related services submitted by ETC Participants based on each ETC Participant's Modality Performance Score (MPS), calculated as described in the proposed rule and section IV.C.5.d of this final rule. We proposed to define the "Modality Performance Score (MPS)" as the numeric performance score calculated for each ETC Participant based on the ETC Participant's home dialysis rate and transplant rate, as described in § 512.370(d) (Modality Performance Score), which is used to determine the amount of the ETC Participant's PPA, as described in § 512.380 (PPA Amounts and Schedule). We sought comment on the composition of the MPS, particularly the inclusion of the transplant rate in the MPS.

We proposed that there would be two types of PPAs: the Clinician PPA and the Facility PPA. We proposed to define the "Clinician PPA" as the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant based on the Managing Clinician's MPS, as described in our regulations at § 512.375(b) (Payments Subject to Adjustment) and § 512.380 (PPA Amounts and Schedule). We proposed to define the "Facility PPA" as the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant based on the ESRD facility's MPS, as described in § 512.375(a) (Payments Subject to Adjustment) and § 512.380 (PPA Amounts and Schedule). We proposed to define the "PPA" as either the Facility PPA or the Clinician PPA.

The following is a summary of the comments received on the calculation of the proposed PPA, and in particular the inclusion of the transplant rate in the MPS used to calculate the PPA, and our responses.

Comment: Several commenters expressed concern about the level of control ETC Participants have over transplants. Commenters expressed concern that the average waitlist stay for a patient is around 4.6 years, and therefore ETC Participants may not be able to receive credit for a transplant that results from getting a beneficiary on the transplant waitlist given the Model's duration. A commenter recommended that we delay the inclusion of the transplant rate in the calculation of the PPA until there are system-wide improvements in the availability of organs for transplant, the transplant rate is redesigned to enhance patient protections, and the Model explicitly accounts for regional variation in transplant rates. Several commenters recommended that CMS use transplant waitlisting instead of actual transplant rates in calculating the PPA, noting that ESRD facilities and Managing Clinicians have influence over waitlisting rates, but not over the actual transplant rates. Some commenters suggested that CMS simply eliminate the transplant rate from the PPA calculation. Some commenters suggested that though organ supply is outside of the control of ESRD facilities and managing clinicians, there are other aspects of the process that can and should be in their control such as how they educate patients and families about living donation and how effectively they interact with transplant centers. They remarked that there is an opportunity for ESRD facilities and managing clinicians to increase care coordination and patient education with respect to living donor transplantation. A commenter expressed concern about the calculation of the MPS, asserting that the proposed home dialysis rate and transplant rate calculations, risk adjustments, reliability adjustments, and comparison

benchmarks seem complex and would make it difficult for ETC Participants to monitor, gauge, and ultimately improve performance.

Response: We thank the commenters for their feedback. CMS believes that using a performance measure related to transplants to determine, in part, an ETC Participant's PPA is vital to incent meaningful behavior change. While CMS does recognize that ETC Participants, as ESRD facilities and Managing Clinicians, do not have control over every step of the transplant process, CMS continues to believe it is appropriate to include a transplant component in the MPS calculation used to determine the PPA. As the health care providers that ESRD beneficiaries see most frequently, ETC Participants play a pivotal role in the transplant process, including: educating beneficiaries about their transplant options, including living donation; helping beneficiaries navigate the transplant process, including helping beneficiaries understand the process; providing referrals for care necessary to meet clinical transplant requirements, and referrals for transplant waitlisting; and coordinating care during the transplant process.

Based on feedback from commenters, however, CMS is drawing a distinction between living donor transplants, which are not subject to the same supply constraints brought up by commenters, and deceased donor transplants, which currently have a more limited supply. For the living donation process, CMS recognizes the important role that ETC Participants have in helping inform and support their patients in the living donor process, and will therefore retain the living donor transplant rate in the transplant rate calculation.

In contrast, CMS recognizes that the current process for deceased donor organ allocation and the current shortage of available deceased donor kidneys makes it difficult to hold ETC Participants accountable for the rate of deceased donor kidney transplants at this time. The proposed rule calculated the transplant rate by adding together all transplants, including pre-

emptive transplants. However, based on feedback from commenters the rate of deceased donor transplants will not be a part of the transplant rate calculation. The transplant rate will still include living donor transplants, including preemptive transplants, but we replaced the deceased donor transplants in the transplant rate calculation with the transplant waitlist rate because CMS also recognizes that ESRD facilities and Managing Clinicians play an essential role in supporting beneficiaries in selecting transplantation and referring beneficiaries to a transplant waitlist, and are well-positioned to work with OPOs and transplant centers to further increase transplant waitlisting. The ETC Model is designed in part to encourage health care providers to form these relationships. The ETC Learning Collaborative, described in section IV.C.13 of this final rule, is designed to facilitate these relationships as part of the dissemination of best practices to increase organ recovery and utilization. We therefore agree with commenters that it is appropriate to hold ETC Participants accountable for transplant waitlisting while implementing other policies to increase the supply of available deceased donor kidneys. These modifications to the transplant component of the MPS calculation is further discussed in section IV.C.5.c.(2) of this final rule.

CMS recognizes that 88.5% of all deceased donor kidney transplants occurred among patients who had been on the waitlist for less than five years. Given that the ETC Model will last over 5 years, the average Medicare beneficiary placed on a waitlist in the first year is expected to receive a transplant by the end of the Model. Accordingly, CMS may consider incorporating a transplant rate into the PPA calculation for later years of the Model through subsequent rulemaking.

Comment: Commenters expressed a desire for other stakeholders like OPOs to also be held financially accountable for transplant rates under the Model if CMS is going to proceed with holding ETC Participants financially accountable for actual transplants. One such

commenter expressed concern that ETC Participants may be unfairly disadvantaged if a transplant program does not put higher risk patients referred by the ETC Participant on the transplant waitlist that other transplant programs might accept.

Response: As discussed in response to the preceding comment and as described in section IV.C.5.d of this final rule, we will not be holding ETC Participants accountable for deceased donor transplants under the ETC Model. Rather, we will use a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate for purposes of the transplant component of the MPS. Regarding the concern that ETC Participants may be unfairly disadvantaged if a transplant program does not put higher risk patients referred by ETC Participants on the transplant waitlist that other transplant programs might accept, CMS acknowledges that transplant programs have different criteria for accepting patients on transplant waitlists. ETC Participants can work with transplant programs in their respective communities to encourage the acceptance of a particular ESRD Beneficiary on the waitlist. ETC Participants could also recommend that their patients register with a particular transplant program that accepts patients with their levels of risk. ETC Participants can also support ESRD Beneficiaries pursuing living donor transplants by educating beneficiaries about their transplant options, including living donation; helping beneficiaries navigate the transplant process, including helping beneficiaries understand the process; providing referrals for care necessary to meet clinical transplant requirements, and referrals for transplant waitlisting; and coordinating care during the transplant process.

Comment: Some commenters recommended that CMS create a blended home dialysis-transplant measure for determining an ETC Participant's PPA. For example, one commenter suggested using a composite endpoint, where home dialysis and transplantation are measured in

one rate, rather than two separate rates, using the same numerator and denominator. Another commenter suggested including an appropriate patient acuity measure and measures that assess social determinants of health and unmet social needs in calculating the home dialysis and transplant rates and issuing the PPA

Response: We appreciate the commenter's suggestion that we create a blended home dialysis and transplant rate to determine an ETC Participant's PPA and recognize that some ETC Participants may excel at supporting beneficiaries in selecting one alternative to in-center HD and not the other. However, we believe it is important that ESRD Beneficiaries receive the support they need to select either home dialysis or transplantation, regardless of the ETC Participant from which they receive dialysis care. As such, we believe it is important to assess ETC Participant performance on the home dialysis rate and transplant rate separately, rather than using a blended approach.

Comment: A commenter recommended that CMS provide an increased payment to dialysis providers for transplants as part of the ETC Model, similar to the transplant bonus payment in the KCC Model.

Response: CMS disagrees with the commenter's suggestion to provide ETC Participants with a bonus payment for transplants, as ETC Participants can receive such a bonus by participating concurrently in the KCC Model.

Comment: A commenter suggested that CMS adjust payment to ESRD facilities using performance data on quality measures that facilities have publicly reported for a period of time because that would allow stakeholders to assess the reliability and validity of the measures, as well as the proposed scoring methodology, and to identify any potential unintended consequences that may be occurring.

Response: CMS disagrees with the comment regarding deriving performance-based quality adjustments for ESRD facilities under the ETC Model from previously publicly reported measures. CMS understands the commenter's assertion that measures that have been in use for some time and have been publicly reported demonstrate reliability, validity, and transparency to stakeholders. However, the home dialysis rate and transplant rate used in the ETC Model are part of the model test, and have been constructed solely for the purposes of the model test. For the purposes of testing this Model, we do not believe that it is necessary for these rates to have been publicly reported in advance of the Model. As described in section IV.C.10 of this final rule, we will monitor for unintended consequences and make modifications to the Model, including the home dialysis rate and transplant rate, if necessary, through subsequent rulemaking.

Comment: Many commenters recommended that CMS use validated measures that are endorsed by the National Quality Forum (NQF).

Response: We appreciate the feedback from commenters that CMS should use NQF-endorsed measures to measure ETC Participant performance under the Model. We note that, at present, there are no NQF-endorsed measures for rates of home dialysis, kidney transplants, or inclusion on the kidney transplant waitlist. However, we believe that it is appropriate to use the rates constructed specifically for the purposes of this Model, as our intent is to measure the impact of the Model's payment adjustments on the rates of home dialysis and transplants. Given the tailored nature of the home dialysis and transplant rates and the lack of extant alternatives, we believe it is appropriate to use these rates for this Model.

Comment: A commenter recommended that CMS add shared decision-making measures (that is, measures demonstrating that a patient and clinician made treatment decisions together

based on what is best for the patient), such as the Decision Conflict Scale or those shared decision-making measures in NQF's *National Quality Partners Playbook™: Shared Decision Making in Healthcare*. The same commenter noted that the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey for In-Center Hemodialysis (ICH CAHPS)[150] includes questions related to home modality options and transplantation, but does not include shared-decision making questions and is limited to beneficiaries using in-center dialysis. The same commenter therefore also suggested using decision-making tools for the ESRD population, such as the Empowering Patients on Choices for Renal Replacement Therapy (EPOCH). Some commenters offered to work with CMS to construct a shared-decision making measure to supplement the proposed home dialysis rate and transplant rate to assess the performance of ETC Participants under the Model and would also protect a beneficiary's choice and patient protections.

Response: CMS appreciates the feedback to include measures of shared decision making so that beneficiaries have a choice in dialysis treatment modality. CMS believes that the informational material required to be posted in the facility, described in § 512.330(a), addresses the need for beneficiaries to be educated about the Model and the beneficiary protections described in section II of this final rule adequately protect beneficiaries' freedom of choice. While education regarding treatment modality is important, CMS will not adopt this recommendation as it does not fit with the Model's goals of adjusting payments in order to improve or maintain quality while reducing costs through increased rates of home dialysis use, ultimately, and kidney transplants.

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[150] CAHPS® is a registered trademark of the Agency for Health Research and Quality, U.S. Department of Health and Human Services.

Comment: A commenter recommended that CMS define a pathway of supportive care services and allow beneficiaries enrolled in the pathway be included in calculation of the proposed home dialysis rate and transplant rate. According to the commenter, supportive care services include medical management, defined as planned, holistic, person-centered care such as interventions to delay progression of kidney disease and minimize risk of adverse events or complications; shared decision making; active symptom management; detailed communication including advance care planning; psychological support; as well as social and family support. The same commenter similarly recommended that CMS explicitly acknowledge, in the final rule, the need for supportive care services for seriously ill beneficiaries with CKD Stage IV, CKD Stage V, and ESRD.

Response: We agree with the commenter that supportive care services are important for seriously ill beneficiaries with CKD Stage IV, CKD Stage V, and ESRD. CMS also appreciates the commenter's recommendation that CMS define a pathway of supportive care services and allow beneficiaries enrolled in such pathway to count toward the calculation of the home dialysis and transplant rates. However, this Model is designed to improve or maintain quality while decreasing costs by creating incentives for Managing Clinicians and ESRD facilities to increase rates of home dialysis and transplants. We believe that the proposed rates, with the modifications described elsewhere in this final rule, best accomplish this goal. Further, to the extent that supportive care services result in beneficiaries initiating home dialysis, receiving a living donor transplant, or being included on the kidney transplant waitlist, their use will be indirectly counted towards the calculation of the home dialysis rate or the transplant rate, respectively.

Comment: A commenter recommended that CMS include kidney transplants with any other organ, and not just with pancreas.

Response: We appreciate the commenter's feedback. We are clarifying that, in referring to a kidney transplant in the proposed rule, we intended to refer to kidney transplants alone or in conjunction with any other organ transplant. By referring to both kidney transplants and kidney-pancreas transplants, our intent was not to exclude kidney transplants in conjunction with organs other than the pancreas. Accordingly, we are defining the term "kidney transplant" in our regulations at § 512.310 to mean the a kidney transplant, alone or in conjunction with any other organ. Accordingly, the transplant waitlist rate calculation included in the transplant rate will include ESRD Beneficiaries listed on a waitlist for any kind of kidney transplant, and the living donor transplant rate calculation included in the transplant rate will include beneficiaries who receive any kind of kidney transplant from a living donor.

Comment: A commenter expressed concern about a proposed measure in ESRD QIP – the Percentage of Prevalent Patients Waitlisted Measure – that, if finalized, may subject an ETC Participant to a second source of negative payment adjustment.

Response: We note that CMS finalized the adoption of the PPPW measure in the CY 2019 ESRD PPS final rule (83 FR 57008). We appreciate the commenter's concern that ESRD facilities that are ETC Participants will receive more than one payment adjustment based on transplant waitlisting. However, we believe that the adjustments under the ESRD QIP and the ETC Model are sufficiently different, in construction, payment adjustment scope and magnitude, and purpose, to support the overlap.

After considering public comments, we are finalizing our general proposals for the Performance Payment Adjustment, with certain modifications. Specific provisions and

modifications are described in the following sections of this final rule. We received no public comment on our proposed definitions of the Performance Payment Adjustment (PPA), Facility Performance Payment Adjustment (Facility PPA), or Clinician Performance Payment Adjustment (Clinician PPA). As such, we are finalizing these definitions in our regulation at § 512.310 as proposed. We received no public comment on our proposed definition of the Modality Performance Score (MPS), and are finalizing this definition in our regulation at § 512.310 with modification to correct an error in an internal cross-reference. Specifically, the proposed definition of MPS referred to § 512.310(a) of our regulations, but we had meant to refer to the MPS calculation in § 512.310(d). We are adding a definition for "kidney transplant waitlist" to our regulations at § 512.310, for the reasons described in section IV.C.5.c(2) of this final rule.

a. Annual Schedule of Performance Assessment and PPA

We proposed to assess ETC Participant performance on the home dialysis rate and the transplant rate, described in the proposed rule and in sections IV.C.5.c.1 and IV.C.5.c.2, respectively, of this final rule, and to make corresponding payment adjustments according to the proposed schedule described later. We proposed in § 512.355(a) that we would assess the home dialysis rate and transplant rate for each ETC Participant during each of the Measurement Years, which would include 12 months of performance data. For the ETC Model, we proposed to define "Measurement Year (MY)" as the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Further, we proposed in § 512.355(b) that we would adjust payments for ETC Participants by the PPA during each of the PPA periods, each of which would correspond to a Measurement Year. We proposed to define

"Performance Payment Adjustment Period (PPA Period)" as the 6-month period during which a PPA is applied pursuant to § 512.380 (PPA Amounts and Schedule). Each MY included in the ETC Model and its corresponding PPA Period would be specified in § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods).

Under our proposal, each MY would overlap with the subsequent MY, if any, for a period of 6 months, as ETC Participant performance would be assessed and payment adjustments would be updated by CMS on a rolling basis. As we noted in the proposed rule, we believe that this method of making rolling performance assessments balances two important factors: the need for sufficient data to produce reliable estimates of performance, and the effectiveness of incentives that are proximate to the period for which performance is assessed. Beginning with MY2, there would be a 6-month period of overlap between a MY and the previous MY. For example, MY1 would begin January 1, 2020, and would run through December 31, 2020; and MY2 would begin 6 months later, running from July 1, 2020, through June 30, 2021. Each MY would have a corresponding PPA Period, which would begin 6 months after the conclusion of the MY.

Table 12, we proposed the following schedule of MYs and PPA Periods:

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

| | **Measurement Year (MY)** | | **Performance Payment Adjustment (PPA) Period** | |
|---|---|---|---|---|
| Beginning CY 2020 | MY1 | 1/1/2020 through 12/31/2020 | PPA Period 1 | 7/1/2021 through 12/31/2021 |
| | MY2 | 7/1/2020 through 6/30/2021 | PPA Period 2 | 1/1/2022 through 6/30/2022 |
| Beginning CY 2021 | MY3 | 1/1/2021 through 12/31/2021 | PPA Period 3 | 7/1/2022 through 12/31/2022 |
| | MY4 | 7/1/2021 through 6/30/2022 | PPA Period 4 | 1/1/2023 through 6/30/2023 |

| | | | | |
|---|---|---|---|---|
| Beginning CY 2022 | MY5 | 1/1/2022 through 12/31/2022 | PPA Period 5 | 7/1/2023 through 12/31/2023 |
| | MY6 | 7/1/2022 through 6/30/2023 | PPA Period 6 | 1/1/2024 through 6/30/2024 |
| Beginning CY 2023 | MY7 | 1/1/2023 through 12/31/2023 | PPA Period 7 | 7/1/2024 through 12/31/2024 |
| | MY8 | 7/1/2023 through 6/30/2024 | PPA Period 8 | 1/1/2025 through 6/30/2025 |
| Beginning CY 2024 | MY9 | 1/1/2024 through 12/31/2024 | PPA Period 9 | 7/1/2025 through 12/31/2025 |
| | MY10 | 7/1/2024 through 6/30/2025 | PPA Period 10 | 1/1/2026 through 6/30/2026 |

We received no public comment on our proposed schedule of performance assessment and PPA. We are finalizing the proposed provisions with modification to reflect the start date of the model, January 1, 2021, as described elsewhere in this final rule. Specifically, we are codifying at § 512.355 that the PPA will be applied based on the schedule of MYs and PPA Periods in Table 12.a, to accommodate the start date for the payment adjustments under the ETC Model finalized in our regulations at § 512.320. As such, we are finalizing the definition of MY as the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Each MY included in the ETC Model and its corresponding PPA Period are

specified in § 512.355(c). We are finalizing the definition of Performance Payment Adjustment Period (PPA Period), as proposed.

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

| | Measurement Year (MY) | Performance Payment Adjustment (PPA) Period |
|---|---|---|
| Beginning CY 2021 | MY 1 – 1/1/2021 through 12/31/2021 | PPA Period 1 – 7/1/2022 through 12/31/2022 |
| | MY 2 – 7/1/2021 through 6/30/2022 | PPA Period 2 – 1/1/2023 through 6/30/2023 |
| Beginning CY 2022 | MY 3 – 1/1/2022 through 12/31/2022 | PPA Period 3 – 7/1/2023 through 12/31/2023 |
| | MY 4 – 7/1/2022 through 6/30/2023 | PPA Period 4 – 1/1/2024 through 6/30/2024 |
| Beginning CY 2023 | MY 5 – 1/1/2023 through 12/31/2023 | PPA Period 5 – 7/1/2024 through 12/31/2024 |
| | MY 6 – 7/1/2023 through 6/30/2024 | PPA Period 6 – 1/1/2025 through 6/30/2025 |
| Beginning CY 2024 | MY 7 – 1/1/2024 through 12/31/2024 | PPA Period 7 – 7/1/2025 through 12/31/2025 |
| | MY 8 – 7/1/2024 through 6/30/2025 | PPA Period 8 – 1/1/2026 through 6/30/2026 |
| Beginning CY 2025 | MY 9 – 1/1/2025 through 12/31/2025 | PPA Period 9 – 7/1/2026 through 12/31/2026 |
| | MY 10 – 7/1/2025 through 6/30/2026 | PPA Period 10 – 1/1/2027 through 6/30/2027 |

b. Beneficiary Population and Attribution

We proposed that, in order to assess the home dialysis rate and transplant rate for ETC Participants, ESRD Beneficiaries would be attributed to participating ESRD facilities and to participating Managing Clinicians. For purposes of the ETC Model, we proposed to define "ESRD Beneficiary" as a beneficiary receiving dialysis or other services for end-stage renal disease, up to and including the month in which he or she receives a kidney or kidney-pancreas transplant. As we noted in the proposed rule, this would include beneficiaries who are on

dialysis for treatment of ESRD, as well as beneficiaries who were on dialysis for treatment of ESRD and received a kidney or kidney-pancreas transplant up to and including the month in which they received their transplant.

Also, we proposed to attribute pre-emptive transplant beneficiaries to Managing Clinicians for purposes of calculating the transplant rate, specifically. We proposed to define a "pre-emptive transplant beneficiary" as a Medicare beneficiary who received a kidney or kidney-pancreas transplant prior to beginning dialysis. We stated that this definition would be mutually exclusive of the proposed definition of an ESRD Beneficiary, as a pre-emptive transplant beneficiary receives a kidney or kidney-pancreas transplant prior to initiating dialysis and therefore is not an ESRD Beneficiary. In the proposed rule, we considered defining this concept as pre-emptive transplant recipients, as there are patients who receive pre-emptive transplants who are not Medicare beneficiaries, but who would have become eligible for Medicare if they did not receive a pre-emptive transplant and progressed to ESRD, requiring dialysis. We noted that this definition would more accurately reflect the total number of transplants occurring in the population of patients who could receive pre-emptive transplants, and including these additional patients who receive pre-emptive transplants in the calculation of the transplant rate could better incentivize Managing Clinicians to support kidney transplants via the Clinician PPA. Due to data limitations about patients who are not Medicare beneficiaries, however, we concluded that we could not include patients who received pre-emptive transplants but were not Medicare beneficiaries in the construction of the transplant rate. Therefore, we proposed to limit the definition of pre-emptive transplant beneficiary to include Medicare beneficiaries only.

We proposed to attribute ESRD Beneficiaries and pre-emptive transplant beneficiaries, where applicable, to ETC Participants for each month of each MY, and we further proposed that

such attribution would be made after the end of each MY. In the proposed rule, we considered attributing beneficiaries to participating ESRD facilities and Managing Clinicians for the entire MY; however, as noted in the proposed rule, we believe monthly attribution would more accurately capture the care relationship between beneficiaries and their ESRD providers and suppliers. As ETC Participant behavior and care relationships with beneficiaries may change as a result of the ETC Model, we stated in the proposed rule that we believe that the level of precision associated with monthly attribution of beneficiaries would better support the ETC Model's design. Under our proposal, an ESRD Beneficiary may be attributed to multiple ESRD facilities and Managing Clinicians in one MY, but would be attributed to only one ESRD facility and one Managing Clinician for a given month during the MY. As we stated in the proposed rule, we believe that conducting attribution retrospectively, after the completion of the MY, would better align with the design of the PPA in the ETC Model. We invited public comment on the proposal to attribute beneficiaries on a monthly basis after the end of the relevant MY.

In the proposed rule, we considered conducting attribution prospectively, before the beginning of the MY. However, we concluded that prospective attribution would not be appropriate given the nature of ESRD and the ESRD Beneficiary population. CKD is a progressive illness, with patients moving from late stage CKD to ESRD – requiring dialysis or a transplant – throughout the course of the year. As noted in the proposed rule, we therefore believe prospective attribution would functionally exclude incident beneficiaries new to dialysis from inclusion in the home dialysis and transplant rates of ETC Participants until the following MY. Additionally, we stated our belief that prospective attribution would not work well for the particular design of this Model. In particular, we noted in the proposed rule that, because the PPA would be determined based on home dialysis and transplant rates during the MY, limiting

attribution to beneficiaries with whom the ETC Participant had a care relationship prior to the MY would not accurately capture what occurred during the MY. As we stated in the proposed rule, we believe that conducting attribution retrospectively, after the completion of the MY, would better align with the design of the PPA in the ETC Model. We invited public comment on the proposal to attribute beneficiaries on a monthly basis after the end of the relevant MY.

We proposed to provide ETC Participants lists of their attributed beneficiaries after attribution has occurred, after the end of the MY. In the proposed rule, we considered providing lists in advance of the MY, or on a more frequent basis. However, we determined that, since we would be conducting attribution after the conclusion of the MY, prospective lists of attributed beneficiaries that attempted to simulate which beneficiaries would be attributed to a participant during the MY would be potentially misleading. Additionally, we noted in the proposed rule that, as the calculation of the home dialysis rate and transplant rate among attributed beneficiaries would be conducted only once every 6 months due to overlapping MYs, we believe providing lists after the MY would provide ETC Participants sufficient information about their attributed beneficiary populations to understand the basis of their rates of home dialysis and transplants.

The following is a summary of the comments received on beneficiary attribution and our responses.

Comment: A commenter agreed that using retrospective attribution is an appropriate approach for beneficiary attribution in a fee for service model. Another commenter agreed with using pre-emptive transplantation for beneficiary attribution.

Response: We thank the commenters for their feedback and support. CMS will use retrospective beneficiary attribution as proposed. However, as described elsewhere in this final

rule, we will use the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, rather than the transplant rate as proposed, to assess ETC Participant performance under the Model. Because the living donor transplant rate calculation will include only pre-emptive transplants from living donors, rather than all pre-emptive transplants, we will only attribute beneficiaries who received pre-emptive transplants from living donors prior to beginning dialysis (defined as pre-emptive living donor transplant (LDT) beneficiaries) to Managing Clinicians.

After considering public comments, we are finalizing our proposed provisions on beneficiary attribution, with modification. Specifically, we are codifying in our regulations at § 512.360(a) that CMS will attribute ESRD Beneficiaries to ETC Participants for each month of each MY for the purposes of assessing an ETC Participant's performance on the home dialysis rate and transplant rate during that MY. We also are codifying in our regulations at § 512.360(a) that an ESRD Beneficiary can be attributed to only one ESRD facility and only one Managing Clinician for a given month during a given MY, and that attribution takes place at the end of the MY. We are codifying in our regulations at § 512.310 the definition of ESRD Beneficiary as proposed, with modification to clarify that a beneficiary who has received a transplant will be considered to be an ESRD Beneficiary if the beneficiary either has a non-AKI dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date, or has a non-AKI dialysis or MCP claim less than 12 months after the beneficiary's latest transplant date and has a kidney transplant failure diagnosis code documented in any Medicare claim. We are making this clarification because, while beneficiaries are excluded from the ESRD Beneficiary definition beginning the month after the beneficiary receives a kidney transplant, it was our intent that any beneficiary receiving dialysis or other services for ESRD would be considered an ESRD

Beneficiary, subject to the exclusions described elsewhere in this final rule. As modified, this definition makes clear that beneficiaries who have already received a kidney transplant in the past will be eligible for attribution to ETC Participants once they restart dialysis or other services for ESRD.

We are modifying several beneficiary attribution provisions in order to address the modification to the transplant rate to include the transplant waitlist rate and the living donor transplant rate, as described in section IV.C.5 of this final rule. We are finalizing the definition of "living donor transplant (LDT) Beneficiary" as an ESRD Beneficiary who received a kidney transplant from a living donor. We are also replacing the term "Pre-emptive transplant beneficiary" with the term "Pre-emptive LDT Beneficiary," which we define a beneficiary who received a kidney transplant from a living donor prior to beginning dialysis. We are modifying the attribution of pre-emptive transplant beneficiaries to Managing Clinicians in § 512.360(a), to apply solely to Pre-emptive LDT Beneficiaries and solely for purposes of assessing the Managing Clinician's performance on the living donor transplant rate, in accordance to the change from the proposed transplant rate to a transplant rate that includes the living donor transplant rate described elsewhere in this final rule.

(1) Beneficiary Exclusions

We proposed to exclude certain categories of beneficiaries from attribution to ETC Participants, consistent with other CMS models and programs for purposes of calculating the

PPA. Specifically, we proposed to exclude an ESRD Beneficiary or a pre-emptive transplant beneficiary if, at any point during the month, the beneficiary:

- Is not enrolled in Medicare Part B, because Medicare Part B pays for the majority of ESRD-related items and services, for which Part B claims are necessary for evaluation of the Model.
- Is enrolled in Medicare Advantage, a cost plan, or other Medicare managed care plans, because these plans have different payment structures than Medicare Parts A and B and do not use FFS billing.
- Does not reside in the United States, because it is more difficult to track and assess the care furnished to beneficiaries who might have received care outside of the U.S.
- Is younger than age 18 at any point in the month, because beneficiaries under age 18 are more likely to have ESRD from rare medical conditions that have different needs and costs associated with them than the typical ESRD Beneficiary.
- Has elected hospice, because hospice care generally indicates cessation of dialysis treatment and curative care.
- Is receiving any dialysis for acute kidney injury (AKI) because renal dialysis services for AKI differ in care and costs from a typical ESRD Beneficiary who is not receiving care for AKI. AKI is usually a temporary loss of kidney function. If the kidney injury becomes permanent, such that the beneficiary is undergoing maintenance dialysis, then the beneficiary would be eligible for attribution.
- Has a diagnosis of dementia because conducting dialysis at home may present an undue challenge for beneficiaries with dementia, and such beneficiaries also may not prove to be appropriate candidates for transplant.

In the proposed rule, we considered excluding beneficiaries from attribution for the purposes of calculating the home dialysis rate whose advanced age (for example, ages 70 and older) could make home dialysis inappropriate; however, we did not ascertain a consensus in the literature that supported any specific age cut-off. In the proposed rule, we also considered excluding beneficiaries with housing insecurity from attribution for the purposes of calculating the home dialysis rate, but did not find an objective way to measure housing instability.

The following is a summary of the comments received on beneficiary exclusions from attribution to ETC Participants and our responses.

Comment: Some commenters suggested that CMS not exclude any categories of beneficiaries from attribution to ETC Participants under the Model, allowing the Model to be as inclusive as possible to beneficiaries, despite the beneficiaries' medical conditions or age. A commenter stated that, after searching peer-reviewed literature and clinical guidelines, the commenter did not find obvious exclusion criteria for home dialysis patients. Another commenter suggested that if a beneficiary is able to receive a transplant or dialyze at home, despite being on the exclusion list, CMS should still include that beneficiary in the numerator and denominator for the ETC Participant, in order to give the ETC Participant credit for all transplants and home dialysis treatments.

Response: CMS appreciates this feedback regarding our proposed beneficiary exclusion criteria under the Model. Like one of the commenters noted, the literature and clinical guidelines do not have clear exclusions for home dialysis beneficiaries. However, our proposed exclusions were intended to exclude from attribution to ETC Participants those categories of beneficiaries more likely to be inappropriate candidates for home dialysis and/or transplant in order to track Managing Clinicians' and ESRD facilities' ability to provide appropriate care to patients who

can, in fact, safely have the opportunity to receive a kidney transplant or home dialysis. Although an otherwise excluded beneficiary that receives home dialysis, receives a LDT, or is placed on the transplant waitlist could be placed in the numerator and the denominator, in aggregate, we believe that these exclusions are appropriate for the reasons described in the proposed rule and previously in this final rule and will apply them in attributing ESRD Beneficiaries to ETC Participants under the Model.

Comment: Commenters supported our proposal to exclude from attribution to ETC Participants those beneficiaries who are not enrolled in Medicare Part B or who do not reside in the United States. A commenter agreed with our proposed exclusion for patients enrolled in Medicare Advantage; however, one physician group suggested attributing beneficiaries with Medicare Advantage plans to ETC Participants in order to appropriately assess the risk pool for the ETC Model since ESRD Beneficiaries may begin enrolling in Medicare Advantage plans beginning in 2021.

Response: CMS appreciates the feedback and support. After considering the public comments, we are finalizing our proposal to exclude beneficiaries not enrolled in Medicare Part B, enrolled in Medicare Advantage or other managed plans, and those not residing in the United States from attribution to ETC Participants under the Model. With respect to the commenter's suggestion that CMS attribute Medicare Advantage beneficiaries to ETC Participants, the ETC Model is a Medicare FFS model and Medicare Advantage plans have different payment structures than Medicare Parts A and B and do not use FFS billing. Including these beneficiaries in the Model's financial calculations could create unintended consequences for ETC Participants and may complicate our evaluation of the Model.

Comment: Multiple commenters recommended that CMS exclude beneficiaries from attribution to ETC Participants based on factors such as socioeconomic status, homelessness, housing instability, lack of transportation, and lack of caregiver or social support. One of those commenters listed other International Classification of Diseases, 10th Revision (ICD-10) codes that address the issues of social determinations of health around housing economic insecurity, specifically ICD-10 codes Z59.1, Z59.7, Z59.8, and Z59.9. Another commenter suggested using the homelessness ICD-10 code Z59.0 for purposes of implementing exclusions specific to homelessness, though the commenter acknowledged that this code may be underutilized. Another commenter suggested excluding dual eligible beneficiaries from attribution to ETC Participants as this group generally represents a population with lower socioeconomic status.

Response: CMS agrees that housing insecurity, transportation issues, and other social determinants of health affect patient choice of renal replacement modality. We also appreciate the few comments mentioning the ICD-10 codes that could be used to identify homelessness and other social determinants of health. However, we also agree with the commenter who stated that the homelessness ICD-10 code Z59.0 is underutilized, and we believe that adopting an exclusion for homelessness based on this code could be subject to gaming, such that this code would not be an objective measure for housing insecurity. CMS also believes that the other codes of Z59.1, Z59.7, Z59.8, and Z59.9 could be subject to gaming. Accordingly, we are not adopting the commenters' suggestions to use these codes for purposes of the Model. However, CMS will assess the use of these and other codes for purposes of adding any additional beneficiary exclusions from attribution to ETC Participants based on socioeconomic status, homelessness, or other social determinants of health through future rulemaking.

Comment: Several commenters appreciated our proposal to exclude pediatric ESRD Beneficiaries from attribution to ETC Participants due to the unique medical needs of this population. A commenter expressed concern about of the lack of quality measures for this small population of patients and suggested implementing different pediatric payment reimbursements for traditional Medicare payment for the pediatric renal beneficiaries.

Response: CMS acknowledges the importance of kidney health in the pediatric population, including the need for quality measures specific to this population, and believe that other HHS initiatives outside of the ETC Model, such as Kidney X and the broader Advancing American Kidney Health Initiative, may address this need. Comments related to provider reimbursement in the Medicare program generally are outside the scope of this final rule.

Comment: Several commenters supported excluding beneficiaries from attribution to ETC Participants due to old age. These commenters suggested excluding beneficiaries over the ages of 65, 70, or 75 from the calculation of either the transplant rate, home dialysis rate, or both, since these patients often do not receive a kidney transplant or have limited access to the caregiver support required for home dialysis. A few commenters recommended that CMS not exclude beneficiaries from attribution to ETC Participants due to age, particularly due to the aging population, and instead stressed the importance of other factors to determine a beneficiary's exclusion under the Model, such as functional status and clinical contradictions for home dialysis and kidney transplantation in order to align with a beneficiary's treatment choice and suitable care.

Response: CMS appreciates the comments on possible beneficiary exclusions due to age but notes that there is no objective scientific evidence to tie old age to incompatibility with home dialysis. Moreover, we believe an age restriction would undermine the Model's focus on

providing beneficiaries the opportunity to select home dialysis. Therefore, CMS will not restrict beneficiary attribution due to age. However, as described in section § 512.365(c) of this final rule, we are finalizing our proposal to exclude beneficiaries over the age of 75 from the numerator and the denominator of the transplant rate calculation since these patients usually are not candidates for transplants.

Additionally, we decline to adopt the commenters' recommendations that CMS establish exclusions based on functional status and clinical contraindications because clinical guidelines for home dialysis or transplant beneficiaries do not have such exclusions. Moreover, the beneficiary attribution exclusions finalized in our regulations at §512.360(b) are intended to address common contraindications for home dialysis and kidney transplant while allowing the maximum number of beneficiaries to benefit from the opportunity to select the renal replacement modality of their choice.

Comment: Several commenters supported our proposal to exclude beneficiaries with AKI from attribution to ETC Participants. A commenter requested clarification on how an AKI diagnosis in one month will affect the application of this exclusion for subsequent months for attribution to ETC Participants.

Response: We thank the commenters for their feedback and support and clarify that receipt of dialysis services for an AKI diagnosis in one month makes a beneficiary ineligible for attribution to an ETC Participant for that month, but if the AKI does not resolve and/or transitions to ESRD, the beneficiary will become eligible for attribution in a subsequent month. CMS acknowledges that patient health status may change over time.

Comment: Many commenters identified possible additional beneficiary exclusions due to clinical contradictions that prevent patients from meeting the clinical criteria for home dialysis or

transplant. Examples included: severe diabetic neuropathy or congestive heart failure, recent vascular disease, significant physical disability (Karnofsky Score <40 percent), cardiomyopathy with EF<20 percent, severe pulmonary or cardiovascular issues, cirrhosis, documented recent cardiac surgery, severe morbid obesity (BMI>50), documented status that a patient is unsuitable for a transplant or home dialysis, active infection, medication non-compliance, uncontrolled psychiatric illness or substance abuse, or blindness. Several commenters also recommended certain exclusion criteria specific to home dialysis, including: recent abdominal surgery, abdominal abscess, peritoneal scarring or failed PD attempts, blindness or impaired vision, irritable bowel syndrome, and diabetic gastroparesis. If these beneficiaries are not excluded from attribution, commenters urged CMS to include these more seriously ill populations in the risk adjustment and PPA in order appropriately compare group benchmarks, align beneficiaries, and provide the ideal care in the ideal setting for these beneficiaries.

Response: CMS appreciates the suggestions from commenters regarding clinical contradictions for home dialysis and kidney transplantation. CMS has responded to comments and concerns related to risk adjustment for seriously ill populations in section IV.C.5.d (*Benchmarking and scoring*) and section IV.C.5.c.(3) (*Risk Adjustment*) of this final rule. CMS believes the beneficiary exclusions in proposed § 512.360(b), with the modifications described elsewhere in this final rule, address common clinical contraindications for home dialysis and kidney transplantation. AKI involves short term use of dialysis, making home dialysis impractical and transplant unnecessary, and as such, the AKI exclusion exists because the Model tests incentives specific to chronic dialysis services. Beneficiaries diagnosed with dementia or who reside in or receive dialysis in a skilled nursing facility (SNF) or nursing facility may not be suitable candidates for both home dialysis or transplantation. The exclusions still provide

suitable incentives for ETC Participants to support the greatest number of ESRD Beneficiaries in receiving home dialysis or being added to the kidney transplant waitlist with the ultimate goal of receiving a kidney transplant. We also note that many of the clinical contraindications suggested by commenters for home dialysis are in fact potential contraindications for PD, and are not contraindications for HHD. Adding a large number of beneficiary exclusion criteria would run counter to the Model's focus on increasing the utilization of home dialysis and transplants for ESRD Beneficiaries, and adopting exclusions based on documentation of clinical condition could be subject to gaming.

Comment: Multiple commenters recommended that CMS exclude from attribution to ETC Participants those beneficiaries with cancer, including those diagnosed with recent solid organ malignancy and patients currently receiving related treatment, as cancer is a contraindication for transplantation candidacy and may result in variable dialysis use, in which a beneficiary's ESRD treatment modality may change frequently based on adjustments in cancer treatment such as chemotherapy timing and dosage. Some commenters stated that home dialysis may be inappropriate for beneficiaries with cancer due to complex needs, need for a caregiver, and challenging care coordination and thus these patients often prefer receiving dialysis in the same setting, suggesting that these patients may prefer in-center dialysis.

Response: CMS appreciates the suggestion to exclude beneficiaries with a diagnosis of cancer and acknowledges commenters' concerns of treatment appropriateness. While CMS understands the burden of cancer for both caregivers and beneficiaries, this exclusion would not advance the Model test because it would not result in the greatest number of ESRD Beneficiaries in receiving home dialysis or being added to the kidney transplant waitlist with the ultimate aim of receiving a kidney transplant. Moreover, there are no clear exclusion criteria for home

dialysis for beneficiaries with any cancer diagnosis, and it is CMS's belief that these beneficiaries often are not automatically ineligible for transplantation. CMS would like to encourage ETC Participants to provide home dialysis and transplantation for as many beneficiaries that would benefit from these care modalities.

Comment: Multiple commenters supported our proposed exclusion of beneficiaries with a diagnosis of dementia. Some of these commenters who supported excluding beneficiaries with a diagnosis of dementia suggested modifying our proposal to nonetheless include beneficiaries with a diagnosis of mild dementia to allow health professionals to determine the appropriateness of home dialysis for the patient, especially for patients with access to assisted home dialysis programs.

Response: CMS appreciates the commenters' suggestion that CMS attribute beneficiaries with a diagnosis of mild dementia to ETC Participants in order to preserve clinical judgement. While CMS understands that beneficiaries with mild dementia may be covered by the exclusion criteria, and thus be excluded from attribution to ETC Participants, we clarify that in order to objectively identify patients with dementia, as described in greater detail later in this final rule, we will use the most current Hierarchical Condition Category (HCC) model codes that assess dementia, and note that there is no objective way to track dementia progression or deterioration. HCC dementia codes that specify "without behavioral disturbance" cannot objectively track progression of dementia.

Comment: Multiple commenters recommended that CMS exclude from attribution to ETC Participants those beneficiaries who reside in group homes or nursing homes, pointing out that SNFs construct an in-center dialysis facility inside the nursing facility and that once beneficiaries are discharged from the SNF, they most often transition back to in-center dialysis.

A few commenters suggested altering the exclusion for beneficiaries by including beneficiaries diagnosed with dementia who reside in a SNF or are treated for AKI at a SNF, as SNFs provide a safer alternative than home dialysis for such beneficiaries needing dialysis.

Response: CMS appreciates the feedback recommending that CMS exclude from attribution to ETC Participants those beneficiaries residing in SNFs and nursing facilities. We share the commenters' concerns about dialysis provided in SNFs, particularly around the misalignment of dialysis utilization in SNFs and nursing facilities with the Model's focus on promoting beneficiary choice of treatment modality. In addition, CMS is concerned that the population of beneficiaries who reside in SNFs and nursing facilities is particularly frail, including beneficiaries diagnosed with dementia, and therefore may not be appropriate candidates for home dialysis. Accordingly, we believe that attributing these ESRD Beneficiaries to ETC Participants would not advance the Model goals of improving or maintaining quality while reducing cost by increasing home dialysis rates and transplant rates with the ultimate aim of receiving a kidney transplant. As such, CMS will exclude all beneficiaries residing in or receiving dialysis in a SNF or nursing facility from attribution to ETC Participants under the Model. We also recognize that some beneficiaries may benefit from the level of care in a SNF or nursing facility, such as beneficiaries with dementia. Dementia beneficiaries are excluded from the attribution to ETC Participants. Including beneficiaries residing in SNFs and nursing facilities does not align with the Model's goals of increase home dialysis in a beneficiaries' home.

Comment: A few commenters supported our proposed exclusion of beneficiaries who have elected hospice from attribution to ETC Participants since hospice care generally indicates cessation of dialysis treatment and dialysis care. A couple of commenters recommended not

excluding beneficiaries who have elected hospice for purposes of calculating the home dialysis rate specifically, since PD is less costly than in-center HD and offers patients treatment options.

Response: We appreciate the feedback from commenters. While we appreciate the commenters' recommendation to include beneficiaries who have elected hospice in the Model's attribution methodology, we do not believe that doing so would offer more treatment choices to beneficiaries because in general, hospice care focuses on palliative care in a beneficiary's final phase of life rather than dialysis services. We agree with the commenters who suggested excluding beneficiaries who elect hospice since hospice care is by definition time limited and indicates that the beneficiary is close to the end of life.

Comment: A few commenters suggested excluding beneficiaries who choose palliative care for their renal care modality. One of these commenters suggested tracking these more seriously ill beneficiaries differently from the healthier ESRD population and rewarding medical management for these patients receiving any type of ESRD care, including those not utilizing dialysis and instead receiving palliative or hospice care.

Response: CMS appreciates the feedback to exclude beneficiaries choosing supportive care. CMS will exclude beneficiaries who have elected hospice; however, we believe rewarding medical management of hospice beneficiaries is outside the scope of the Model and addressed in other HHS and CMS initiatives, such as the Medicare Care Choices Model.

Comment: A commenter agreed with our proposals to attribute beneficiaries to ETC Participants on a monthly basis and not exclude beneficiaries with Medicare as a secondary payer from attribution. However, the commenter suggested that we provide beneficiary attribution data to ETC Participants on a more frequent basis.

Response: CMS appreciates the feedback and support. Beneficiary attribution will occur on a monthly basis. However, attribution will occur after the MY is over. Thus, while CMS will endeavor to provide attribution data to ETC Participants on a timely basis, these data will be provided only after the MY is over. CMS believes providing accurate beneficiary attribution data is vital to ETC participants. Because the MYs overlap, beneficiary attribution data for one MY will be available during the fourth quarter of the following MY, which will provide the most accurate information within a reasonable amount of time.

After considering public comments, we are finalizing our proposed provisions regarding the exclusion of certain categories of beneficiaries from attribution to ETC Participants with modification. CMS will use the claim service date for purposes of the general attribution criteria described in § 512.360. However, Managing Clinicians and ESRD Facilities utilize different billing requirements and forms. For consistency with these billing requirements and forms, CMS will use the claim service date at the claim line through date to attribute beneficiaries to Managing Clinicians and will use the claim service date at the claim header through date to attribute beneficiaries to ESRD Facilities.

In addition, in this final rule, we are modifying our proposed exclusions from attribution for ESRD Beneficiaries with a diagnosis of dementia to clarify that such diagnosis must be made at any point during the month or the preceding 12 months, as identified using the most recent dementia criteria at the time of beneficiary attribution, defined using the dementia-related codes from the Hierarchical Condition Category (HCC) Risk Adjustment Model ICD-10-CM Mappings. We will use the HCC Risk Adjustment Model because it includes all objectively related dementia diagnosis codes. A 13- month lookback period, which includes the entire month in question plus the preceding 12 months lookback period for the dementia exclusion

aligns with the periodicity with which the HCC Risk Adjustment Model codes are updated, and will ensure that CMS has sufficient data to identify a dementia diagnosis, while also ensuring that any such diagnoses are still relevant and current for the beneficiary. For reference, the 2020 Midyear Final ICD-10-CM Mappings are found at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/Risk2020.

In addition, we are modifying our exclusion for beneficiaries younger than 18 years of age to state that a beneficiary will be excluded from attribution to an ETC Participant if he or she is younger than 18 years old before the first day of the month of the claim service date. We will identify the beneficiary's age on the first day of the month (rather than for the entire month), as it is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). In addition, because we will be assessing ETC Participant performance on the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate in response to public comments, we have removed references to pre-emptive transplant beneficiaries from our regulation at § 512.360(b), and replaced them with references to Pre-emptive LDT Beneficiaries, where appropriate.

In sum, we are codifying in our regulation at § 512.360(b) that ESRD Beneficiaries that fall in the enumerated categories, with the modifications described, will be excluded from attribution to ETC Participants for a month for the purposes of calculating the transplant rate and home dialysis rate under the Model. In addition, based on public comments, we are also excluding beneficiaries from attribution for any month in which they receive dialysis in or reside in a SNF or nursing facility.

(2) Attribution Services

(a) Attribution to ESRD Facilities

We proposed that, to be attributed to an ESRD facility for a month, an ESRD Beneficiary must have received renal dialysis services, other than renal dialysis services for AKI, during the month from the ESRD facility. Because it is possible that a single ESRD Beneficiary receives dialysis treatment from more than one ESRD facility during a month, we further proposed that ESRD Beneficiaries would be attributed to an ESRD facility for a given month based on the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis treatments in that month. As we noted in the proposed rule, we believe the plurality rule would provide a sufficient standard for attribution because it ensures that ESRD Beneficiaries would be attributed to an ESRD facility when they receive more renal dialysis services from that ESRD facility than from any other ESRD facility. In the event that an ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, we proposed that the ESRD Beneficiary would be attributed to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month.

We proposed that we would identify dialysis claims 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 which attribution is being determined. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. Facility code 7 paired with type of care code 2 indicates that the claim occurred at a clinic or hospital based ESRD facility.

In the proposed rule we considered, in the alternative, attributing ESRD Beneficiaries to the ESRD facility at which they had their first dialysis treatment for which a claim was submitted in a given month. However, we determined that using the plurality of claims rather than earliest claim better identifies the ESRD facility that has the most substantial care relationship with the

ESRD Beneficiary in question for the given month. For example, using the earliest claim approach could result in attributing a beneficiary that received dialysis treatments from Facility A once during a given month and dialysis treatments from Facility B at all other times during that month to Facility A, even though Facility B is the facility where the beneficiary received most of his or her dialysis treatments that month. As noted in the proposed rule, we would, however, plan to use the earliest date of service in the event that two or more ESRD facilities have furnished the same amount of services to a beneficiary because, as between two or more facilities that performed the same number of dialysis treatments for the beneficiary during a month, the facility that furnished services to the beneficiary first may have established the beneficiary's care plan and therefore is the one more likely to have the most significant treatment relationship with the beneficiary.

In the proposed rule we also considered using a minimum number of treatments at an ESRD facility for purposes of ESRD Beneficiary attribution. However, we determined that, because we are attributing ESRD Beneficiaries on a month-by-month basis, the plurality of treatments method would be more appropriate because it would result in a greater number of ESRD Beneficiaries attributed to the ESRD facilities where they receive care, which may enhance the viability of the ETC Model test. In the proposed rule we also considered including a minimum duration that an ESRD Beneficiary must be on dialysis before the beneficiary can be attributed to an ESRD facility. We determined that this approach was not suitable for this model test, however, as a key factor that influences whether or not a beneficiary chooses to dialyze at home is if the beneficiary begins dialysis at home, rather than in-center. Requiring a minimum duration on dialysis would exclude these early months of dialysis treatment from attribution,

which may be key to a beneficiary's modality choice, and would therefore run counter to the intent of the ETC Model.

We proposed that CMS would not attribute pre-emptive transplant beneficiaries to ESRD facilities because beneficiaries who receive pre-emptive transplants do so before they have initiated dialysis and thus do not have a care relationship with the ESRD facility.

The following is a summary of the comments received on ESRD Beneficiary attribution to ESRD facilities and our responses.

Comment: A commenter recommended that CMS exclude from attribution to an ESRD facility those ESRD Beneficiaries who have three or more dialysis treatments in another ESRD facility for that month. The commenter instead suggested that CMS attribute an ESRD Beneficiary to the ESRD facility at which the ESRD Beneficiary received the most treatments, which the commenter referenced as the ESRD Beneficiary's "home facility."

Response: As noted in the proposed rule, we believe that the plurality of dialysis treatments approach for attributing ESRD Beneficiaries to ESRD facilities provides a sufficient standard for attribution because it ensures that ESRD Beneficiaries will be attributed to an ESRD facility that has the primary responsibility for the beneficiary's renal dialysis services.

After considering public comments, we are finalizing our proposed provisions on the services used to attribute ESRD Beneficiaries to ESRD facilities with modification. Specifically, we are codifying in our regulations at § 512.360(c)(1) that ESRD Beneficiaries will be attributed to an ESRD facility for a given month based on the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis services in that month, other than renal dialysis services for AKI, based on claims with claim service date at the claim header date during that month with Type of Bill 072X. We are modifying the regulation text to clarify that an

ESRD Beneficiary would not be attributed to an ESRD facility if the beneficiary is excluded from attribution based on the criteria specified in our regulations at § 512.360(b), described elsewhere in this final rule. We are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. We are making this change because while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service, requiring us to use claim date of service to identify the PPA Period in which the service was furnished. We are also codifying in our regulation at § 512.360(c)(1) that, in the event that an ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, the ESRD Beneficiary will be attributed to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month, as proposed. We clarify that this policy for attributing ESRD Beneficiaries who have received an equal number of dialysis treatments from two or more ESRD facilities would apply regardless of whether the ESRD facility is an ETC Participant or an ESRD facility located in a Comparison Geographic Area. As described elsewhere in this final rule, we have modified our proposal to attribute pre-emptive transplant beneficiaries to Managing Clinicians such that we will attribute only pre-emptive LDT beneficiaries. We therefore modified our regulation at § 512.360(c)(1) to clarify that CMS does not attribute pre-emptive LDT beneficiaries to ESRD facilities.

(b) Attribution to Managing Clinicians

We proposed that, for Managing Clinicians, an ESRD Beneficiary would be attributed to the Managing Clinician who submitted an MCP claim with a claim through date in a given

month for certain services furnished to the ESRD Beneficiary. Per the conditions for billing the MCP, the MCP can only be billed once per month for a given beneficiary.[151] Therefore, as noted in the proposed rule, we believe there is no need to create a decision rule for attributing ESRD Beneficiaries to a Managing Clinician for a given month if there are multiple MCP claims that month, as that should never happen. We proposed that, for purposes of ESRD Beneficiary attribution to Managing Clinicians, we would include MCP claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12-19, or 20 years of age and older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2-3, 4 or more). CPT® codes 90965 and 90966 are for ESRD-related services for home dialysis per full month, and indicate the age of the beneficiary (12-19, or 20 years of age and older). We explained in the proposed rule that, taken together, these are all the CPT® codes that are used to bill the MCP that include beneficiaries 18 years old or older, including patients who dialyze at home and patients who dialyze in-center.

Additionally, for the transplant rate for Managing Clinicians, we proposed to attribute pre-emptive transplant beneficiaries to Managing Clinicians. Because pre-emptive transplant beneficiaries have not started dialysis at the time of their transplant, we explained we would not be able to attribute them to Managing Clinicians based on MCP claims, as we would for ESRD Beneficiaries. Rather, we proposed that pre-emptive transplant beneficiaries would be attributed to a Managing Clinician based on the Managing Clinician with whom the beneficiary had the

[151] Medicare Claims Processing Manual, Chapter 8; https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf

most services between the start of the MY and the month in which the beneficiary received the transplant, and that the pre-emptive transplant beneficiary would be attributed to the Managing Clinician for all months between the start of the MY and the month in which the beneficiary received the transplant. In the proposed rule we considered attributing pre-emptive transplant beneficiaries on a month-by-month basis, mirroring the month-by-month attribution of ESRD Beneficiaries. However, we concluded that this approach would under-attribute beneficiary months to the denominator. Unlike ESRD Beneficiaries who see their Managing Clinician every month for dialysis management, pre-emptive transplant beneficiaries generally do not see a Managing Clinician every month because they have not started dialysis. However, that does not mean that an ongoing care relationship does not exist between the pre-emptive transplant beneficiary and the Managing Clinician in a month with no claim.

The following is a summary of the comments received on beneficiary attribution to Managing Clinicians and our responses.

Comment: A commenter stated that some complex patients have two nephrologists managing their care and suggested that both of these Managing Clinicians should receive attribution in these scenarios. Another commenter suggested that pre-emptive transplant beneficiaries be attributed to the Managing Clinician who initiated the referral to the transplant center to allow "proactive management." Other commenters stressed the importance of educating beneficiaries on renal replacement modality options and the shared decision-making process in order to empower beneficiaries to select from among the available treatment choices and suggested that CMS attribute beneficiaries to ESRD facilities and Managing Clinicians that, through extensive education, time, and effort, refer ESRD Beneficiaries to facilities that offer home dialysis. Many of these same commenters suggested attribution based on the Managing

Clinician who educated the beneficiary on treatment modality instead of the Managing Clinician providing a certain dialysis-related service.

Response: CMS appreciates the feedback from the commenters about beneficiary attribution to Managing Clinicians. While CMS acknowledges that two or more Managing Clinicians may manage care for a given ESRD Beneficiary, for the purposes of this Model, we believe that attribution to one Managing Clinician is most appropriate because generally only one MCP is billed for a given ESRD Beneficiary during a month, even if multiple Managing Clinicians are involved in beneficiary's care. In addition, if the ESRD Beneficiary receives care from one or more other clinicians within the practice of the Managing Clinician to whom the ESRD Beneficiary is attributed, the care furnished to that ESRD Beneficiary will be considered in assessing the performance for all such clinicians under the aggregation methodology described elsewhere in section IV of this final rule. Additionally, while we appreciate feedback about the attribution of pre-emptive transplant beneficiaries, we do not believe that attributing pre-emptive transplant beneficiaries to the Managing Clinician who refers them to the transplant center is appropriate for the Model. As described elsewhere in this final rule, we are now only attributing Pre-emptive LDT Beneficiaries to Managing Clinicians given the change to the calculation of the transplant rate. Attributing these Pre-emptive LDT Beneficiaries to Managing Clinicians based on who refers a Pre-emptive LDT Beneficiary to a transplant center may not identify the Managing Clinician primarily responsible for supporting the beneficiary through the living donor transplant process. Rather, we believe that the main care relationship between Pre-emptive LDT Beneficiary and Managing Clinician is more accurately identified using the methodology included in this final rule.

After considering public comments, we are finalizing our proposed provisions on the services used to attribute beneficiaries to Managing Clinicians, with modification. We are finalizing in our regulation at § 512.360(c)(2) that we will attribute ESRD Beneficiaries to the Managing Clinician who bills an MCP for services furnished to the beneficiary claim service date at the claim line through date during the entire month in question, and that such claims will be identified by CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. We stated in the proposed rule that there is no need to create a decision rule for attributing ESRD Beneficiaries to a Managing Clinician for a given month because the full month MCP CPT® codes can only be billed once per month for a given beneficiary. However, we found a very small number of instances where the full month MCP code was billed by multiple Managing Clinicians for a given beneficiary. To address the rare case that an MCP is billed in a single month by more than one Managing Clinician, we also added new text to our regulation at § 512.360(c)(2) to clarify that, in cases where more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with a claim service date at the claim line through date in a month, the ESRD Beneficiary will be attributed to the Managing Clinician associated with the earliest claim service date at the claim line through date that month. In cases where more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary for the same earliest claim service date at the claim line through date for that month, the ESRD Beneficiary will be randomly attributed to one of these Managing Clinicians.

In addition, we are modifying our proposed method for attributing pre-emptive transplant beneficiaries to Managing Clinicians. As described in section IV.C.5 of this final rule, the transplant rate calculation will include only living donor transplants, rather than all kidney transplants including those received from deceased donors. As such, we are modifying pre-

emptive transplant beneficiary attribution to Managing Clinicians in § 512.360(c)(2) of our regulation to include only Pre-emptive LDT Beneficiaries, rather than all beneficiaries who receive a kidney transplant prior to beginning dialysis, including from deceased donors. Consistent with our approach for attributing pre-emptive transplant beneficiaries to Managing Clinicians, we are finalizing that a Pre-emptive LDT Beneficiary will be attributed to the Managing Clinician with whom the beneficiary had the most claims between the start of the MY and the month of the transplant. We are also finalizing that, in the event that no Managing Clinician had the plurality of claims for a given Pre-emptive LDT Beneficiary, such that multiple Managing Clinicians each had the same number of claims for that beneficiary during the MY, that beneficiary will be attributed to the Managing Clinician with the latest claim service date at the claim line through date for the beneficiary, up to and including the month of the transplant. If more than one of these Managing Clinicians has the latest claim service date at the claim line through date for that beneficiary, the Pre-emptive LDT Beneficiary will be randomly attributed to one of those Managing Clinicians.

In addition, we are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. We are making this change because while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service, requiring us to use claim date of service to identify the PPA Period in which the service occurred. We have revised § 512.360(c)(2) of this final rule accordingly.

c. Performance Measurement

We proposed to calculate the home dialysis and transplant rates for ESRD facilities and Managing Clinicians using Medicare claims data and Medicare administrative data about beneficiaries, providers, and suppliers. We noted in the proposed rule that Medicare administrative data refers to non-claims data that Medicare uses as part of regular operations. This includes information about beneficiaries, such as enrollment information, eligibility information, and demographic information. Medicare administrative data also refers to information about Medicare-enrolled providers and suppliers, including Medicare enrollment and eligibility information, practice and facility information, and Medicare billing information. For the transplant rate calculations, we also proposed to use data from the Scientific Registry of Transplant Recipients (SRTR), which contains comprehensive information about transplants that occur in the U.S., to identify transplants among attributed beneficiaries for inclusion in the numerator about the occurrence of kidney and kidney-pancreas transplants. In the proposed rule, we considered requiring ETC Participants to report on their home dialysis and transplant rates, as this would give ETC Participants more transparency into their rates. However, as noted in the proposed rule, we believe basing the rates on claims data, supplemented with Medicare administrative data about beneficiary enrollment and transplant registry data about transplant occurrences, will ensure there is no new reporting burden on ETC Participants. Additionally, using these existing data sources would be more cost effective for CMS, as it would not require

the construction and maintenance of a new reporting portal, or changes to an existing reporting portal to support this data collection.

We solicited comment on our proposed use of claims data, Medicare beneficiary enrollment data, and transplant registry data to calculate the home dialysis rate and transplant rate. The following is a summary of the comments received and our responses.

Comment: A commenter supported our proposal to use Medicare claims data and Medicare administrative data for purposes of calculating the home dialysis rate and the transplant rate, and our proposal to use data from the SRTR for purposes of calculating the transplant rate.

Response: We appreciate the feedback and support from the commenter. As described in the proposed rule, we proposed to use these existing data sources to avoid imposing an administrative burden on ETC Participants.

After considering public comments, we are finalizing our proposed provisions on the sources of data used for measuring the performance of ETC Participants under the Model with modification. Specifically, as the transplant rate calculation will include only living donor transplants, rather than all kidney transplants including those received from deceased donors, we are modifying our regulation at § 512.365(a) to refer to Pre-emptive LDT Beneficiaries rather than pre-emptive transplant beneficiaries.

(1) Home Dialysis Rate

We proposed to define "home dialysis rate" as the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY, as described in § 512.365(b) (Home Dialysis Rate). We proposed to construct the home dialysis rate for ETC Participants that are ESRD facilities as described in the proposed rule and section IV.C.5.c.1.a of this final rule and for ETC Participants who are Managing Clinicians as described in the

proposed rule and section IV.C.5.c.1.b of this final rule. We described in the proposed rule and describe later in this final rule our proposed plan for risk adjusting and reliability adjusting these rates.

The following is a summary of the comments received on the home dialysis rate and our responses

Comment: Multiple commenters stated that it is important to protect patient choice of treatment modality, which may depend on the beneficiary's financial resources, housing, social support, and personal preference even after proper education on all possible ESRD treatment choices. These commenters recommended that CMS consider revising the home dialysis rate to include shared-decision making measures that take into account the treatment modality most clinically and socially appropriate for the beneficiary.

Response: We agree with commenters that it is important to protect patient choice of treatment modality, but disagree that a shared decision measure should be included in the home dialysis rate calculation due to possible gaming and lack of shared decision making measures specific to home dialysis.

Comment: A few commenters suggested including ESRD Beneficiaries enrolled in Medicare Advantage plans in the numerator of the home dialysis rate calculation, with one of those commenters explaining that these beneficiaries often utilize in-center self-care dialysis. According to the commenters, adding these beneficiaries, presumably to the numerator of the home dialysis rate calculation, could mitigate risks that Managing Clinicians have for these more serious, medically complex beneficiaries for whom in-center self-care dialysis is a safer option than home dialysis.

Response: Consistent with the beneficiary exclusions from attribution codified in our regulations at § 512.360(b), we will not include ESRD Beneficiaries enrolled in Medicare Advantage in the calculation of the home dialysis rate because the ETC Model is not a test of the Medicare Advantage program or payment. Specifically, the ETC Model is designed as a test within Medicare FFS, which excludes Medicare Advantage enrollees from attribution to ETC Participants for purposes of the Model's financial calculations, including the PPA. As such, it would be inappropriate to include beneficiaries enrolled in Medicare Advantage in the construction of the home dialysis rate.

Comment: Several commenters recommended that we exclude beneficiaries residing in or receiving dialysis in a SNF or nursing facility from our calculation of the home dialysis rate. Some commenters clarified that beneficiaries often reside in a nursing facility or utilize a SNF as a more permanent residence, and as such, the dialysis received in a SNF more resembles in-center dialysis. A commenter suggested that we apply the exclusion only to the denominator of the home dialysis rate such that such beneficiaries would be included in the numerator if they received home dialysis. A commenter recommended classifying SNFs, inpatient rehabilitation facilities, and long-term care hospitals (LTCH) as a home dialysis site for patients that receive on-site dialysis at one of the respective locations.

Multiple commenters supported the inclusion of beneficiaries who dialyze at SNFs in the calculation of the home dialysis rate, with some commenters pointing out that ESRD facilities may provide dialysis services to SNF residents within an approved home training and support modality in cases where beneficiaries, such as those with AKI or dementia, may have better quality of life when receiving dialysis in a SNF.

Response: We appreciate these comments, and share the commenters' concerns about including beneficiaries residing in or receiving dialysis in a SNF or nursing facility in the home dialysis rate calculations. We disagree with commenters that support including these beneficiaries in the home dialysis rate. As described previously in section IV.B.1 of this final rule, in our regulations at § 512.360(b), we are excluding beneficiaries who are residing in or receiving dialysis services in SNFs and nursing facilities from attribution to ETC Participations for purposes of the PPA calculation generally for the reasons described in section IV.B.1.

After considering public comments, we are finalizing our general proposal regarding the home dialysis rate as proposed. We are also finalizing the definition of the home dialysis rate as proposed without modification in our regulation at § 512.310. Specific provisions regarding the home dialysis rate calculation for ESRD facilities and Managing Clinicians are detailed in the following sections of this final rule.

(a) Home Dialysis Rate for ESRD Facilities

We proposed that the denominator of the home dialysis rate for ESRD facilities would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. We would identify months during which an attributed ESRD Beneficiary received maintenance dialysis based on claims, specifically claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2. Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility, and the Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities.

We proposed that the numerator of the home dialysis rate for ESRD facilities would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home. Home dialysis treatment beneficiary years included in the numerator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. We would identify maintenance dialysis at home months based on claims, specifically claims with Type of Bill 072X, where the type of facility code is 7 and the type of care code is 2, with condition codes 74, 75, 76, or 80. Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. We stated in the proposed rule that condition codes 74 and 75 indicate billing for a patient who received dialysis services at home, and condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a nursing facility. Condition code 76 indicates billing for a patient who dialyzes at home but received back-up dialysis in a facility. As noted in the proposed rule, taken together, we believe these condition codes capture home dialysis services furnished by ESRD facilities. Information used to calculate the ESRD facility home dialysis rate includes Medicare claims data and Medicare administrative data.

In the proposed rule, we considered including beneficiaries whose dialysis modality is self-dialysis or temporary PD furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC Model, to increase beneficiary choice regarding ESRD treatment modality. However, we concluded that these modalities lack clear definitions in the literature and delivery of care for

these modalities is billed through the same codes as in-center HD, making it impossible for CMS to identify the relevant claims.

The following is a summary of the comments received on the home dialysis rate calculation for ESRD facilities and our responses.

Comment: Some commenters agreed with the primary construction of the home dialysis rate, as proposed. Other commenters argued that condition codes of 74, 75, 76, and 80 provide little predictive value. Many commenters stated that self-dialysis should be included in the home dialysis rate numerator, particularly for patients who may be more seriously ill and for whom self-care in-center dialysis is a better treatment modality. CMS received a letter from a coalition of 26 stakeholders including nephrologists, ESRD facilities, patients, and manufacturers, which recommended that self-dialysis should be included in the numerator for home dialysis rate calculation for ESRD facilities. The coalition's letter also urged that the definition of self-dialysis be further clarified beyond what is already present in 42 CFR 494.10 and recommended that CMS identify self-dialysis using condition code 72, since self-care in-center dialysis is tracked through this code. Other commenters similarly suggested a broader definition for self-care dialysis or suggested that CMS use the commenters' ESRD facilities' criteria for establishing a patient as "self-care", such as a patient setting up the machine without assistance or pulling the needle at the end of treatment. A commenter suggested treating homeless beneficiaries receiving self-dialysis in-center as a home dialysis patient for purposes of calculating the home dialysis rate, since these patients do not have the option of dialyzing at home.

Response: CMS appreciates the commenters' suggestions for identifying self-care in-center dialysis patients. We agree with commenter feedback that self-dialysis can be identified

with condition code 72. We also appreciate that self-dialysis may serve as a way to provide a gradual transition from in-center dialysis to home dialysis, allowing patients to become comfortable with conducting dialysis under medical supervision. We considered including beneficiaries whose treatment modality is self-dialysis in the numerator of the home dialysis rate in the proposed rule, pointing out that it was consistent with the overarching goals of the ETC Model and helped to promote beneficiary choice of treatment modalities. Our concern in the proposed rule was that there was not a clear, universally accepted definition of self-care dialysis in the literature or a clear way for CMS to identify these claims. However, commenters pointed out that there is an already defined condition code under the ESRD PPS for self-dialysis. Therefore, we are finalizing the home dialysis rate numerator for ESRD facilities to include self-dialysis, as identified by condition code 72, at one half of the value of home dialysis. We believe this policy will effectively balance the benefits of self-dialysis and its ability to help beneficiaries transition to home dialysis with the recognition that self-dialysis is not home dialysis and does not have all of the same benefits. Specifically, each beneficiary month for which an attributed beneficiary receives self-dialysis will contribute one half month to the numerator.

Comment: Several commenters suggested including beneficiaries who have received home dialysis training, as identified by claims with condition code 73, in the numerator of the home dialysis rate calculation for ESRD facilities. Other commenters suggested that CMS include in the numerator beneficiaries who have received re-training treatment (as identified by conditions code 87 and full care in unit (as identified by condition code 71), when used in combination with the Revenue Code 0831 (urgent start PD) to encourage transitions to home dialysis as well as to capture patients who require abdominal surgery and hope to transition back to home dialysis. A commenter suggested that we allow at least 90 days to classify patients

under these PD condition codes before including these beneficiaries in the numerator of the home dialysis rate calculation to take into account delays of PD use for various health reasons that would not negatively affect ETC Participants.

Response: We appreciate the feedback from the commenters, and recognize the importance of home dialysis training, as well as retraining and full care in unit. We believe that including beneficiaries who have received these services in the numerator of the home dialysis rate for ESRD facilities is not necessary to create the financial incentives we seek to test under the proposed ETC Model and that training incentives are captured through training add-on payment adjustment for home dialysis under the ESRD PPS.

After considering public comments, we are finalizing our proposed provisions on the calculation of the home dialysis rate for ESRD facilities, with modifications. Specifically, we are codifying in our regulation at § 512.365(b)(1) that the denominator of the home dialysis rate for ESRD facilities will be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, as proposed. We are codifying in our regulation at § 512.365(b)(1) that the numerator of the home dialysis rate for ESRD facilities will be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home, as identified by claims with Type of Bill 072X, with condition codes 74 or 76. While we proposed to include claims with condition code 75, we are no longer including these claims because we have since learned that this condition code is no longer valid. Additionally, in this final rule, we will not include claims with condition code 80, as proposed, because condition code 80 indicates billing for a patient who received dialysis services at home and the patient's home is a SNF or nursing facility, and we are excluding beneficiaries residing in or receiving dialysis in a SNF or nursing facility from attribution to ETC

Participants for purposes of the PPA calculation generally, as described elsewhere in this final rule. We are further modifying this proposal to also include one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via self-dialysis, as identified by claims with Type of Bill 072X and condition code 72, and are clarifying that self-dialysis treatment beneficiary years included in the numerator are those months in which attributed ESRD Beneficiaries received self-dialysis in-center, such that one beneficiary year is comprised of 12 beneficiary months. Of note, we have removed references to the risk adjustment methodology as we are not finalizing the proposed risk adjustment methodology for the home dialysis rate for ESRD facilities, as described in section IV.C.5.c.(3) of this final rule. We are also modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the home dialysis rate for ESRD facilities, as described in section IV.C.5.c.(4) of this final rule.

(b) Home Dialysis Rate for Managing Clinicians

We proposed that the denominator of the home dialysis rate for Managing Clinicians would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. We noted that we would identify maintenance dialysis months based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12-19 years of age or 20 years of age

and older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2-3, 4 or more). CPT® codes 90965 and 90966 are for ESRD related services for home dialysis per full month, and indicate the age of the beneficiary (12-19 years of age or 20 years of age and older). Taken together, these codes are used to bill the MCP for beneficiaries aged 18 or older, including patients who dialyze at home and patients who dialyze in-center.

As proposed, the numerator for the home dialysis rate for Managing Clinicians would be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home. Home dialysis treatment beneficiary years included in the numerator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. We would identify maintenance dialysis at home months based on claims, specifically claims with CPT® codes 90965 or 90966. CPT® code 90965 is for ESRD related services for home dialysis per full month for patients 12-19 years of age. CPT® code 90966 is for ESRD related services for home dialysis per full month for patients 20 years of age and older. These two codes are used to bill the MCP for beneficiaries aged 18 and older who dialyze at home. Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data.

In the proposed rule, we considered including beneficiaries whose dialysis modality is self-dialysis or temporary PD furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC Model, to increase beneficiary choice regarding ESRD treatment modality. However, we noted in the proposed rule that these modalities lack clear definitions in the literature and

delivery of care for these modalities is billed through the same codes as in-center HD, making it impossible for CMS to identify the relevant claims.

The following is a summary of the comments received on the home dialysis rate calculation for Managing Clinicians and our responses.

Comment: Many commenters suggested including self-care in-center dialysis patients in the numerator of the home dialysis rate calculation for ESRD facilities using condition code 72, and one of these commenters suggested removing these patients from the denominator of the home dialysis rate calculation so that these patients do not count against the ESRD facilities or Managing Clinicians. CMS received a letter from a coalition of 26 stakeholders including nephrologists, dialysis facilities, patients, and manufacturers urging that the definition of self-dialysis be further clarified beyond what is already present in 42 CFR 494.10 and that self-dialysis should be included in the numerator for the ETC Model and be monitored using condition code 72 since self-care in-center dialysis is tracked through this code.

Response: CMS appreciates the commenters' suggestions for identifying self-care in-center dialysis patients. We agree with commenter feedback that self-dialysis can be identified with condition code 72. We also appreciate that self-dialysis may serve as a way to provide a gradual transition from in-center dialysis to home dialysis, allowing patients to become comfortable with conducting dialysis under medical supervision. We considered including self-dialysis in the numerator of the proposed rule, pointing out that it was consistent with the overarching goals of the ETC Model and helped to promote beneficiary choice of treatment modalities. The concern we expressed in the proposed rule was that there was not a clear, consistent definition of self-dialysis in the literature or a clear way for CMS to identify these

claims. However, comments from stakeholders point out that there is an already defined claim code in the ESRD PPS and a clear definition in federal law at 42 CFR 494.10.

After considering public comments, we are finalizing our proposed provisions on the home dialysis rate calculation for Managing Clinicians, with modification. Specifically, we are codifying in our regulation at § 512.365(b)(2) that the denominator of the home dialysis rate for Managing Clinicians will be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, as proposed. We are codifying in our regulation at § 512.365(b)(2) that the numerator of the home dialysis rate for Managing Clinicians will be the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis at home, as identified by CPT® codes 90965 or 90966; however, we are modifying this proposal to also include one half of the total number of dialysis treatment beneficiary years during the MY in which attributed ESRD Beneficiaries received maintenance dialysis via self-dialysis. Specifically, each beneficiary month for which an attributed beneficiary receives self-dialysis will contribute one half month to the numerator. Self-dialysis treatment beneficiary years included in the numerator are composed of those months during which an attributed ESRD Beneficiary received self-dialysis in center, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received self-dialysis will be identified by claims with Type of Bill 072X, with condition code 72. We are using condition code 72 because self-dialysis cannot be identified using CPT® codes submitted by Managing Clinicians. We are making this change for consistency with the modifications made to the home dialysis rate calculation for ERSD facilities in response to comments, and similarly believe this policy change, as applied to the home dialysis rate for Managing Clinicians, will effectively balance the benefits of self-dialysis and its ability to help

beneficiaries transition to home dialysis with the recognition that it is not home dialysis and does not have all of the same benefits. Of note, we have removed references to the risk adjustment methodology because we are not finalizing the proposed risk adjustment methodology for the home dialysis rate for Managing Clinicians, as described in section IV.C.5.c.(3) of this final rule. We are also modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the home dialysis rate for Managing Clinicians, as described in section IV.C.5.c.(4) of this final rule.

(2) Transplant Rate

We proposed to define the "transplant rate" as the rate of ESRD Beneficiaries and, if applicable, pre-emptive transplant beneficiaries attributed to the ETC Participant who received a kidney or kidney-pancreas transplant during the MY, as described in proposed § 512.365(c) (Transplant Rate). We proposed to construct the transplant rate for ETC Participants that are ESRD facilities as described in the proposed rule and section IV.C.5.c.(2)(a) of this final rule, and for ETC Participants who are Managing Clinicians as described in the proposed rule and section IV.C.5.c.(2)(b) of this final rule.

For purposes of constructing the transplant rate, we proposed two transplant rate-specific beneficiary exclusions. Specifically, we proposed to exclude an attributed beneficiary from the transplant rate calculations for any months during which the beneficiary was 75 years of age or older at any point during the month, and for any months in which the beneficiary was in a SNF at any point during the month. We proposed these additional exclusions to recognize that, while these beneficiaries can be candidates for home dialysis, they are generally not considered candidates for transplantation. As we noted in the proposed rule, these exclusions would be similar to the exclusions used in the PPPW measure that has been adopted by the ESRD QIP.

We sought comment on the proposal to exclude from the transplant rate beneficiaries aged 75 or older and beneficiaries in SNFs. The transplant rate calculations would also exclude beneficiaries who elected hospice, as we proposed to exclude beneficiaries who have elected hospice from attribution generally under the ETC Model and therefore they would be excluded from the calculation of both the transplant rate and the home dialysis rate.

In the proposed rule, we considered using rates of transplant waitlisting rather than the actual transplant rate. However, for the ETC Model, we proposed to test the effectiveness of the Model's incentives on outcomes, rather than on processes. We stated in the proposed rule that the relevant outcome for purposes of the ETC Model is the receipt of a kidney or kidney-pancreas transplant, not getting on and remaining on the kidney transplant waitlist. While we acknowledged in the proposed rule that getting a beneficiary on the transplant waitlist is more directly influenced by the ESRD facility and/or the Managing Clinician than the beneficiary actually receiving the transplant, we stated that we believed that ESRD facilities and Managing Clinicians are well positioned to assist beneficiaries through the transplant process, and we wanted to incentivize this focus. We also acknowledged in the proposed rule that transplant waitlist measures do not capture living donation, which is an additional path to a successful kidney transplant, and ESRD facilities and Managing Clinicians may support this process. Details about the PPPW Clinical Measure can be found in the CY 2019 ESRD PPS final rule (83 FR 56922, 57003-08). We solicited comment on our proposal to not test the effectiveness of the Model's incentives on increasing the number of patients added to the kidney transplant waitlist. Additionally, we solicited comment on an alternative transplant waitlist measure that would also capture living donation.

We proposed using one year of data, from an MY, to construct the transplant rate to align with the construction of the home dialysis rate. However, we noted that because transplants are rare events for statistical purposes, we may not have sufficient statistical power to detect meaningful variation using only one year of performance information at the ETC Participant level. In order to ensure that we would have sufficient statistical power to detect meaningful variation in performance, in the proposed rule we also considered the alternative of using 2, 3, or 4 years of data, corresponding with the MY plus the calendar year or years immediately prior to the MY, to construct the transplant rate. However, we wanted to avoid adjusting ETC Participant payment based on performance that occurred prior to the implementation of the ETC Model, if finalized, and concluded that the proposed reliability adjustment aggregation methodology, described in the proposed rule and section IV.C.5.c.(4) of this final rule, would compensate for any lack of statistical power, and would therefore eliminate the need to include data from calendar years prior to the MY in order to produce a reliable and valid transplant rate. We discuss later in this final rule our proposal for risk adjusting and reliability adjusting these rates.

The following is a summary of the comments received on the use of the transplant rate and the alternatives considered, and our responses.

Comment: Several commenters agreed with CMS's proposal to use transplantation to assess ESRD facility performance on the transplant rate since transplantation generally provides the best outcomes for patients and promotes collaboration for transplant efforts. Some of these same commenters suggested that increasing the number of patients on the transplant waitlist may not correlate with an increase in transplantation rates. Instead of the transplant rate, some commenters suggested a focus on patient education around treatment modality choices or the

transplant process. However, multiple other commenters stated that they are concerned that complexities outside of health care providers' and patients' control, including policy barriers, lack of available organs, which is often due to the way deceased organs are procured, long waitlist times, patient choice, and the lack of a clinical fit for transplant do not support the proposed methodology to assess ETC Participant performance based on a transplant rate. Some commenters instead suggested using the PPPW measure and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) measure, but pointed out that the SWR does not include pre-emptive transplants in its data and that the PPPW measures prevalence of beneficiaries on the waitlist, which includes beneficiaries who have been on the waitlist for a long duration and may not account for other barriers to transplantation.

Response: CMS appreciates this feedback. In the proposed rule, we specifically solicited comment on our proposal not to test the effectiveness of the Model's incentives on increasing the number of patients added to the transplant waitlist. We appreciate commenters concerns that certain factors that impact the transplant rate are beyond the control of the ETC Participant, particularly regarding the supply of deceased donor organs available for transplantation. While we believe that other efforts intended to increase the supply of deceased donor organs, including the ETC Learning Collaborative (described in section IV.C.12 of this final rule) and extending the Kidney Disease Education benefit to multiple provider types (described in section IV.C.7.b of this final rule) will help to address this concern, we also acknowledge that these efforts will take time to produce results. As such, we are modifying our proposed transplant rate and will instead use a transplant rate that is calculated as the sum of the transplant waitlist rate and the living donor transplant rate for purposes of the PPA calculation under the Model. This policy change aligns with suggestions from commenters that, particularly in light of the current shortage

of deceased donor organs for transplant, a transplant waitlist rate is more within the control of the ETC Participant. This approach will allow the changes made by the proposed rule issued December 23, 2019 entitled Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement (CMS-3380-P) and the proposed rule published December 20, 2019 entitled Removing Financial Disincentives to Living Organ Donation, if finalized, as well as the ETC Learning Collaborative under the Model time to have an effect on deceased donor organ supply before holding ETC Participants accountable for their performance on the transplant rate that includes deceased donor organ transplants. It is our intent to observe the supply of deceased donor organs available for transplantation. Any change to the composition of the transplant rate to include the rate of deceased donor kidney transplants for the purposes of the PPA calculation under the Model would be established through future rulemaking.

We also sought comment on an alternative transplant waitlist measure that would capture living donation, which is an alternative path to a successful kidney transplant. We did not receive any suggestions of alternative measures of transplant waitlisting that would capture living donation. However, we wanted to recognize the important role that ETC Participants, as ESRD facilities and Managing Clinicians, can play in increasing the rates of living donor kidney transplants outside the transplant waitlist process and are keeping living donor transplants in the transplant rate calculation alongside the transplant waitlist rate, instead of deceased donor transplants as was in the proposed rule. We define the "living donor transplant rate" as the rate of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant who received a kidney transplant from a living donor during the MY.

To accommodate this change, we are modifying the definition of the "transplant rate" as the sum of the transplant waitlist rate and the living donor transplant rate. We define the "transplant waitlist rate" as the rate of ESRD Beneficiaries attributed to the ETC Participant who were on the kidney transplant waitlist during the MY, as described in § 512.365(c)(1)(i) and § 512.365(c)(2)(i). We acknowledge that there are existing transplant waitlist measures, including the PPPW and SWR identified by commenters. However, we believe that constructing a transplant waitlist rate specific to the ETC Model is the best approach. The transplant waitlist rate for the ETC Model is similar in concept to the PPPW but uses the attribution methodology specific to the ETC Model. As noted previously in this final rule, we may seek to modify the ETC Model in the future to use a transplant rate that includes deceased donor transplants, and would do so through subsequent rulemaking. In the final rule, we are clarifying that CMS will obtain data about the kidney transplant waitlist from SRTR, which maintains all transplant waitlists.

Comment: Several commenters recommended that we exclude beneficiaries in SNFs from our calculation of the transplant rate. Other commenters stated that CMS should factor the longevity of the organ transplant into the transplant rate. A commenter stated that CMS should add in beneficiaries who have received a transplant into the denominator of the transplant rate calculation. Several commenters suggesting removing from the denominator of the transplant rate calculation those beneficiaries who are ineligible for transplant.

Response: CMS appreciates the feedback. CMS is now excluding ESRD Beneficiaries who reside in or receive dialysis at a SNF or nursing home facility from attribution to ETC Participants for purposes of calculating the PPA, as described in section IV.C.5.b.(1) of this final rule, and therefore these beneficiaries will be excluded from the calculation of the transplant rate

well as the home dialysis rate. We believe that the beneficiary attribution exclusions as well as not including beneficiaries over the age of 75 in the transplant rate calculation remove the majority of beneficiaries who are ineligible for transplantation from the denominator of the transplant rate. In addition, because we are modifying our proposal and will use the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate rather than the transplant rate including deceased donor transplants, the longevity of the organs is no longer a relevant consideration. If the transplant rate originally proposed is adopted for later years of the Model through subsequent rulemaking, CMS may consider incorporating organ longevity as part of the transplant rate and/or altering the denominator of the transplant rate calculation in a manner suggested by the commenters, and would solicit public comment on such a change through a future notice of proposed rulemaking. We also note that organ longevity is a consideration for the KCC Model, which is testing the efficacy of payment incentives on post-transplant care via a kidney transplant bonus. Through this kidney transplant bonus, CMS aims to test the impact of making a payment reward to model participants for each aligned beneficiary who receives a kidney transplant. This kidney transplant bonus payment would be made in each of the three years following the transplant in which the transplant remains successful, meaning the beneficiary does not return to dialysis.

In terms of the recommendation that CMS add in beneficiaries who have received a transplant into the denominator of the transplant rate calculation, as described elsewhere in this final rule, CMS is modifying the definition of ESRD Beneficiary to clarify that a beneficiary who has received a kidney transplant would be considered an ESRD Beneficiary (and therefore included in the denominator of the transplant waitlist rate and the living donor transplant rate) if the beneficiary either: (1) has a dialysis or MCP claim at least 12 months after the beneficiary's

latest transplant date; or (2) has a dialysis or MCP claim less than 12 months after the beneficiary's latest transplant date that includes a kidney transplant failure diagnosis code documented in any Medicare claim. These beneficiaries also would be included in the numerator of the transplant waitlist rate if the beneficiary is added to the kidney transplant waitlist, and in the numerator of the living donor transplant rate if the beneficiary received a transplant from a living donor.

After considering public comments, we are finalizing our general proposal on the transplant rate, with modifications. Specifically, in response to comments received, we are replacing the transplant rate we had proposed to use for purposes of calculating the PPA with the transplant rate calculated as the sum of the living donor transplant rate that had been included as part of the original transplant rate calculation and the transplant waitlist rate on which we had solicited comments. In addition, we are not finalizing the definition of transplant rate as proposed. Rather, in our regulation at § 512.310, we are modifying the definition of "transplant rate" to mean the sum of the transplant waitlist rate and the living donor transplant rate. We are defining the term "transplant waitlist rate" to mean the rate of ESRD Beneficiaries attributed to the ETC Participant who were on the kidney transplant waitlist during the MY, as described in § 512.365(c). We are also defining the term "living donor transplant rate" to mean the rate of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant who received a kidney transplant from a living donor during the MY.

(a) Transplant Rate for ESRD Facilities

For ESRD facilities, we proposed that the denominator for the transplant rate would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, subject to the aforementioned exclusions. Dialysis treatment beneficiary years included in the

denominator would be composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that 1 beneficiary year would be comprised of 12 attributed beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis would be identified by claims with Type of Bill 072X. We explained in the proposed rule that Facility code 7 paired with type of care code 2, indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X captures all renal dialysis services furnished at or through ESRD facilities. However, in order to effectuate the exclusions previously described, we would exclude claims for attributed ESRD Beneficiaries who were 75 years of age or older at any point during the month or were in a SNF at any point during the month.

We proposed that the numerator for the transplant rate for ESRD facilities would be the total number of attributed beneficiaries who received a kidney transplant or a kidney-pancreas transplant during the MY. We would identify kidney and kidney-pancreas transplants using Medicare claims data, Medicare administrative data, and SRTR data. For Medicare claims data, we would use claims with Medicare Severity Diagnosis Related Groups (MS-DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD-10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach). Because kidney-pancreas transplants are billed by including an ICD-10 procedure code for the type of kidney transplant and a separate ICD-10 procedure code for the type of pancreas transplant, in the proposed rule

we determined that we would not need to include additional ICD-10 codes to capture kidney-pancreas transplants beyond the ICD-10 codes for kidney transplants listed. We proposed that we would supplement Medicare claims data on kidney and kidney-pancreas transplants with information from the SRTR Database and Medicare administrative data about the occurrence of kidney and kidney-pancreas transplants not identified through claims. If a beneficiary who receives a transplant during a MY returns to dialysis during the same MY, the beneficiary would remain in the numerator.

In the proposed rule, we also considered constructing the numerator for the ESRD facility transplant rate such that the number of attributed beneficiaries who received transplants during a MY would remain in the numerator for every MY after the transplant during which the transplanted beneficiary does not return to dialysis, for the duration of the proposed ETC Model. Keeping attributed beneficiaries who received transplants in a MY in the numerator for MYs subsequent to the MY in which the transplant occurs would acknowledge the significant efforts made by ESRD facilities to successfully assist beneficiaries through the transplant process. However, as noted in the proposed rule, we believe this approach would artificially inflate transplant rates in later years of the Model and disproportionately disadvantage new ESRD facilities who begin providing care to ESRD Beneficiaries in later years of the Model. In the proposed rule we concluded that this potential for artificially inflated rates and the disadvantage that would result for new ESRD facilities outweighed the advantage of accruing transplants over time.

The following is a summary of the comments received on the proposed transplant rate for ESRD facilities and our responses.

Comment: Multiple commenters mentioned that ESRD facilities can control only evaluation and referral of patients to transplant centers. A commenter suggested that ETC Participants be required to refer any patient with an Estimated Post Transplant Survival (EPTS) Score of 75 percent or below to receive a transplant evaluation.

Response: We appreciate the feedback from the commenters. As described in section IV.C.5 of this final rule, we appreciate the complexity of the transplant process, including the number of transplant providers involved and the different roles they play. For this reason, we are modifying our proposal and will instead use a transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate for purposes of calculating the Facility PPA. As the health care providers that ESRD beneficiaries see most frequently, ESRD facilities play a pivotal role in the living donor and transplant waitlist process, including: educating beneficiaries about their transplant options, including living donation; helping beneficiaries navigate the transplant process, including helping beneficiaries understand the process; providing referrals for care necessary to meet clinical transplant requirements, and referrals for transplant waitlisting; and coordinating care during the transplant process.

As noted previously in this final rule, we may seek to modify the ETC Model through subsequent rulemaking to use a transplant rate that incorporates the rate of deceased donor transplants.

After considering public comments, we are finalizing our proposed provisions on the transplant rate for ESRD facilities in our regulations at § 512.365(c)(1), with modifications. Specifically, in response to comments received, the transplant rate for ESRD facilities is calculated as the sum of the transplant waitlist rate for ESRD facilities and the living donor transplant rate for ESRD facilities. As was the case with the proposed transplant rate for ESRD

facilities, the denominator for the transplant waitlist rate for ESRD facilities and the living donor transplant rate for ESRD facilities is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that 1 beneficiary year is comprised of 12 attributed beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X. Beneficiaries who are 75 years of age or older at any point during the month are excluded from the denominator. Because beneficiaries who reside in SNFs or nursing facilities are now excluded from attribution to ETC Participants for purposes of the PPA calculation in general, it is not necessary to specifically exclude beneficiaries who were in a SNF from the transplant waitlist rate denominator, as we had proposed to do for purposes of the transplant rate.

The numerator for the transplant waitlist rate for ESRD facilities is the number of beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist during the MY. As noted previously, we are clarifying in this final rule that CMS will obtain transplant waitlist data from SRTR, which maintains data on all transplant waitlists.

The denominator for the living donor transplant rate for ESRD facilities will be calculated in the same manner as the denominator for the transplant waitlist rate finalized for ESRD facilities. The numerator for the living donor transplant rate for ESRD facilities is the total number of attributed beneficiary years for LDT Beneficiaries during the MY. Beneficiary years for LDT Beneficiaries included in the numerator are composed of the number of months from the beginning of the MY up to and including the month of the transplant for LDT Beneficiaries attributed to the ESRD facility during the month of the transplant. This method of

determining the number of months associated with a LDT mirrors the method for determining beneficiary attribution for pre-emptive transplant beneficiaries included in the proposed rule and for determining beneficiary attribution for Pre-emptive LDT Beneficiaries as described in section IV.C.5.b.(2)(b) of this final rule. This method is necessary in order to transform a singular event, in particular receipt of a living donor transplant, into a number of beneficiary months such that the numerators for the transplant waitlist rate and the living donor transplant rate can be combined into the transplant rate. CMS will obtain living donor transplant data from SRTR, which maintains data on all transplant, including living donor transplants, and from Medicare claims. We would identify kidney transplants using Medicare claims and administrative data, and SRTR data. As was the case in the proposed rule, to identify kidney transplants using Medicare claims data, we will use claims with Medicare Severity Diagnosis Related Groups (MS-DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD-10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach) We are also defining LDT Beneficiary in our regulations at § 512.310 to mean an ESRD Beneficiary who received a kidney transplant from a living donor during the MY.

Of note, we are modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the transplant rate for ESRD facilities, as described in section IV.C.5.c.(4) of this final rule.

(b) Transplant Rate for Managing Clinicians

As we noted in the proposed rule, whereas ESRD facilities provide care to beneficiaries only once they have begun dialysis, Managing Clinicians provide care for beneficiaries before they begin dialysis. Therefore, we proposed to use a numerator and denominator for the transplant rate for Managing Clinicians that would include pre-emptive transplant beneficiaries, that is, beneficiaries who receive transplants before beginning dialysis, in addition to ESRD Beneficiaries. In this construction, a pre-emptive transplant beneficiary would be included in the numerator for the Managing Clinician as a transplant and in the denominator for the Managing Clinician for the number of months from the beginning of the MY up to and including the month of the transplant. In the proposed rule, we considered including pre-emptive transplants during the MY among attributed pre-emptive transplant beneficiaries in the numerator, to acknowledge Managing Clinician efforts in assisting ESRD Beneficiaries with pre-emptive transplants, without including them in the denominator. However, we concluded that this would disproportionately favor pre-emptive transplants in the construction of the rate. We sought comment on the proposed inclusion of pre-emptive transplants in both the numerator and the denominator for the Managing Clinician transplant rate calculation.

We proposed that the denominator for the transplant rate for Managing Clinicians would be the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY, plus the total number of attributed beneficiary years for pre-emptive transplant beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator would be composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance

dialysis would be identified based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD related services monthly, and indicate beneficiary age (12-19 or 20 years of age or older) and the number of face-to-face visits with a physician or other qualified health care professional per month (1, 2-3, 4 or more). CPT® codes 90965 and 90966 are for ESRD related services for home dialysis per full month, and indicate the age of the beneficiary (12-19 or 20 years of age or older). Taken together, these codes are used to bill the MCP, including patients who dialyze at home and patients who dialyze in-center. However, in order to effectuate the exclusions previously described, we proposed to exclude claims for attributed ESRD Beneficiaries who were 75 years of age or older at any point during the month or were in a SNF at any point during the month.

For pre-emptive transplant beneficiaries, attributed beneficiary years included in the denominator would be composed of those months during which a pre-emptive transplant beneficiary is attributed to the Managing Clinician, between the start of the MY and the month of the transplant. In the proposed rule we recognized that including pre-emptive transplant beneficiary years in the denominator may create a bias in favor of pre-emptive transplants occurring at the beginning of the MY, which may influence Managing Clinician behavior. As pre-emptive transplant beneficiaries only contribute months to the denominator from the start of the MY to the month of the transplant, the earlier in the MY the transplant occurs, the fewer months are included in the denominator, and the higher the Managing Clinician's transplant rate. However, as noted in the proposed rule, we believed that the potential for this bias to impact Managing Clinician behavior is small due to the complexity of scheduling in the pre-emptive transplant process (such as surgeon availability, donor and recipient schedules, etc.).

We proposed that the numerator for the transplant rate for Managing Clinicians would be the number of attributed ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant during the MY, plus the number of pre-emptive transplant beneficiaries attributed to the Managing Clinician for the MY. We proposed to identify kidney and kidney-pancreas transplants using Medicare claims data, Medicare administrative data, and SRTR data. For Medicare claims data, we would use claims with Medicare Severity Diagnosis Related Groups (MS-DRGs) 008 (simultaneous pancreas-kidney transplant) and 652 (kidney transplant); and claims with ICD-10 procedure codes 0TY00Z0 (transplantation of right kidney, allogeneic, open approach), 0TY00Z1 (transplantation of right kidney, syngeneic, open approach), 0TY00Z2 (transplantation of right kidney, zooplastic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplastic, open approach). Because kidney-pancreas transplants are billed by including an ICD-10 procedure code for the type of kidney transplant and a separate ICD-10 procedure code for the type of pancreas transplant, we concluded that we would not need to include additional ICD-10 codes to capture kidney-pancreas transplants beyond the ICD-10 codes for kidney transplants listed. We proposed that we would supplement Medicare claims data on kidney and kidney-pancreas transplants with information from the SRTR Database and Medicare administrative data about the occurrence of kidney and kidney-pancreas transplants not identified through claims. We stated that if a beneficiary who receives a transplant during an MY returns to dialysis during the same MY, the beneficiary would remain in the numerator, to acknowledge the efforts of the Managing Clinician in facilitating the transplant but also to hold the Managing Clinician harmless for transplant failure, which may be outside of the Managing Clinician's control.

In the proposed rule we also considered constructing the numerator for the Managing Clinician transplant rate such that the number of attributed beneficiaries who received transplants during a MY would remain in the numerator for every MY after the transplant for which the transplanted beneficiary does not return to dialysis, for the duration of the ETC Model. Keeping transplants in the numerator for MYs subsequent to the MY in which the transplant occurs would acknowledge the significant efforts made by Managing Clinicians to successfully assist beneficiaries through the transplant process. However, as noted in the proposed rule, we believed this approach would artificially inflate transplant rates in later years of the Model and disproportionately disadvantage new Managing Clinicians who begin providing care to ESRD Beneficiaries in later years of the Model. We concluded that this potential for artificially inflated rates and the disadvantage that would result for new ESRD facilities outweighed the advantage of accruing transplants over time.

The following is a summary of the comments received on the proposed transplant rate for Managing Clinicians and our responses.

Comment: We received one comment recommending that CMS include claims for beneficiaries who have received a transplant in the numerator of the transplant rate for Managing Clinicians, even for the MYs after the transplant, to give Managing Clinicians credit for helping to manage patient care and improve post-transplant outcomes for these beneficiaries.

Response: We appreciate the feedback from the commenter. As we are modifying the transplant portion of the MPS used in calculating the PPA to use the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, instead of the transplant rate as proposed, we do not believe it would be appropriate to include beneficiaries in the transplant waitlist rate calculation post-transplant, as there would generally be no need for

Managing Clinicians to add these beneficiaries to a transplant waitlist. We also do not believe it would be necessary to include post-transplant LDT Beneficiaries or Pre-emptive LDT Beneficiaries in the living donor transplant rate beyond the MYs in which the transplant occurs, as the focus of the rate is whether or not a transplant occurred, not what occurs post-transplant. However, if we modify the MPS calculation to use a transplant rate that includes deceased donor transplants or a similar measure for future MYs through subsequent rulemaking, we may consider proposing to incorporate post-transplant outcomes through such subsequent rulemaking.

After considering public comments, we are finalizing our proposed provisions on the transplant rate for Managing Clinicians in our regulation at § 512.356(c)(2), with modification. The transplant rate for Managing Clinicians is calculated as the sum of the transplant waitlist rate for Managing Clinicians and the living donor transplant rate for Managing Clinicians. The denominator for the transplant waitlist rate for Managing Clinicians is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. As was the case with the proposed transplant rate for Managing Clinicians, dialysis treatment beneficiary years included in the denominator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home or in an ESRD facility, such that 1 beneficiary year is comprised of 12 attributed beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified based on claims, specifically claims with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966. Beneficiaries who are 75 years of age or older at any point during the month are excluded from the denominator. Because beneficiaries who reside in or receive dialysis in SNFs or nursing facilities during the month are now excluded from attribution in general, we are also excluding beneficiaries who were residing in or receiving dialysis a skilled nursing facility or nursing home

facility from the transplant waitlist rate denominator. Of note, the denominator for the Managing Clinician transplant waitlist rate does not include attributed Pre-emptive LDT Beneficiaries, as these beneficiaries do not have to be on the transplant waitlist to receive their transplant because living donor organs are not allocated through the transplant waitlist.

The numerator for the transplant waitlist rate for Managing Clinicians is the number of beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist during the MY. We are clarifying in this final rule that CMS will identify months during which an attributed ESRD beneficiary was on the kidney transplant waitlist using data from the SRTR database, which maintains data on all transplant waitlists.

The denominator for the living donor transplant rate for Managing Clinicians is the sum of total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY and the total number of attributed beneficiary years for attributed Pre-emptive LDT Beneficiaries during the MY. We define a Pre-emptive LDT Beneficiary in our regulations at § 512.310 as a beneficiary who received a pre-emptive kidney transplant from a living donor during the MY. Including Pre-emptive LDT Beneficiaries in the living donor transplant rate denominator for Managing Clinicians follows the same reasoning and method as described in the proposed rule for including pre-emptive transplant beneficiaries in the transplant rate for Managing Clinicians. That is, whereas ESRD facilities provide care to beneficiaries only once they have begun dialysis, Managing Clinicians provide care for beneficiaries before they begin dialysis. However, the construction of the denominator for the living donor transplant rate differs from the proposed construction of the denominator for the proposed transplant rate because the living donor transplant rate includes only pre-emptive transplants that came from living donors. As such, the denominator for the living donor transplant rate for Managing Clinicians does not

include beneficiaries who received a pre-emptive transplant from a deceased donor. Dialysis treatment beneficiary years included in the denominator of the living donor transplant rate for Managing Clinicians are the same as those included in the denominator of the transplant waitlist rate, as described above. As was the case for preemptive transplant beneficiary years in the proposed rule, pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to the Managing Clinician, between the start of the MY and up to and including the month of the transplant. The numerator for the living donor transplant rate for Managing Clinicians is the total number of attributed beneficiary years for LDT Beneficiaries during the MY plus the total number of attributed beneficiary years for Pre-emptive LDT Beneficiaries during the MY. Beneficiary years for LDT Beneficiaries included in the numerator are composed of the number of months from the beginning of the MY up to and including the month of the transplant for LDT Beneficiaries attributed to the Managing Clinician during the month of the transplant. As described above in regards to the living donor transplant rate for ESRD facilities, this method is necessary in order to transform a singular event, in particular a living donor transplant, into a number of beneficiary months such that the numerators for the transplant waitlist rate and the living donor transplant rate can be combined into the transplant rate. As with the denominator for the living donor transplant rate for Managing Clinicians, pre-emptive LDT beneficiary years included in the numerator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to the Managing Clinician, between the start of the MY and up to and including the month of the transplant.

CMS will obtain transplant waitlist data from SRTR, which maintains status data for all transplant waitlists and transplants, including living donor transplants. CMS will obtain living

donor transplant data from SRTR, which contains comprehensive information about transplants that occur in the U.S., as well as from Medicare claims. Of note, we are modifying references to the proposed reliability adjustment methodology and are replacing them with references to the aggregation methodology for the transplant rate for Managing Clinicians, as described in section IV.C.5.c.(4) of this final rule.

(3) Risk Adjustment

In order to account for underlying variation in the population of beneficiaries attributed to participating ESRD facilities and Managing Clinicians, we proposed that CMS would risk adjust both the home dialysis rate and the transplant rate.

For the home dialysis rate, we proposed to use the most recent final risk score for the beneficiary, calculated using the CMS-HCC (Hierarchical Condition Category) ESRD Dialysis Model used for risk adjusting payment in the Medicare Advantage program, to risk adjust the home dialysis rate under the proposed ETC Model. As noted in the proposed rule, internal analyses completed by CMS show that lower HCC risk scores are associated with beneficiaries on home dialysis than with beneficiaries on in-center HD. The risk adjustment methodology we proposed for the ETC Model home dialysis rate would account for ESRD facilities and Managing Clinicians with a population that is relatively sicker than the general Medicare population. As we explained in the proposed rule, the CMS-HCC risk adjustment models were developed for the Medicare Advantage program and use a Medicare beneficiary's medical conditions and demographic information to predict Medicare expenditures for the next year. In the Medicare Advantage context, the per-person capitation amount paid to each Medicare

Advantage plan is adjusted using a risk score calculated using the CMS-HCC Models.[152] We proposed to use the most recent final risk score calculated for the beneficiary that is available at the time of the calculation of ESRD facility and Managing Clinician home dialysis rates to risk adjust the ETC Model home dialysis rate for that MY and corresponding PPA Period.

In the proposed rule, we summarized at a high level how the CMS-HCC Models are developed and used in risk adjusting payment to Medicare Advantage plans

We explained that CMS proposes and adopts the CMS-HCC ESRD Dialysis Model for risk adjusting payments to Medicare Advantage organizations for a particular payment year through the Advance Notice and Rate Announcement for the Medicare Advantage program.[153] This happens the year before the payment year begins, meaning that the CMS-HCC ESRD Dialysis Model used to risk adjust payments for 2020 was adopted and announced in April 2019. However, CMS does not calculate final risk scores for a particular payment year until several months after the close of the payment year.

We explained in the proposed rule that using risk scores developed using the CMS-HCC ESRD Dialysis Model to risk adjust the ETC Model home dialysis rate would be appropriate as it can be more difficult to transition sicker beneficiaries to home dialysis, and risk adjusting the home dialysis rate using risk scores calculated using the CMS-HCC ESRD Dialysis Model would account for the relative sickness of the population of ESRD Beneficiaries attributed to

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[152] CMS. Report to Congress: Risk adjustment in Medicare Advantage. December 2018; cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf

[153] For example, CMS, Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter, January 30, 2019. cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf and CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2019; https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

each ETC Participant relative to the national benchmark. We also stated that use of these final risk scores for the ETC Model would mean use of the same methodology and the same coefficients for the relevant HCCs as the CMS-HCC ESRD Dialysis Model used for the prior Medicare Advantage payment year. The CMS-HCC ESRD Dialysis Model includes the risk factors outlined in § 422.308(c)(1) and (c)(2)(ii), so those risk factors would be used in risk adjustment for the ETC Model. Under our proposal, the risk scores used for the ETC Model would also be adjusted with the same coding pattern and normalization factors that are adopted for the CMS-HCC ESRD Dialysis Model for the relevant year but, for the ETC Model, we did not propose to use a frailty adjustment (for example, outlined in § 422.308(c)(4)) as is used in the Medicare Advantage program for certain special needs plans.

In the proposed rule, we also considered not applying a risk adjustment methodology to the ETC Model home dialysis rate in recognition of the limitations of existing risk adjustment methodologies to account for housing instability, which is a key factor preventing utilization of home dialysis. However, we concluded that not risk adjusting the home dialysis rate would disproportionately disadvantage ETC Participants that provide care to sicker beneficiaries. We also stated that we considered creating a custom risk-adjustment methodology for the ETC Model based on certain factors found in the literature to affect rates of home dialysis, but said that we believed that the HCC system currently in use in the Medicare Advantage program would be sufficient for the purposes of this Model, without the effort required to develop a new methodology.

We proposed that the risk-adjustment methodologies for the home dialysis rate and transplant rate would be applied independently. In the proposed rule we also considered using the same risk adjustment strategy for both rates, but recognized that the risk factors that may

impact the ability of an ESRD Beneficiary to successfully dialyze at home are different from the risk factors that may impact the ability of an ESRD Beneficiary or pre-emptive transplant beneficiary to receive a kidney transplant. We further noted that, even in the Medicare Advantage program, a different CMS-HCC Model is used for beneficiaries who have received a transplant and stated our belief that the benefit of separate risk adjustment methodologies would outweigh the additional complexity. For the transplant rate, we noted in the proposed rule that we wanted to use a risk adjustment methodology that aligns with a risk adjustment methodology with which ESRD facilities and Managing Clinicians are likely to be familiar and that similarly would not require development of a new and unfamiliar methodology. In the proposed rule we noted that we believe that the methodology used for purposes of risk adjusting the PPPW satisfies these criteria and would be appropriate to apply in risk adjusting the transplant rate. Specifically, we proposed that the ESRD facility and Managing Clinician transplant rates would be risk adjusted for beneficiary age, using the similar age categories, with corresponding risk coefficients, used for purposes of the PPPW measure described earlier (83 FR 57004).

Although age alone is not a contraindication to transplantation, we stated in the proposed rule that older patients are likely to have more comorbidities and generally be more frail, thus making them potentially less suitable candidates for transplantation, and therefore some may be appropriately excluded from waitlisting for transplantation. The risk adjustment model for the PPPW contains risk coefficients specific to each of the following age categories of beneficiaries (with age computed on the last day of each reporting month): under 15; 15-55; 56-70; and 71-74. Given that the ETC Model would exclude beneficiaries under 18 from the attribution methodology used for purposes of calculating the transplant rates, we proposed to use the risk coefficients calculated for the PPPW for the populations aged 18-55, 56-70, and 71-74, with age

computed on the last day of each month of the MY. Transplant rates for ESRD facilities and Managing Clinicians would be adjusted to account for the relative percentage of the population of beneficiaries attributed to each ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution. Further information on the risk adjustment model used for purposes of the PPPW can be found in the PPPW Methodology Report (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Report-for-Percentage-of-Prevalent-Patients-Waitlisted.pdf).

In the proposed rule, we stated that we had considered using the risk adjustment methodology used in the Standardized Waitlist Ratio available online at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/Report-for-Standardized-First-Kidney-Transplant-Waitlist-Ratio-for-Incident-Dialysis-Facilities.pdf for risk adjusting the ETC Model transplant rate. However, we decided not to as this measure is focused only on incident beneficiaries in their first year of dialysis, rather than the broader population of beneficiaries that would be included in the ETC Model.

In the proposed rule we also considered using the CMS-HCC ESRD Transplant Model for risk adjusting the ETC Model transplant rate. However, we decided not to as the model is focused on costs once a beneficiary receives a transplant, rather than the beneficiary's suitability for receiving a transplant.

The following is a summary of the comments received on the risk adjustment methodology for the home dialysis rate, the risk adjustment methodology for the transplant rate, and our responses.

Comment: We received several comments urging CMS to not use the CMS ESRD-HCC Risk Score methodology for risk adjusting the home dialysis rate as proposed. Many commenters commented that although there is a correlation between healthier beneficiaries and home dialysis utilization, the relationship is not causative, nor is beneficiary health status the most important factor affecting home dialysis uptake rates. Other commenters commented that the CMS ESRD-HCC Risk Score methodology is built using fee for services data to project Medicare Advantage spending, not relative levels of illness; the commenters also pointed out that a beneficiary whose risk score is twice that of another is not necessarily half as likely to be an effective candidate for home dialysis. Commenters also raised concerns that this proposed methodology was not transparent as ESRD facilities and Managing Clinicians do not necessarily receive the CMS ESRD-HCC risk score information for their patients. One dialysis company noted in its comments that the CMS ESRD-HCC risk score methodology has a different methodology for beneficiaries who are new to the Medicare program and that the HCC risk scores may be less predictive for this population given the increased rates of home dialysis utilization among beneficiaries who are new to dialysis.

Response: After receiving comments on the proposed rule, we performed an additional analysis that showed a correlation between lower CMS-HCC risk scores and an increased likelihood to receive home dialysis as opposed to in-center dialysis. The average CMS-HCC risk score for a beneficiary receiving home dialysis is 0.9, while the average CMS-HCC risk score for a beneficiary receiving in-center hemodialysis is 1.03, and this difference is statistically significant with a p-value of .02. However, the same analysis done by CMS after receiving comments on the proposed rule showed that, although the difference in CMS-HCC risk scores between these two populations is statistically significant, CMS-HCC risk scores have an

explanatory ability of only 1.5 percent for determining whether a beneficiary will receive home dialysis rather than in-center dialysis, and vice versa. Based on the low explanatory power of the CMS-HCC risk score in predicting whether a beneficiary will receive home dialysis, together with the other issues with the proposed risk-adjustment methodology raised by the commentators, we do not believe that there is a significant value in risk adjusting the home dialysis rate based on this proposed methodology, and therefore we are not finalizing this approach. We are instead finalizing the home dialysis rate calculation without a risk-adjustment methodology and we seek input from commenters about risk adjustment methodologies to be proposed in future rulemaking. We recognize that in the proposed rule, we stated that we believed that not risk adjusting the home dialysis rate would disproportionately disadvantage ETC Participants that provide care to sicker beneficiaries. However, our subsequent analysis indicated that although there is a statistically significant correlation between beneficiary risk scores and propensity for home dialysis, the relationship had very little explanatory power, meaning that we do not believe our proposed risk adjustment methodology will help to address this issue. We intend to monitor for whether the lack of a risk-adjustment methodology for the home dialysis rate has any negative consequences for ETC Participants and ESRD Beneficiaries and may modify the ETC Model to add a risk-adjustment methodology for calculation to the home dialysis rate through subsequent rulemaking.

Comment: Many commenters recommended that CMS consider using socioeconomic factors for purposes of risk adjusting the home dialysis rate, as these factors can preclude beneficiaries from being appropriate candidates for home dialysis. The commenters asserted that beneficiaries suffering from housing insecurity or homelessness are not good candidates for the home dialysis modality and that peritonitis, an infection of the perineum that can result from PD

and prevents beneficiaries from being able to continue receiving PD is more common among socially disadvantaged groups. Commenters had several suggestions as to which socioeconomic factors CMS could use to risk-adjust the home dialysis rate, including using dual eligibility status as a proxy for socioeconomic status, using the ZIP code or the ZIP+4 based on the location of the beneficiary or the ESRD facility, using Z-codes in ICD-10 to track socioeconomic status or homelessness, looking at the urban/rural divide, using presence on the kidney transplant waitlist as a proxy for health status, or setting up a standardized ratio measure based on projected rates of transplants.

Three separate commenters--including a dialysis company, a patient advocacy group, and a nephrology practice--each independently recommended that CMS use the risk adjustment methodology from the Hospital Readmissions Reduction Program, as laid out in the FY 2018 IPPS final rule[154] (82 FR 37990, 38221 (August 14, 2017)) in order to risk-adjust the home dialysis rate for socioeconomic factors.

Response: We thank the commenters for their recommendations and believe that risk adjusting the home dialysis rate based on socioeconomic factors may have merit. However, risk adjusting the home dialysis rate based on socioeconomic factors would represent a significant departure from the risk adjustment methodology outlined in the proposed rule. Accordingly, we are not finalizing a risk-adjustment methodology based on socioeconomic factors at this time. As described previously in this final rule, we are finalizing the home dialysis rate calculation without a risk adjustment methodology. We seek input from the public on how to construct a risk adjustment methodology for the home dialysis rate that could account for socioeconomic

[154] https://www.govinfo.gov/content/pkg/FR-2017-08-14/pdf/2017-16434.pdf

factors, like the one from the Hospital Readmissions Reduction Program, to inform any future rulemaking on this topic.

Comment: We received several comments critiquing the risk adjustment methodology from the PPPW measure we proposed to apply to the transplant rate. A commenter raised issues with the methodology, pointing out that it was not NQF endorsed and that it risk adjusts by age in a way that has abrupt cut points, rather than using age as a continuous variable.

Response: We continue to believe that the risk adjustment methodology for the PPPW measure is appropriate to use for the transplant waitlist rate, which we are finalizing as part of the transplant rate. We extensively tested the PPPW measure, including its risk adjustment methodology, before we adopted that measure for the ESRD QIP, and our rationale supporting the use of a similar risk adjustment methodology for the transplant waitlist rate is consistent with the rationale that supports our use of that methodology for the ESRD QIP. The specific design of the risk adjustment methodology for the PPPW measure, including the cut points, is designed to best fit the transplant waitlist data in the PPPW measure. Though it is not an NQF-endorsed measure, this is a measure currently used by CMS and we believe the methodology to be sound.

Comment: Some commenters asserted that the proposed risk adjustment methodology for the transplant rate should also include other factors related to the transplant process, including diagnoses of malignancy, cardiac surgery, or other comorbidities that could prevent a beneficiary from being a transplant candidate. Other commenters urged CMS to consider other factors related to transplant eligibility or to recognize different levels of access to kidneys in different geographies.

Response: CMS believes that by modifying the transplant rate to remove deceased donor organ transplants, as described previously in this final rule, we do not need to risk adjust the

transplant rate for these specific issues around organ supply that may affect access to kidneys, in particular deceased donor organs, in different geographies. In addition, though there are disparaties in the transplant process, CMS also decided not to include other factors in risk adjusting the transplant waitlist rate to align with the risk adjustment methodology for the PPPW measure, which also did not include these factors. Additionally, we believe that the exclusions from beneficiary attribution to ETC Participants described in section IV.C.5.b.(1) of this final rule sufficiently account for relevant contraindications to transplant and that additional risk adjustment for these factors is not necessary.

After considering public comments, we are finalizing our proposed provisions for risk adjusting the home dialysis rate and the transplant rate, with modifications. Specifically, in response to the methodological concerns highlighted by commenters regarding our proposed methodology for risk adjusting the home dialysis rate and subsequent analysis conducted by CMS, we are finalizing the home dialysis rate calculation without a risk adjustment methodology. CMS may add a risk adjustment methodology to the home dialysis rate calculation, taking into account the comments received and any additional feedback received from the public, in future rulemaking. We are finalizing in our regulation at § 512.365(d) that the transplant waitlist rate portion of the transplant rate will be risk adjusted based on beneficiary age with separate risk coefficients for the following age categories of beneficiaries, with age computed on the last day of each month of the MY: 18 to 55; 56 to 70; and 71 to 74. We are also finalizing in our regulation at § 512.365(d) that the transplant waitlist rate portion of the transplant rate will be adjusted to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age

distribution of beneficiaries not excluded from attribution. The living donor transplant rate portion of the transplant rate will not be risk adjusted due to small sample sizes.

(4) Reliability Adjustments and Aggregation

In order to overcome low reliability of the home dialysis rate and transplant rate related to small numbers of beneficiaries attributed to individual ETC Participants, we proposed to employ a reliability adjustment. Under this approach, we proposed using statistical modeling to make reliability adjustments such that the home dialysis rate and the transplant rate would produce reliable estimates for all ETC Participants, regardless of the number of beneficiaries for whom they provide care. We also proposed this approach to improve comparisons between ETC Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model for purposes of achievement benchmarking and scoring, described in the proposed rule and section IV.C.5.d of this final rule. The proposed reliability adjustment approach would create a weighted average between the individual ETC Participant's home dialysis rate and transplant rate and the home dialysis rate and transplant rate among the ETC Participant's aggregation group (previously described), with the relative weights of the two components based on the statistical reliability of the individual ETC Participant's home dialysis rate and transplant rate, as applicable. For example, if an ETC Participant's home dialysis rate has high statistical reliability, then the ETC Participant's individual home dialysis rate would contribute a large portion of the ETC Participant's reliability-adjusted home dialysis rate and the aggregation group's home dialysis rate would contribute a small portion of the ETC Participant's reliability-adjusted home dialysis rate. We currently employ this technique in a variety of settings, including the measures used in creating hospital ratings for Hospital Compare. We explained in the proposed rule that the advantage of using this approach is that we could use one method to

produce comparable performance rates for ESRD facilities and Managing Clinicians across the size spectrum. We also noted that the disadvantage of using this approach is that reliability adjusted performance rankings do not necessarily reflect absolute or observed performance, and may be difficult to interpret directly. We stated that we believed this approach balanced the need for individualized performance assessment and incentives with the importance of reliably assessing the performance of each ETC Participant.

For Managing Clinicians, we proposed that the performance on these measures would be first aggregated up to the practice level, as identified by the practice Taxpayer Identification Number (TIN) for Managing Clinicians who are in a group practice, and at the individual National Provider Identifier (NPI) level for Managing Clinicians who are not in a group practice, that is, solo practitioners. We proposed to define "TIN" as a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109-1. We proposed to define "NPI" as the standard unique health identifier used by health care providers for billing payers assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162. We proposed these definitions because they are used elsewhere by the Medicare program (see 42 CFR 414.502). Performance would then be aggregated to the aggregation group level. We proposed that the aggregation group for Managing Clinicians, once aggregated to the group practice or solo practitioner level, as applicable, would be all Managing Clinicians within the HRR in which the group practice is located (for group practices) or the Managing Clinician's HRR (for solo practitioners).

For ESRD facilities, we proposed that the individual unit would be the ESRD facility. We proposed to define a "Subsidiary ESRD facility" as an ESRD facility owned in whole or in part by another legal entity. We proposed this definition in recognition of the structure of the

dialysis market, as described in this rule. We proposed that the aggregation group for Subsidiary ESRD facilities would be all ESRD facilities located within the ESRD facility's HRR owned in whole or in part by the same company, and that ESRD facilities that are not Subsidiary ESRD facilities would be in an aggregation group with all other ESRD facilities located within the same HRR (with the exception of those ESRD facilities that are Subsidiary ESRD facilities).

We sought input on our proposal to use reliability adjustments to address reliability issues related to small numbers, as well as on our proposed aggregation groups for conducting the reliability adjustment for ESRD facilities and Managing Clinicians that are ETC Participants.

In the proposed rule, we acknowledged that for some segments of the dialysis market, companies operating ESRD facilities may operate specific ESRD facilities that focus on home dialysis, which furnish home dialysis services to all patients receiving home dialysis through that company in a given area. Therefore, assessing home dialysis rates at the individual ESRD facility level may not accurately reflect access to home dialysis for beneficiaries receiving care from a specific company in the area. In the proposed rule, we stated that we believed that the reliability adjustment approach would help to address this concern, because the construction of the reliability adjustment for Subsidiary ESRD facilities would aggregate to the company level within a given HRR and thus incorporate this dynamic. In the proposed rule, we considered using a single aggregated home dialysis rate for all ESRD facilities owned in whole or in part by the same company within a given HRR to account for this market dynamic. However, in the proposed rule we stated that producing individual ESRD facility rates and reliability adjusting individual ESRD facility scores would be necessary to incentivize ESRD facilities within the same company in the same HRR to provide the same level of care to all of their attributed beneficiaries.

The following is a summary of the comments received on the proposed reliability adjustment and aggregation methodologies and our responses.

Comment: We received comments that our proposed reliability adjustment lacked transparency and was difficult to understand. Commenters noted that there was not sufficient detail for them to assess the potential impacts of the proposed policy.

Response: We appreciate the feedback from commenters about the proposed reliability adjustment. In response to these comments, we are not finalizing the proposed reliability adjustment policy. CMS no longer believes that the reliability adjustment is necessary for Managing Clinicians or for ESRD facilities in light of the changes to the aggregation policies described in this section of this final rule, under which the performance of Managing Clinicians will be assessed at the practice level, if applicable, and the performance of ESRD facilities will be assessed at the aggregation group level instead of at the individual facility level. In addition, as discussed in section IV.C.5.f of this final rule, we have increased the low-volume threshold relative to the low-volume threshold outlined in the proposed rule, which will remove greater numbers of the smallest ETC Participants from the application of the PPA, further increasing the statistical reliability of the rates used as part of the PPA calculation.

Comment: We received comments in support of our proposal to aggregate performance on the home dialysis rate and transplant rate for Managing Clinicians in a group practice at the TIN level. We also received comments recommending that performance for a Managing Clinician should be assessed only based on the performance of other Managing Clinicians with whom the Managing Clinician shares a business relationship.

Response: We appreciate the commenters' support and are finalizing our proposal to assess the performance of Managing Clinicians in a group practice at the TIN level and to assess

the performance of Managing Clinicians who are not in a group practice, that is, solo practitioners at the NPI level. However, we no longer plan to further aggregate performance for Managing Clinicians up to the HRR level, as proposed. Based on comments received, we recognize that it is most appropriate to aggregate performance for Managing Clinicians only for Managing Clinicians practicing under a common group practice (as identified by a TIN), and that the performance of solo practitioner Managing Clinicians should not be aggregated with that of any other Managing Clinicians. Specifically, we do not believe the Managing Clinician should be held accountable for the performance of Managing Clinicians in unaffiliated practices at the HRR level because of their lack of business relationships.

Comment: We received multiple comments objecting to our proposed aggregation methodology for ESRD facilities, pointing out that dialysis companies often concentrate their home dialysis patients at certain regional centers that solely focus on home dialysis. Additionally, we received comments that requiring a home dialysis program to be built at each ESRD facility would be duplicative and would not necessarily improve patient care. We also received comments that ESRD Beneficiaries who receive treatment from ESRD facilities that are ETC Participants may receive home dialysis services from a home dialysis facility that is owned in whole or in part by the same dialysis company, but that is not necessarily within the same HRR as the ESRD facility.

Response: Based on comments received from the public, we believe that the nature of the dialysis market means that assessing home dialysis rates at the individual ESRD facility level may not accurately reflect access to home dialysis through that company in a given area. Our intent is to ensure that home dialysis is available to every ESRD Beneficiary, not necessarily at every individual ESRD facility. In order to better align with market dynamics, we will assess

ESRD facility performance at the aggregation group level, rather than at the facility level. However, as proposed, the aggregation group for a Subsidiary ESRD facility will include only those ESRD facilities owned in whole or in part by the same company located in the same HRR. Based off of our analyses, CMS found rare instances of typographical errors for facility information in PECOS. We will address these inconsistencies by identifying those ESRD facilities owned in whole or in part by the same company using the Chain TIN and Chain Name from PECOS with adjustments made for any mismatches arising from typographical errors in those fields in PECOS using CrownWEB and other CMS data sources.

While we understand the commenters' concerns that dialysis companies may operate across multiple HRRs, as described in sections IV.C.5.3.b and IV.C.5.3.c.(1) of this final rule, we believe HRRs are the best representation of patterns of care and, unlike other geographic units of selection considered in the proposed rule, also include rural areas. Additionally, CMS does not have sufficient information regarding the location of home dialysis facilities relative to other Subsidiary ESRD facilities of the same dialysis companies in order to make informed aggregation decisions on that basis (also, these arrangements are likely subject to change). Moreover, tailoring ESRD facility aggregation based on each dialysis company's corporate structure would be difficult to administer for CMS and could be subject to gaming by the dialysis companies.

Comment: We received multiple comments in support of our proposal that the aggregation group for Subsidiary ESRD Facilities should be all ESRD facilities located within the ESRD facility's HRR owned in whole or in part by the same company. Additionally, we received comments suggesting that all ESRD facilities located in the same HRR should receive a single combined score regardless of their ownership status.

Response: We appreciate comments supporting our proposal that the aggregation group for Subsidiary ESRD facilities would be all ESRD facilities owned in whole or in part by the same company within an HRR. We believe this is a fair approach that allows the performance for ESRD facilities to be assessed based solely on the performance of facilities that are owned in whole or in part by the same company, rather than facilities that may be owned by different companies. Additionally, we see the benefits of grouping ESRD facilities within the same HRR, as the boundaries of the HRRs reflect referral patterns and because an ESRD facility is more likely to refer patients for home dialysis and other services to an ESRD facility located in the same geographic area than to an ESRD facility located farther away.

Comment: We received a comment recommending that CMS create a virtual group for small or low-volume ESRD facilities with a smaller presence in the specific HRR to aggregate performance.

Response: We appreciate this recommendation but do not believe that creating a virtual group will be necessary to improve the reliability of the home dialysis rates and transplant rates for low-volume ESRD facilities. In addition to the operational complexities that implementing a virtual group would present for CMS, we believe that the increased low-volume threshold described in section IV.C.5.f. of this final rule will help to improve the statistical reliability of the home dialysis rates and transplant rates for small ESRD facilities, while ensuring a viable model test.

After considering public comments, we are finalizing our proposed provisions for reliability adjustment and aggregation of the home dialysis rate and transplant rate, with modifications. Specifically, we are removing the reliability adjustment for both ESRD facilities and Managing Clinicians. Additionally, we are codifying in our regulation at § 512.365(e)(2)

that a Managing Clinician's performance on the home dialysis rate and transplant rate will be aggregated to the Managing Clinician's aggregation group, which is identified at the TIN level for Managing Clinicians in a group practice and at the individual NPI level for Managing Clinicians who are solo practitioners. We are not finalizing our proposal to further aggregate Managing Clinician performance with all other Managing Clinicians located within the HRR. Additionally, in § 512.365(e)(1), we are finalizing our proposal that ESRD facilities' home dialysis rate and transplant rate will be aggregated to the ESRD facility's aggregation group, which is defined as all ESRD facilities owned in whole or in part by the same company within an HRR for a Subsidiary ESRD facility. As discussed previously in this final rule rule, CMS is finalizing its proposal to use PECOS to verify the correct zip code of the ESRD facility location for purposes of selecting ESRD facilities for participation in the Model. However, CMS received public comments regarding our proposed aggregation policy suggesting that CMS use resources in addition to PECOS to correctly identify ESRD facilities. Subsequent CMS analyses also found rare instances of typographical errors for facility information in PECOS. In response, we are modifying our policy in this final rule such that Subsidiary ESRD facilities will be identified using the Chain TIN and Chain Name from PECOS and that CMS will use other CMS data sources, including CrownWEB, to identify and correct any mismatches arising from typographical errors in those fields in PECOS. CMS may notify ESRD facilities of their status as a Subsidary ESRD Facility and, if applicable, the other Subsidiary ESRD Facilities with which CMS has identified a common ownership relationship during the MY to allow ESRD facilities the opportunity to confirm and provide feedback before CMS calculates the PPA for that MY. We are also modifying our aggregation approach for ESRD facilities that are not Subsidiary ESRD facilities, such that these ESRD facilities will not be aggregated with other

facilities located within the HRR in which the facility is located or otherwise. We are also finalizing the Taxpayer Identification Number (TIN), National Provider Identifier (NPI), and Subsidiary ESRD facility definitions, as proposed, in our regulation at § 512.310.

d. Benchmarking and Scoring

We proposed calculating two types of benchmarks for rates of home dialysis and transplants against which to assess ETC Participant performance in MY1 and MY2 (both of which would begin in CY 2020). Under our proposal, risk-adjusted and reliability-adjusted ETC Participant performance for the home dialysis rate and the transplant rate would be assessed against these benchmarks on both achievement and improvement at the ETC Participant level.

The first set of benchmarks would be used in calculating an achievement score for the ETC Participant on both the home dialysis rate and the transplant rate. This set of benchmarks would be constructed based on historical rates of home dialysis and transplants in Comparison Geographic Areas. We proposed constructing the benchmarks using 12 months of data, beginning 18 months before the start of the MY and ending 6 months before the start of the MY, to allow time for claims run-out and calculation. We proposed to refer to this period of time as the "benchmark year." We proposed using data from ESRD facilities and Managing Clinicians located in Comparison Geographic Areas to construct these benchmarks. In the proposed rule, we alternatively considered using national performance rates to construct these benchmarks. However, in order to prevent the impact of the model intervention altering benchmarks for subsequent MYs, we decided against this alternative in the proposed rule. We proposed to calculate the home dialysis rate and transplant rate benchmarks for ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year using the same methodologies that we use to calculate the home dialysis rate and transplant rate for

ESRD facilities and Managing Clinicians located in Selected Geographic Areas during the MYs. We stated our intent to establish the benchmarking methodology for future MYs through subsequent rulemaking.

As stated in the proposed rule, our intent in future MYs is to increase achievement benchmarks among ETC Participants above the rates observed in Comparison Geographic Areas. By MY9 and MY10, in order to receive the maximum achievement score, as noted in the proposed rule, we were considering that an ETC Participant would have to have a combined home dialysis rate and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant. We sought public comment on our intent to increase achievement benchmarks over the duration of the Model.

The second set of benchmarks would be used in calculating an improvement score for the ETC Participant on both the home dialysis rate and the transplant rate. This set of benchmarks would be constructed based on historical rates of home dialysis and transplants by the ETC Participant during the Benchmark Year. We proposed to calculate the improvement score by comparing MY performance on the home dialysis rate and transplant rate against past ETC Participant performance to acknowledge efforts made in practice transformation to improve rates of home dialysis and transplants. However, we proposed that an ETC Participant could not attain the highest scoring level through improvement scoring. Specifically, while an ETC Participant could earn an achievement score of up to 2 points for the transplant rate and the home dialysis rate, the maximum possible improvement score is 1.5 points for each of the rates. We explained that this policy would be consistent with other CMS programs and initiatives employing similar improvement scoring methodologies, including the CEC Model.

In the proposed rule, we considered not including improvement scoring for the first two MYs, as this would mean assessing improvement in the MY against ETC Participant performance before the ETC Model would begin. However, as noted in the proposed rule, we believe that including improvement scoring for the first two MYs is appropriate, as it acknowledges performance improvement gains while participating in the ETC Model. We sought input on the use of improvement scoring in assessing ETC Participant performance for the first two MYs. Table 13 details the proposed scoring methodology for assessment of MY1 and MY2 achievement scores and improvement scores on the home dialysis rate and transplant rate.

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

| Achievement Score Scale for MYs 1 and 2 | Points | Improvement Score Scale for MYs 1 and 2 |
|---|---|---|
| 90$^{th}$+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year | 2 | Not a scoring option |
| 75$^{th}$+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year | 1.5 | Greater than 10 percent improvement relative to Benchmark Year rate |
| 50$^{th}$+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year | 1 | Greater than 5 percent improvement relative to Benchmark Year rate |
| 30$^{th}$+ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year | 0.5 | Greater than 0 percent improvement relative to Benchmark Year rate |
| <30$^{th}$ Percentile of benchmark rates for Comparison Geographic Areas during the Benchmark Year | 0 | Less than or equal to Benchmark Year rate |

Under our proposal, the ETC Participant would receive the higher of the achievement score or improvement score for the home dialysis rate and the higher of the achievement score or improvement score for the transplant rate, which would be combined to produce the ETC

Participant's Modality Performance Score (MPS). We proposed the following formula for determining the MPS:

$$MPS = 2 \times (The\ higher\ of\ the\ home\ dialysis\ rate\ achievement\ or\ improvement\ score) + (The\ higher\ of\ the\ transplant\ rate\ achievement\ or\ improvement\ score)$$

We proposed that the home dialysis rate score would constitute two thirds of the MPS, and that the transplant rate score would constitute one third of the MPS. In the proposed rule, we considered making the home dialysis rate score and the transplant rate score equal components of the MPS, to emphasize the importance of both home dialysis and transplants as alternative renal replacement therapy modalities. However, we recognized that transplant rates may be more difficult for ETC Participants to improve than home dialysis rates, due to the limited supply of organs and the number of other providers and suppliers that are part of the transplant process but are not included as participants in the ETC Model. For this reason, we proposed that the home dialysis rate component take a greater weight than the transplant rate component of the MPS.

The following is a summary of the comments received on the proposed benchmarking and scoring methodology and our responses.

Comment: Several commenters opposed our proposal to use a comparative or percentile based methodology for purposes of calculating the achievement benchmarks. According to some of these commenters, this comparative approach would not accurately reflect ETC Participant performance or the care being provided. Some of these commenters stated that this comparative approach serves only as a way for CMS to ensure Model savings, as some ETC Participants' performance would fall below the achievement benchmarks, resulting in a negative payment adjustment. A commenter opined that the percentile based achievement scoring approach would not be operational at the ESRD facility level because, based on the commenter's analysis, there

would be no differentiation in home dialysis rates for the three lowest scoring groups. This comment was cited by several other commenters.

Response: We disagree that using a comparative approach for calculating achievement benchmarks, percentile-based or otherwise, does not reflect ETC Participant performance or the care being provided. On the contrary, comparative benchmarks reflect the performance of the ETC Participant relative to their peers. We also disagree that a comparative approach serves only as a way to ensure Model savings for two reasons. First, because achievement benchmarks are constructed based on performance of those not selected for participation in the Model, it is possible that many ETC Participants will meet or exceed the level of performance necessary to not receive a negative adjustment through achievement scoring alone. Second, the use of improvement scoring alongside achievement scoring means that ETC Participants can avoid negative payment adjustments through improvement alone, regardless of their performance in relation to the achievement benchmarks. We disagree with the commenter's analysis suggesting that there would be no differentiation between the lowest three benchmark groups if home dialysis rates were assessed at the ESRD facility level based on our analyses of claims data conducted in the development of this final rule. Specifically, our analyses indicated that after the application of the aggregation group methodology to the performance of ESRD facilities located in Selected Geographic Areas, there is differentiation in the home dialysis rates among ESRD facilities at or below the 50$^{th}$ percentile of benchmark rates for Comparison Geographic Areas, which corresponds with the lowest three groups used for purposes of assessing an ESRD facility's achievement score. We also note that, as proposed, we will calculate the benchmarks for the home dialysis rate and the transplant rate for ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year using the same

methodologies that we use to calculate the home dialysis rate and transplant rates for ESRD facilities and Managing Clinicians located in Selected Geographic Areas during the MYs. Accordingly, we will be aggregating Subsidiary ESRD facilities with all ESRD facilities owned in whole or in part by the same dialysis organization located in the same HRR when constructing the benchmarks, as described in section IV.C.5.c.(4) of this final rule.

Comment: A commenter supported our proposal to use Comparison Geographic Areas to create achievement benchmarks, and concurred with CMS's decision not to use national performance rates to construct these benchmarks because the model design adequately controls for any spillover effects due to the national nature of the dialysis market.

Response: We appreciate the feedback and support from the commenter and agree that the model design adequately controls for any spillover effects due to the national nature of the dialysis market.

Comment: Several commenters opposed the construction of achievement benchmarks based on rates in Comparison Geographic Areas, for the following reasons. First, several of these commenters pointed out that, due to the national nature of the dialysis market, dialysis companies operating nationally may implement practices that improve rates nationwide, not just in Selected Geographic Areas, so achievement benchmarks based on rates in Comparison Geographic Areas would not remain constant over time. Second, one of these commenters stated that basing achievement benchmarks on Comparison Geographic Areas when dialysis organizations have ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas creates an incentive for those dialysis organizations to lower rates of home dialysis and transplants in Comparison Geographic Areas to improve the performance of their locations that are ETC Participants.

A commenter recommended that CMS monitor the rates of home dialysis and transplants between Selected Geographic Areas and Comparison Geographic Areas to determine whether the Model is resulting in unintended consequences – including market consolidation, manipulation of achievement benchmarks, declining rates of home dialysis or transplant in Comparison Geographic Areas, or adverse patient outcomes – due to the distribution of LDOs in both Selected Geographic Areas and Comparison Geographic Areas. A commenter recommended that the use of Comparison Geographic Areas for achievement benchmarks be contingent on achieving statistical balance on certain covariates that may impact rates of home dialysis and transplantation between Selected Geographic Areas and Comparison Geographic Areas, to avoid making inappropriate comparisons between the two.

Response: We anticipate that rates for home dialysis, transplant waitlisting, and living donor transplants will change in Selected Geographic Areas, and may change in Comparison Geographic Areas, over the course of the Model. As stated in the proposed rule and in section IV.C.5.d of this final rule, we intend to establish a different method for establishing achievement benchmarks for future years of the Model through subsequent rulemaking. We expect that this method would not be based solely based on rates in Comparison Geographic Areas, and would be designed to incentivize improved performance in Selected Geographic Areas. We believe that this approach would mitigate concerns that dialysis organizations operating ESRD facilities in both Selected Geographic Areas and Comparison Geographic Areas may exert influence on achievement benchmarks by altering the provision of home dialysis or transplant services in Comparison Geographic Areas. As described in section IV.C.10 of this final rule, we intend to monitor for unintended consequences, such as those enumerated by commenters, and to make adjustments to the Model through subsequent rulemaking should such unintended consequences

arise. We appreciate the suggestion that we check for balance on certain covariates that may impact rates of home dialysis and transplantation between Selected Geographic Areas and Comparison Geographic Areas. However, we believe that our policy of establishing Selected Geographic Areas by stratified randomization of a sufficiently large number of HRRs adequately accounts for underlying variation.

Comment: A commenter recommended calculating achievement benchmarks separately for each Selected Geographic Area, or including a geographic adjustment factor in the achievement benchmark calculation, to account for regional variation in rates. A commenter recommended that CMS create achievement benchmarks for each Selected Geographic Area for the transplant rate, to account for historical variation in the availability of organs and rates of transplantation across the country. Another commenter opined that achievement benchmarks for home dialysis rates should not be the same nationally because there may be underlying factors that vary across the country that impact patient preference for home dialysis. A commenter opposed constructing benchmarks specific to each Selected Geographic Area, opining that this would be overly complicated.

Response: We appreciate the commenters' recommendations that we calculate more regionally specific achievement benchmarks. However, we agree with the commenter that stated that calculating achievement benchmarks specific to each Selected Geographic Area would be overly complicated, and we also believe that this approach would perpetuate regional differences in home dialysis and transplant rates that are not beneficial for beneficiaries. Accordingly, we are finalizing our proposal to establish a single achievement benchmark for each MY based on rates of home dialysis, transplant waitlisting, and living donor transplants in the Comparison Geographic Areas.

Comment: A commenter stated that any changes to the organ allocation system, such as those under consideration by the Organ Procurement and Transplant Network (OPTN), may make achievement benchmarks for transplant rates based on historical performance in Comparison Geographic Areas an inappropriate comparison for purposes of assessing current transplant rates due to intervening changes in organ availability by region.

Response: We appreciate the feedback from this commenter. As described in section IV.C.5.c.(2) of this rule, we are modifying the transplant rate used to assess ETC Participant performance such that it no longer includes deceased donor transplants. As such, we do not believe that changes to the organ allocation system will impact performance benchmark construction, as these changes do not directly impact transplant waitlisting or living donation. Additionally, as discussed in the proposed rule and previously in this final rule, we intend to make changes to the achievement benchmarking approach for future MYs through subsequent rulemaking, including to set benchmarks that are not dependent on historical rates of transplants in Comparison Geographic Areas. We will take this comment into consideration as we consider any such future changes, to ensure that any changes in the organ allocation system will not disproportionately impact the achievement benchmarks used in future MYs.

Comment: A commenter recommended that CMS establish achievement benchmarks that are not based on Comparison Geographic Areas.

Response: We appreciate the input from the commenter. We continue to believe that using Comparison Geographic Areas to establish achievement benchmarks for the initial years of the Model is appropriate. However, we will consider this input about establishing achievement benchmarks that are not based on Comparison Geographic Areas if we make changes to the

achievement benchmarking methodology for future years of the Model through subsequent rulemaking.

Comment: Several commenters opposed our stated intent to increase achievement benchmarks for future MYs through subsequent rulemaking. Some commenters opined that this approach lacks transparency, unfairly penalizes ETC Participants by changing the target over time, and undermines ETC Participant success in the Model. Several commenters expressed concern that CMS would adjust the benchmarking methodology for future MYs to achieve Model savings rather than to accurately reflect ETC Participant performance and incentivize ETC Participants to achieve the Model's goals of improving or maintaining quality and reducing costs by increasing rates of home dialysis and transplantation. Several commenters recommended that CMS maintain the benchmarking methodology proposed for MY1 and MY2 for the duration of the Model. Several commenters stated that CMS should establish the benchmarking methodology for all MYs before the Model begins to give ETC Participants the opportunity to plan accordingly.

Response: We appreciate the commenters' concerns about the need for transparency and for ETC Participants to be successful in the Model. However, we believe that our approach would be transparent, as any changes to the achievement benchmarking methodology for subsequent MYs would be established through notice and comment rulemaking. While we do not intend to maintain the benchmarking methodology we are finalizing now through the duration of the Model, as we expect that this methodology would not provide a sufficient incentive for ETC Participants to raise home dialysis and transplant rates at a rate faster than would occur absent the Model, we do acknowledge that finalizing our proposal to apply this methodology only for MY1 and MY2 would create some uncertainty about the benchmarking

methodology for MYs immediately following MY2. For this reason, we are specifying that we will continue to use the achievement benchmarking methodology we proposed and are finalizing for MY1 and MY2 for future MYs if subsequent rulemaking cannot be completed with sufficient notice in advance of those MYs.

Comment: Several commenters expressed support for setting ambitious goals for home dialysis and transplant rates, and stated that higher rates of home dialysis and transplantation are achievable. A commenter who expressed such support recommended lowering our goal for future MYs from a combined home dialysis rate and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant to 50 percent, which they suggested was still ambitious but more attainable for ETC Participants. Another commenter recommended that our goal for future MYs should be reduced to a more attainable level in consultation with the kidney community.

Response: We appreciate this feedback from the commenters and the support for setting ambitious goals. While we did not codify these goals in the final rule, we anticipate that we will codify more ambitious achievement goals in subsequent rulemaking. We appreciate the commenter's concern about setting the achievement goal at 80 percent, as well as the suggestion of using 50 percent as the goal. We will take these comments into consideration as we consider any future changes to the achievement benchmark methodology.

Comment: Multiple commenters expressed opposition to the goal of having 80 percent of attributed beneficiaries dialyzing at home and/or receiving a kidney or kidney-pancreas transplant. Commenters stated that there is not empirical or clinical evidence that the 80 percent goal is achievable or desirable in the U.S., or within the timeframe of the Model. Several commenters stated that this goal would lead to inappropriate pressure on beneficiaries to select

home dialysis, when home dialysis may not be their preferred form of renal replacement therapy. A commenter stated that this goal would ensure that ETC Participants are not successful in future MYs. A commenter pointed out that the Regulatory Impact Analysis for the proposed ETC Model projected a conservative growth rate in home dialysis and no growth in transplantation, which contradicts the 80 percent goal. A commenter pointed out that without significant increases in organ availability, it would not be possible for ETC Participants to achieve increases in the transplant rate over the duration of the Model necessary to achieve the 80 percent goal. A commenter stated that CMS should raise achievement benchmarks over the duration of the Model at a rate that is reasonable in relation to historic performance.

Response: We clarify that, as described in the proposed rule, the 80 percent goal would be the target for receiving the highest payment adjustment in the final MYs of the Model. However, any changes to the achievement benchmark methodologies for the later MYs of the Model would be made through subsequent rulemaking. We appreciate this feedback from commenters about the feasibility of the goal we are considering for MY9 and MY10 and will take these comments into consideration as we consider any future changes to the achievement benchmark methodology.

Comment: A commenter stated that CMS should propose all benchmarks through notice and comment rulemaking. A commenter suggested that the achievement benchmarks not be communicated to ETC Participants in advance of the MY to which they apply, in order to avoid a "performance floor" effect in which ETC Participants aim to meet only the minimum necessary performance.

Response: We proposed the achievement benchmark methodology for the initial MYs of the Model in the proposed rule, which we are finalizing with modification in this final rule, and

will establish any changes to these benchmarking methodologies through notice and comment rulemaking. However, in order to provide achievement benchmarks for each MY that reflect changing rates of home dialysis and transplant in a timely manner, we do not intend to propose the benchmarks themselves through rulemaking. Rather, we will use the methodologies finalized through rulemaking to calculate the applicable achievement benchmark in advance of each MY. We do not believe that it would be fair to ETC Participants not to announce achievement benchmarks in advance of the period to which those benchmarks apply and therefore decline to adopt the commenter's suggestion that benchmarks should not be communicated to participants in advance of the MY.

Comment: A commenter stated that CMS should consider geographic and socioeconomic factors that impact home dialysis and transplant rates when establishing achievement benchmarks.

Response: We appreciate the feedback from the commenter, and recognize that there is variation in rates of home dialysis and transplantation by region and by socioeconomic status. Were we to make adjustments to account for these factors, we would do so in the risk adjustment methodology for the home dialysis rate and transplant rate, rather than by adjusting the achievement benchmarks for each ETC Participant such that we would be able to provide one set of general achievement benchmarks rather than achievement benchmarks specific to particular regions or populations. In section IV.C.5.c.(3) of this final rule, we discuss the risk adjustment methodology for the ETC Model.

Comment: Several commenters supported the proposed inclusion of improvement scoring, but opposed our proposal that ETC Participants cannot obtain full points on the basis of improvement scoring. Several commenters stated that it would be inappropriate to limit ETC

Participants' ability to achieve the highest score based on improvement scoring, particularly because the proposed achievement benchmarks would not account for regional variation in home dialysis rates and transplant rates. A commenter pointed out that ETC Participants that improve significantly on the home dialysis rate may nonetheless not receive an upward payment adjustment if their home dialysis rates are below the 50th percentile achievement benchmark or their transplant rates are not above the 50th percentile achievement benchmark. Several commenters recommended changing the improvement scoring methodology to provide greater recognition of improvement over time. In particular, commenters recommended that improvement greater than 10 percent be awarded two points.

Response: We appreciate the feedback from these commenters, and acknowledge the importance of incentivizing improvement over time. However, as stated in the proposed rule and previously in this final rule, we proposed not to award full points for improvement for consistency with other CMS programs and initiatives employing similar improvement scoring methodologies. The ETC Model is designed to focus on outcomes. While improvement is laudable and deserving of recognition through improvement scoring, awarding maximum points for improvement scoring is inconsistent with the Model's focus. As such, we will award full points for achievement scoring only.

Comment: A commenter raised concerns that the proposed construction of the MPS places greater weight on home dialysis rates, and therefore gives ETC Participants a greater incentive to improve rates of home dialysis than transplantation rates, when the goal of the Model should be to ensure that all appropriate ESRD Beneficiaries receive transplants. A commenter stated that the proposed approach for weighting home dialysis rates and transplant rates in calculating the MPS penalizes small ESRD facilities that cannot develop and maintain

home dialysis programs. A commenter stated that, given how little control ESRD facilities have over who receives a kidney transplant, the inclusion of the transplant rate as one third of the MPS does not accurately reflect dialysis provider efforts or performance.

Response: We appreciate the feedback from commenters on the relative weights of the home dialysis portion and the transplant portion of the MPS. We disagree that the goal of the Model should be to ensure that all appropriate ESRD Beneficiaries receive transplants, as the stated goal is to maintain or improve quality and reduce Medicare expenditures through increased rates of home dialysis and transplants. As we stated in the proposed rule, we considered making the home dialysis rate score and the transplant rate score equal components of the MPS, to emphasize the importance of both home dialysis and transplants as alternative renal replacement therapy modalities. However, we recognized that transplant rates may be more difficult for ETC Participants to improve than home dialysis rates, due to the limited supply of organs and the number of other providers and suppliers that are part of the transplant process. The transplant portion of the MPS is now based on performance on the transplant rate calculated as the sum of the transplant waitlist rate and the living donor transplant rate, as described in sections IV.C.5 and IV.C.5.c.(2) of this final rule, which addresses the commenter's concern that the transplant rate does not accurately reflect ESRD facility performance due to factors outside of their control, given that the main limiting factor is the availability of deceased donor organs. Despite this change to the transplant portion of the MPS, we continue to believe that the transplant waitlist and living donor processes involve similar challenges for ETC Participants as the transplant process overall, including the number of other providers and suppliers that are part of the transplant process. Therefore, we continue to believe that it is appropriate that the home

dialysis rate constitute two thirds of the MPS and that the transplant rate constitute one third of the MPS.

Comment: Several commenters recommended that CMS use the benchmarking and scoring methodology used by the ESRD QIP for purposes of the MPS calculation. These commenters stated that ESRD facilities are familiar with these methodologies, and that using them in this Model would make the two initiatives more consistent with each other. A commenter recommended that CMS adapt the quality benchmarking and scoring methodology used by the CEC Model for purposes of the MPS calculation under the Model.

Response: While we acknowledge that ESRD facilities are familiar with the ESRD QIP benchmarking and scoring methodologies, we do not believe these methodologies are well suited to this Model. The ETC Model is designed to test the ability of the Model's payment adjustments to improve or maintain quality while reducing costs through increased rates of home dialysis and transplantation. The benchmarking methodology for the ETC Model must be designed with this goal in mind. While the ESRD QIP performance standard setting methodology substitutes performance standards from previous years if those performance standards are higher than the performance standards that would otherwise apply, it does not ensure escalating performance standards over time. Rather, the ESRD QIP performance standard setting methodology ensures that performance standards do not decrease over time. As stated in the proposed rule and elsewhere in this final rule, we may consider increasing the achievement benchmarks used under this Model for future MYs. Any such changes would be made through future rulemaking. While we may consider increasing the performance standards, we do not intend to adopt a policy to specifically prevent that achievement benchmarks do not decrease. Additionally, Managing Clinicians are not subject to the ESRD QIP, and therefore may not be

familiar with the ESRD QIP methodology. We believe it is important to maintain consistency within the ETC Model for the two types of ETC Participants – namely ESRD facilities and Managing Clinicians. We point out that we are using the same benchmarking and scoring methodology as the one used by the CEC Model for scoring quality performance.

After considering public comments, we are finalizing our proposed provisions on the benchmarking and scoring methodology in our regulation at § 512.370(a), with modification. Specifically, while we proposed to apply our proposed achievement benchmark policy only for MY1 and MY2, in response to public comments, we will apply the achievement benchmarking methodology we are finalizing in this final rule for MY1 (January 1, 2021 to December 31, 2021) and MY2 (July 1, 2021 to June 30, 2022), and for subsequent MYs, if not first modified by subsequent rulemaking. We are also finalizing our proposal to define the "Benchmark Year" as the 12-month period of data that begins 18 months prior to the start of a given MY from which data is used to construct benchmarks against which to score an ETC Participants achievement and improvement on the home dialysis rate and transplant rate for the purpose of calculating the ETC Participant's MPS in our regulation at § 512.310. In addition, we are making a technical change to capitalize the term "Benchmark Year" in the final rule.

e. Performance Payment Adjustments

We proposed that CMS would make upward and downward adjustments to payments for claims for dialysis and dialysis-related services, described in the proposed rule and in section IV.C.5.e of this final rule, submitted by each ETC Participant with a claim through date during the applicable PPA period based on the ETC Participant's PPA. We proposed that the magnitude of the potential positive and negative payment adjustments would increase over the PPA Periods of the ETC Model. The magnitude of the PPAs were designed to be comparable to the MIPS

payment adjustment factors for MIPS eligible clinicians, as described in the proposed rule and in sections IV.C.5.e.(1) and IV.C.5.e.(2) of this final rule. Specifically, the PPAs were designed to be substantial enough to incentivize appropriate behavior without overly harming ETC Participants through reduced payments. The payment adjustments proposed for the ETC Model would start at the same 5 percent level in 2020 as the MIPS payment adjustment at 42 CFR 414.1405(c). As discussed in the proposed rule, the PPAs proposed for the ETC Model were also designed to increase over time and to be asymmetrical—with larger negative adjustments than positive adjustments—in order to create stronger financial incentives.

As we noted in the proposed rule, CMS believes that downside risk is a critical component of this Model in order to create strong incentives for behavioral change among ETC Participants. We proposed that the negative adjustments would be greater for ESRD facilities than for Managing Clinicians, in recognition of the ESRD facilities' larger size and ability to bear downside financial risk relative to individual clinicians. As noted in the proposed rule, we believe that the exclusion of ESRD facilities that fall below the low-volume threshold described in the proposed rule and in section IV.C.5.f.(1) of this final rule would ensure that only those ESRD facilities with the financial capacity to bear downside risk would be subject to application of the Facility PPA.

The following is a summary of the comments received on the proposed PPA and our responses.

Comment: A commenter expressed support for our proposal to subject Managing Clinicians to less downside risk than ESRD facilities. A commenter recommended that CMS not apply a negative PPA to ESRD facility home dialysis treatments, even if an ESRD facility earns a negative PPA. The same commenter recommended that CMS remove negative payment

adjustments from the Model altogether, and instead create upside financial incentives for the more than 50 percent of ESRD facilities that currently do not offer home dialysis. Another commenter recommended that CMS apply any negative PPA amount only to in-center treatment payments, and not to home dialysis treatment or home training payments.

Response: We thank the commenters for their feedback. CMS believes that negatively adjusting home dialysis claims is appropriate when an ETC Participant earns a negative PPA, just as CMS believes it is appropriate to positively adjust home dialysis claims when an ETC Participant earns a positive PPA. As discussed in the proposed rule, the PPA is designed to be substantial enough to provide an incentive robust enough to spur positive behavior change without overly harming ETC Participants through reduced payments.

CMS disagrees that eliminating the negative payment adjustment or subjecting ESRD facilities that currently do not furnish home dialysis to upside financial incentives only would be appropriate given the goals of the Model. Specifically, CMS intends for the ETC Model to both encourage ESRD facilities who do not currently offer home dialysis to establish home dialysis programs, and for ESRD facilities who currently do offer home dialysis to increase the provision of these services. The proposed PPA accomplishes this goal by holding all ESRD facilities accountable for their rates of home dialysis, which CMS believes provides a powerful incentive to establish successful home dialysis programs. We further believe that imposing the HDPA only, or a similar upside financial incentive, to ESRD facilities that do not currently provide home dialysis would not provide a strong enough incentive to create the behavior change CMS seeks in implementing this Model.

In addition, CMS believes that negatively adjusting claims for in-center dialysis only would not produce a sufficient incentive to encourage the behavior change that the Model is designed to produce.

Comment: Many commenters expressed concerns about our proposal to apply significant downside risk for MY1, reasoning that ETC Participants would not have sufficient time to build out a clinical model and the necessary infrastructure to establish or build upon a home dialysis program before being subject to downside financial risk for their rates of home dialysis. Several commenters recommended that CMS delay implementing the PPA for one year. Other commenters recommended that CMS delay implementing the PPA for two years. Those commenters recommending that the PPA be delayed asserted that such a change would allow more time for ETC Participants to receive positive adjustments from the HDPA and ensure that ETC Participants would have access to performance data before being subjected to downside risk. Other commenters asserted that delaying the implementation of the PPA would better allow ETC Participants to build infrastructure, gather necessary resources and equipment, and spread out the potential for financial losses, without risking closure of ESRD facilities and possibly limiting patients' access to care, particularly in urban and rural areas where ESRD facility margins are low and housing instability rates are high. Some commenters recommended that CMS delay implementing downside risk related to transplant until CMS can learn from the many comments submitted in response to the request for information in the CY 2020 Hospital Outpatient Prospective Payment System proposed rule (84 FR 39398) related to OPOs and transplant centers (84 FR 39597).

Response: CMS believes that applying downside financial risk via the PPA, as proposed, is more appropriate than the alternatives suggested by the commenters. CMS believes it is

important to apply downside risk at the beginning of the Model to create strong incentives for behavior change. As described in the proposed rule and earlier in this final rule, CMS carefully considered the timeline for applying the HDPA and the PPA, and CMS continues to believe that the proposed schedules of each optimally balances the timing and magnitude of the process-based incentive, the HDPA, with the outcome-based incentive, the PPA. Further, the PPA starts at its lowest point while the HDPA starts at its highest point, which gives ETC Participants the time to build out their clinical models and necessary infrastructure to establish or build upon their home dialysis programs. While CMS understands the commenters' view that delays in the application of the PPA would allow ETC Participants more time to take all steps necessary to increase provision of home dialysis, CMS intends for the ETC Model to incent behavior change, and CMS continues to believe that the proposed PPA and HDPA schedule best accomplishes that goal.

Regarding the comments that CMS can learn from the comments submitted in response to the request for information in the CY 2020 Hospital Outpatient Prospective Payment System proposed rule (84 FR 39398) related to OPOs and transplant centers (84 FR 39597), CMS will not change the PPA policy in this final rule based on those comments, but those comments may inform future policy changes under the Model.

Comment: A commenter that supported a delay in implementing downside financial risk under the Model recommended that CMS implement a transplant bonus to incentivize ETC Participants and other stakeholders to implement new programs and processes needed to support transplant rate growth.

Response: CMS disagrees with the recommendation to implement a transplant bonus in the ETC Model. CMS believes that the PPA sufficiently rewards high performing ETC

Participants for successfully increasing their transplant waitlisting rate and living donor transplant rate, which may ultimately result in higher rates of kidney transplants. Further, ETC Participants may simultaneously participate in the KCC Model, which includes a kidney transplant bonus payment. It is likely that at least some ETC Participants will also participate in the KCC Model, such that implementing a kidney transplant bonus payment under the ETC Model would present the risk of "double paying" ETC Participants for successful transplants. In addition, using distinct payment methodologies in the KCC Model, which has a kidney transplant bonus payment, and the ETC Model, which does not, will better allow CMS to determine the effectiveness of a transplant bonus in incentivizing support and care for beneficiaries through the kidney transplant process, including after transplantation, as CMS will be able to test the effects of different payment methodologies under the two models as well as the effects of overlapping incentives.

Comment: A commenter expressed support for the ETC Model's two-sided risk structure. Another commenter expressed general support for both the Clinician PPA and Facility PPA.

Response: We appreciate the feedback and support from the commenters.

Comment: Several commenters expressed concern that the PPA could have unintended consequences, including ESRD facility closure, reduced patient choice, reduced quality of care for beneficiaries, and/or beneficiaries who receive in-center dialysis being required to travel longer distances to receive treatment. Some of these commenters articulated specific reasons why they expected the PPA would result in such unintended consequences, such as smaller entities needing to expend substantial capital to prepare for the Model, hire nephrology nurses, build or expand training space, and increase administrative capabilities. A few of these

commenters expressed concern that the PPA could lead to facility closures for small, independent, and/or rural ESRD facilities, which the commenters suggested are less able than LDOs to absorb financial losses that may result from the application of the PPA. A commenter expressed concern that the PPA would destabilize the Medicare ESRD benefit, which the commenter asserted is already underfunded. Some commenters expressed concern that potential for downside risk due to the application of the PPA would incentivize ETC Participants to push ESRD Beneficiaries to home dialysis modalities even when it is not clinically or socially appropriate. One such commenter identified housing insecurity and social isolation as social factors that may make a beneficiary ill-suited for home dialysis, and recommended that CMS consider social and clinical factors in determining the magnitude of an ESRD facility's PPA.

Response: CMS disagrees with the comments expressing concern that the PPA will cause ESRD facility closure, reduce patient choice, reduce quality of care, and/or force ESRD Beneficiaries to travel longer distances to receive treatment. The Model aims to increase choice by addressing a notable lack of home dialysis provision, and thus increase ESRD Beneficiary choice among renal replacement modalities and, in many cases, eliminate the commutes ESRD Beneficiaries must currently make to receive treatment in center. CMS also disagrees with comments expressing concern that the PPA will especially harm small, independent, and/or rural ESRD facilities, as opposed to LDOs, since the PPA uses percentages rather than absolute figures in making its adjustments. While LDOs are larger and, as a result, may be better able to absorb financial losses, an LDO and a non-LDO who perform equally poorly will face proportionate reductions in Medicare reimbursement under the Model, and vice versa. Moreover, even if the proposed PPA would have the unintended consequences cited by commenters, as discussed later in this final rule, CMS is finalizing a reduction in the magnitude of the Clinician

PPA and Facility PPA in response to the comments received. CMS also disagrees that the proposed PPA would incent ETC Participants to push ESRD Beneficiaries into clinically or socially inappropriate modalities. CMS believes that ESRD facilities and Managing Clinicians alike will continue to act in their patients' best interest, and will respond to the Model's financial incentives, including the PPA, with positive behavior change and creativity in appropriately increasing beneficiary access to home dialysis while being mindful of social issues, such as social isolation.

Comment: A few commenters expressed concern that the proposed PPA appeared to be designed to reduce Medicare payments to ESRD facilities and Managing Clinicians over the duration of the Model. One such commenter expressed opposition to using the ETC Model to cut Medicare payments, reasoning that ETC Participants would need to make increased investments to achieve the delivery system reform that CMS envisions, which would be more difficult with less money. A few commenters recommended that CMS proceed with a budget-neutral or budget-saving model. One such commenter recommended that a budget-neutral or budget-saving model could provide positive incentives and resources for ESRD facilities to increase their provision of home dialysis and transplant-related services, while reducing the total cost of care to Medicare in the long run by generating savings through improved care quality. Other commenters recommended that CMS eliminate the downside risk in the proposed PPA and provide only bonus payments. A few commenters expressed concern that the proposed PPA was set arbitrarily or without a rationale for its magnitude, and/or that CMS failed to provide an articulated and substantial defense of the magnitude of the PPA under the Model. One such commenter characterized the PPA as reducing Medicare payments to ESRD facilities and

Managing Clinicians every year, even if those ESRD facilities and Managing Clinicians improve their performance.

Response: Congress established the Innovation Center to design and test innovative payment and service delivery models, like this ETC Model, that are expected to reduce Medicare expenditures while preserving or enhancing the quality of care. While CMS understands the commenters' concerns that moving toward more home dialysis therapy may require investments on the part of ETC Participants, the Model provides higher payments to those ETC Participants who produce results. Regarding the commenters' suggestion that CMS proceed with a budget-neutral or budget-saving model, CMS expects the ETC Model will be a budget-saving model. Specifically, CMS anticipates that the Model will reduce Medicare expenditures, and will likely generate long-term cost savings by reducing the total costs of care, just as the commenter suggested. Regarding the rationale for the magnitude of the PPAs, CMS proposed the magnitude of the Facility PPA and Clinician PPA after careful consideration, hoping to provide a robust incentive to drive significant behavior change among ETC Participants without causing harm to beneficiaries. As described later in this final rule, CMS is reducing the magnitude of the PPAs in response to comments received, which should lessen the concerns expressed by commenters that the PPA will impose too much downside risk on ETC Participants. Finally, CMS disagrees with the comments recommending that CMS either eliminate the downside risk of the PPA but keep the upward adjustment or simply eliminate the PPA altogether. The PPA, by providing meaningful downside risk, represents the most important incentive in the Model for encouraging ESRD facilities and Managing Clinicians to increase the volume of home dialysis services and transplants.

Comment: Several commenters expressed concern over the proposed magnitude of the PPA, especially the magnitude of the potential downward adjustments from the PPA. Some commenters recommended that CMS reduce the magnitude of the PPA as compared to what was proposed. A commenter recommended that CMS reduce the downward payment adjustments for the initial MYs to encourage ETC Participants to commit resources and make early investments in infrastructure needed to succeed in the Model. A commenter recommended that CMS modify the PPA such that potential upward adjustments exceed potential downward adjustments. Another commenter expressed concern over the proposed magnitude of the negative PPA adjustment given the commenter's belief that the home dialysis rate and transplant rate measures are often unrelated to providers' and suppliers' actual rates of performance. Other commenters offered more concrete alternatives. A commenter recommended that CMS reduce the Facility PPA adjustments from +10 percent and -13 percent for MY9 and MY10 to +2.75 percent and -3.25 percent for MY9 and MY10, reasoning that these lower margins are similar to those used in ESRD QIP, which the commenter believed has been successful in driving behavior. Other commenters similarly urged CMS to align the magnitude of the PPA adjustments to that seen in the ESRD QIP. Two commenters recommended that the negative PPA adjustment be limited to a maximum of -2 percent, one of whom viewed as aligning with the ESRD QIP, and other commenters expressed a belief that the -2 percent penalty from the ESRD QIP has produced results. One of these two commenters also recommended that this reduction to the negative PPA adjustment could be accompanied by a corresponding reduction in the positive PPA adjustment. Another commenter recommended that CMS implement a payment methodology similar to that used in the ESRD QIP, wherein attainment and improvement would be determined using a

method like that used in the ERSD QIP rather than based on performance relative to Comparison Geographic Areas or the ETC Participant's own historical performance.

Response: CMS understands the commenters' concern about the magnitude of the PPA, and specifically the downside risk of the PPA. After taking into consideration these comments, CMS also agrees that the proposed magnitudes of the Facility PPA and Clinician PPA were higher than necessary to achieve the Model's goals. However, CMS believes that they were not much higher than necessary. Thus, while CMS is reducing the magnitude of the PPAs in response to comments received, which should lessen the concerns expressed by commenters that the PPA will impose too much downside risk on ETC Participants, CMS declines to adopt the specific alternatives suggested by the commenters. First, CMS notes that the PPA adjustments are structured differently from the ESRD QIP adjustments in that an ETC Participant can receive a positive PPA, whereas the ESRD QIP adjustments do not offer the possibility of a positive adjustment to facilities (which are the only entities that can participate in the program). Second, commenters' recommendations that CMS reduce the magnitude of the PPA adjustments to as low as +2.75 percent/-3.25 percent (or lower) would not provide the level of incentive to increase home dialysis and transplant rates that CMS sees as necessary to effectuate meaningful behavior change. The PPA amounts that CMS is finalizing in this rule optimally balance CMS's interests in achieving the Model's goals while not imposing too much financial risk on ETC Participants. The PPA amounts begin at around the same level of the payment adjustments under MIPS (which, for 2020, generally are +/-5 percent subject to a scaling factor), and then gradually increase in magnitude over time. CMS believes that generally following the MIPS payment adjustment amounts in PPA Period 1 of the ETC Model will provide an initial incentive amount that some ETC Participants have become accustomed to under MIPS, and thus which should be

manageable, before the magnitude of the PPA gradually increases. The financial risk imposed on ETC Participants by the PPA will be incremental given this gradual increase, and will eventually provide a stronger incentive than that currently offered under MIPS or the ESRD QIP program, but without asking ETC Participants to take on the same level of risk they might under another model tested under section 1115A of the Act, such as the KCC Model. For example, under the CMS Kidney Care First (KCF) option of the KCC Model, KCF Participants that perform poorly in terms of quality and utilization may receive a downward adjustment of up to 20 percent to certain payments under the model.

Comment: Several commenters recommended that CMS redesign the PPA such that the ETC Model is an Advanced APM. Another commenter who recommended that CMS eliminate the PPA altogether reasoned that nephrologists who are MIPS eligible clinicians already participate in MIPS, which subjects those nephrologists to positive or negative payment adjustments based on performance, and that unless the ETC Model is redesigned to qualify as an Advanced APM, such nephrologists will be subjected to two uncoordinated pay-for-performance initiatives. Two commenters recommended that CMS exempt Managing Clinicians participating in the ETC Model from MIPS.

Response: We appreciate the recommendations from the commenters, but we decline to adopt either. We received many comments expressing concern about the magnitude of the PPA, and nearly as many comments recommending that we reduce the magnitude, especially the negative magnitude, of the PPA. We have responded to those comments by modifying the proposed PPA such that its magnitude is reduced, and we find this change to be most appropriate in light of the comments received globally. Modifying this Model to be an Advanced APM would require that we subject ETC Participants to significant downside risk starting in MY1,

which we believe would put many ETC Participants in a difficult financial position. Instead, we believe that adjusting payments by the HDPA only during the first two MYs and then introducing the PPA adjustments is the most appropriate design given the Model's articulated goals and the comments received. Regarding the recommendation that CMS exempt Managing Clinicians who are ETC Participants from MIPS, it is not clear that the Innovation Center has the authority to categorically exempt any eligible clinicians, including Managing Clinicians as that term is defined for purposes of this Model, from MIPS. Moreover, even if CMS had the authority to exempt Managing Clinicians from MIPS, CMS believes this would undermine MIPS. MIPS provides important incentives based on, among other things, performance on quality and cost measures that this Model does not. This Model is not intended to replace MIPS, but instead to place emphasis on increasing rates of home dialysis and transplants.

After reviewing public comments, we are finalizing our general proposals regarding the Performance Payment Adjustment, with modifications. CMS will modify the proposed schedule for the Facility PPA and Clinician PPA in our regulation at § 512.380 in accordance with the revised start date for the payment adjustments under the ETC Model, described in section IV.C.1 of this final rule. In addition, after reviewing the comments regarding the proposed magnitude of the PPA amounts, we are reducing the magnitude of the PPA amounts. Specifically, relative to the magnitude of the PPA amounts described in the proposed rule, CMS is reducing the magnitude of the maximum PPA amounts each PPA period by 2 percent. We chose to reduce the PPA amounts by 2 percentages points in response to commenter feedback that the proposed PPA amounts were too high, and to more closely align the finalized PPA amounts with the payment adjustments under MIPS, which generally will be +/-7% in 2021 and +/-9% in 2022, subject to a

scaling factor. The specific final magnitudes of the Facility PPA and the Managing Clinician PPA are discussed in sections IV.C.5.e.(1) and IV.C.5.e.(2) of this final rule.

(1) Facility PPA

For ESRD facilities that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we proposed to adjust certain payments for renal dialysis services by the Facility PPA. Specifically, we would adjust the Adjusted ESRD PPS per Treatment Base Rate for claim lines with Type of Bill 072x, where the type of facility code is 7 and the type of care code is 2, and for which the beneficiary is 18 or older for the entire month and where the claim through date is during the applicable PPA Period as described in proposed § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods). We explained in the proposed rule that facility code 7 paired with type of care code 2 indicates that the claim occurred at a clinic or hospital based ESRD facility. Type of Bill 072X therefore captures all renal dialysis services furnished at or through ESRD facilities. As with the HDPA, we proposed to apply the Facility PPA to claims where Medicare is the secondary payer.

We proposed that the formula for determining the final ESRD PPS per treatment payment amount with the Facility PPA would be as follows:

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

We further proposed that, for time periods and claim lines for which both the Facility HDPA and the Facility PPA apply, the formula for determining the final ESRD PPS per treatment payment amount would be as follows:

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

As discussed previously in sections II.B.1 and IV.C.4.b of this final rule, after we published the proposed rule for the ETC Model, CMS established a new payment adjustment under the ESRD PPS called the TPNIES, which could apply to certain claims as soon as CY 2021. The TPNIES is part of the calculation of the ESRD PPS per treatment payment amount under 42 CFR 413.230 and, like the TDAPA, is applied after the facility-level and patient-level adjustments. We discuss the implications of this change for the Facility PPA later in this section of the final rule.

Table 14 depicts the proposed amounts and schedule for the Facility PPA over the ETC Model's PPA periods, which we proposed to codify in proposed § 512.380.

**TABLE 14: PROPOSED FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE**

| | | Performance Payment Adjustment Period | | | | |
|---|---|---|---|---|---|---|
| | MPS | 1 and 2 | 3 and 4 | 5 and 6 | 7 and 8 | 9 and 10 |
| Facility Performance Payment Adjustment | ≤ 6 | +5.0% | +6.0% | +7.0% | +8.0% | +10.0% |
| | ≤ 5 | +2.5% | +3.0% | +3.5% | +4.0% | +5.0% |
| | ≤ 3.5 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| | ≤ 2 | -4.0% | -4.5% | -5.0% | -6.0% | -6.5% |
| | ≤ .5 | -8.0% | -9.0% | -10.0% | -12.0% | -13.0% |

Also, as we described in the proposed rule and in section IV.C.7.a of this final rule, we proposed that the Facility PPA would not affect beneficiary cost sharing. Beneficiary cost sharing would instead be based on the amount that would have been paid under the ESRD PPS absent the Facility PPA.

The following is a summary of the comments received on the proposed Facility PPA and our responses.

Comment: A few commenters expressed support for the proposal to apply the Facility PPA to claims where Medicare is the secondary payer.

Response: We appreciate this feedback and support from the commenters.

Comment: A few commenters recommended that CMS include condition code 73 in the types of claims adjusted by the Facility PPA, as condition code 73 corresponds to home dialysis training.

Response: We thank the commenters for their feedback. As noted previously in this final rule, condition code 73 is related to training a beneficiary on home dialysis and the inclusion of this code on a claim is one way in which CMS determines the start of Medicare coverage for an ESRD Beneficiary. CMS believes it is unnecessary and inappropriate to include condition code 73 in the payments adjusted by the PPA. First, as noted previously in this final rule, under the ETC Model, CMS seeks to adjust payments for and incentivize the provision of home dialysis services, and not home dialysis training *per se*, and adjusting payments for claims that include condition code 73 may encourage "gaming" wherein ETC Participants train all beneficiaries on home dialysis, regardless of whether the ETC Participant believes home dialysis is the most appropriate modality for the beneficiary. Second, we note that any dialysis claim submitted for an ESRD Beneficiary after the claim containing condition code 73 would be adjusted by the Facility PPA, providing a robust enough incentive to ETC Participants to increase the provision of home dialysis services. Further, if CMS were to adjust claims containing condition code 73 by the Facility PPA and an ESRD facility received a negative Facility PPA, the ESRD facility would face a disincentive to train ESRD Beneficiaries on home dialysis. CMS therefore believes it is most appropriate to exclude claims with condition code 73 from the payments adjusted by the Facility PPA.

Comment: A commenter expressed support for the proposal that the Facility PPA would not affect beneficiary cost sharing, reasoning that beneficiaries included in the Model should not be financially harmed or be discouraged from obtaining care necessary to obtain optimal patient health outcomes. A commenter expressed concern that CMS did not explain in the proposed rule how the PPA would impact ESRD Beneficiary co-insurance.

Response: We thank the commenters for their feedback and support. In the proposed rule, we indicated that the PPA would not affect beneficiary cost sharing. We clarify that cost sharing refers to both the deductible and beneficiary co-insurance. As described in the proposed rule, beneficiary cost sharing would instead be based on the amount that would have been paid under the ESRD PPS absent the Facility PPA.

In addition, we are clarifying that the formula for calculating the final ESRD PPS per treatment payment amount with the Facility PPA will reflect the addition of the TPNIES. Because CMS would apply the TPNIES in the calculation of the per treatment payment amount after the application of the patient-level adjustments and facility-level adjustments, in the same manner as the TDAPA, the TPNIES does not alter the proposed application of the Facility PPA. We had proposed to adjust the Adjusted ESRD PPS per Treatment Base Rate, meaning the per treatment payment amount as defined in § 413.230, including patient-level adjustments and facility-level adjustments and excluding any applicable training adjustment add-on payment amount, outlier payment amount, and TDAPA amount, by the Facility PPA. We are revising the formula for determining the final ESRD PPS per treatment payment amount with the Facility PPA alone and the Facility PPA and Facility HDPA to reflect the addition of the TPNIES be as follows:

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

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

We note that, under our regulations at § 512.355, the PPA will not apply to any claims until the first PPA Period, which starts on July 1, 2022.

After considering public comments, we are finalizing our proposed provisions for the Facility PPA, with modification. Specifically, we are modifying the magnitude of the Facility PPA for each MPS and each PPA Period relative to what we proposed, as described in Table 14.a, and codifying the modified Facility PPA in Table 1 to our regulation at § 512.380. We are finalizing in our regulation at § 512.375(a) that the PPA will adjust the Adjusted ESRD PPS per Treatment Base Rate, as proposed, as well as that the PPA will apply only to claims for beneficiaries 18 years of age or older. While we had proposed to apply the PPA only to claims for which the beneficiary was 18 years of age or older for the entire month of the claim, in the final rule we are modifying the language to state that the beneficiary must be age 18 or older "before the first day of the month," which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old before the first date of a month will be at least 18 years old for that entire month). We are also modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim date of service to identify the

PPA Period in which the service was furnished. We are also modifying the definition of Adjusted ESRD PPS per Treatment Base Rate in our regulation at § 512.310 to reflect that it excludes any applicable TPNIES amount, as discussed previously in section IV.C.4.a and this section of the final rule.

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

| | | Performance Payment Adjustment Period | | | | |
|---|---|---|---|---|---|---|
| | MPS | 1 and 2 | 3 and 4 | 5 and 6 | 7 and 8 | 9 and 10 |
| Facility Performance Payment Adjustment | ≤ 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% |

(2) Clinician PPA

For Managing Clinicians that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we proposed to adjust payments for managing dialysis beneficiaries by the Clinician PPA. Specifically, we would adjust the amount otherwise paid under Part B with respect to the MCP claims on claim lines with CPT® codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, by the Clinician PPA when the claim is submitted by an ETC Participant who is a Managing Clinician and the beneficiary is 18 or older for the entire month and where the claim through date is during the applicable PPA Period as described in proposed § 512.355(c) (Measurement Years and Performance Payment Adjustment Periods). We explained in the proposed rule that CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962 are for ESRD-related services furnished monthly, and indicate beneficiary age (12-19 or 20 years of age or older) and the number of face-to-face visits with a physician or other

qualified health care professional per month (1, 2-3, 4 or more). CPT® codes 90965 and 90966 are for ESRD-related services for home dialysis per full month, and indicate the age of the beneficiary (12-19 or 20 years of age or older). Taken together, these codes are used to bill the MCP for ESRD-related services furnished to beneficiaries age 18 and older, including patients who dialyze at home and patients who dialyze in-center. As with the HDPA, we proposed to apply the Clinician PPA to claims where Medicare is the secondary payer.

Table 15 depicts the proposed amounts and schedule for the Clinician PPA over the ETC Model's PPA periods, which we proposed to codify in proposed § 512.380.

**TABLE 15: PROPOSED CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE**

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

We proposed to adjust the amount otherwise paid under Part B by the Clinician PPA so that beneficiary cost sharing would not be affected by the application of the Clinician PPA. The Clinician PPA would apply only to the amount otherwise paid for the MCP absent the Clinician PPA.

The following is a summary of the comments received on the proposed Clinician PPA and our responses.

Comment: A commenter expressed support for CMS's proposal to apply the Clinician PPA to claims where Medicare is the secondary payer.

Response: We thank the commenter for the feedback and support.

After considering public comments, we are finalizing our proposed provisions for the Clinician PPA, with modification. Specifically, we are modifying the amounts of the Clinician PPA from those proposed, to reduce the magnitude of the Clinician PPA for each MPS and PPA Period relative to what we proposed, as described in Table 15.a, and codifying the modified Clinician PPA in Table 2 to our regulation at § 512.380. We are finalizing that the Clinician PPA will adjust the amount otherwise paid for the MCP as proposed, as well as that the Clinician PPA will only apply to claims for beneficiaries 18 years of age or older. While we had proposed to apply the Clinician PPA only to claims for which the beneficiary was 18 years of age or older during the entire month of the claim, we are changing the language to state that the beneficiary must be at least 18 years of age "before the first date of the month," which is easier for CMS to operationalize and has the same practical effect (that is, a beneficiary who is at least 18 years old on the first date of the month will be at least 18 years old for that entire month). We are modifying which date associated with the claim we are using to determine if the claim occurred during the applicable PPA Period. Whereas we proposed using the claim through date, we are finalizing using the date of service on the claim, to align with Medicare claims processing standards. Specifically, while Medicare claims data contains both claim through dates and dates of service, Medicare claims are processed based on dates of service. Thus, we must use the claim service date to identify the PPA Period in which the service was furnished.

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

| | MPS | Performance Payment Adjustment Period | | | | |
|---|---|---|---|---|---|---|
| | | 1 and 2 | 3 and 4 | 5 and 6 | 7 and 8 | 9 and 10 |
| Clinician Performance Payment Adjustment | ≤ 6 | +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% |
| | ≤ .5 | -5.0% | -6.0% | -7.0% | -8.0% | -9.0% |

f. Low-Volume Threshold Exclusions for the PPA

(1) ESRD Facilities

We proposed excluding ETC Participants that are ESRD facilities that have fewer than 11 attributed beneficiary-years during a given MY from the application of the PPA during the corresponding PPA Period. Each beneficiary-year would be equivalent to 12 attributed beneficiary months, where a beneficiary month is one calendar month for which an ESRD Beneficiary is attributed to an ETC Participant using the attribution methodology described in the proposed rule and in section IV.C.5.b of this final rule, meaning that an ESRD facility must have at least 132 total attributed beneficiary months for a MY in order to be subject to the PPA for the corresponding PPA Period. Under our proposal, a beneficiary year could be comprised of attributed beneficiary months from multiple beneficiaries. We proposed this exclusion threshold to increase statistical reliability and to exclude low-volume ESRD facilities from the application of the Facility PPA. We selected this particular threshold because it is similar to the 11 qualifying patient minimum threshold that the ESRD QIP uses for purposes of scoring certain measures during the performance period. In the proposed rule, we stated that we had considered using the 11 qualifying patients threshold used for purposes of scoring some measures under the ESRD QIP, but due to differences in beneficiary attribution methodologies between the ESRD QIP and the proposed ETC Model, we concluded that using beneficiary-years was more

appropriate for purposes of testing the ETC Model, as the rates proposed for the ETC Model are based on beneficiary-years.

We invited public comment on our proposal for excluding ESRD facilities with fewer than 11 attributed beneficiary-years from the application of the PPA during the applicable PPA Period, as well as the alternatives considered.

The following is a summary of the comments received on the proposed low-volume exclusion from the application of the PPA for ESRD facilities and our responses.

Comment: A commenter expressed opposition to the proposed low-volume exclusion for ESRD facilities, opining that CMS's reasons for proposing the low-volume exclusion for ESRD facilities do not outweigh the need to promote home dialysis to patients of low-volume facilities who want such services. The same commenter recommended that instead of a low-volume exclusion for ESRD facilities, CMS should create a mechanism for small and low-volume ESRD facilities to aggregate their performance to a virtual group to strengthen the ability of these ESRD facilities to perform in the Model. The same commenter expressed concern that excluding ESRD facilities from the application of the PPA based on volume alone may not be sufficiently nuanced to account for ESRD facilities that serve an important access need, and thus serve a relatively high volume of ESRD Beneficiaries, but that are unable to bear downside financial risk.

On the other hand, another commenter expressed concern that the proposed low-volume exclusion for ERSD facilities would cover only a small number of ESRD facilities which operate with narrow profit margins or even narrow losses. The same commenter provided data suggesting of the 353 rural ESRD facilities reporting financial losses in 2017, only 64 of these ESRD facilities would be designated as "low-volume" under the Model and thus be excluded

from the application of the Facility PPA. Another commenter expressed concern that rural ESRD facilities, which often have few insured patients and high numbers of patients with little support at home, will not and cannot perform well in the Model, and may be forced to close, leaving rural beneficiaries without access to care. A commenter recommended that an ESRD facility farther than 20 miles away from the next nearest ESRD facility should not be subjected to negative payment adjustments, but still be able to receive positive payment adjustments, reasoning that if such an ESRD facility performs poorly, it may have to close and cause its patients to travel much farther to receive care. Another commenter suggested that CMS use the ESRD PPS definition of a "low-volume facility" and not apply negative PPA adjustments to those ESRD facilities. Another commenter recommended that CMS still apply positive PPA adjustments to ESRD facilities excluded under the low-volume exclusion, but not subject them to negative PPA adjustments.

Another commenter recommended that CMS broaden the proposed low-volume exclusion for ESRD facilities to exclude from the application of the PPA all low-volume and rural ESRD facilities owned by organizations with 35 or fewer ESRD facilities, unless the ESRD facility voluntarily elects to be subject to the PPA, reasoning that low-volume and rural ESRD facilities are disproportionately less likely to offer home dialysis therapy, and that a substantial number of low-volume and rural ESRD facilities are small and independent providers that operate with negative Medicare margins and lack sufficient resources to make the investments necessary to establish a home dialysis program. The same commenter expressed concern that the current low-volume exclusion policy for ESRD facilities is inadequate to protect beneficiary access to care and prevent further market consolidation. Another commenter recommended that CMS provide an exclusion for low-volume ESRD facilities and for Managing Clinicians

providing services at low-volume ESRD facilities. The same commenter expressed concern that small and independent facilities that have 12 ESRD Beneficiaries (and thus would not be excluded from the application of the Facility PPA under our proposed low-volume exclusion), all of whom are unable or unwilling to receive home dialysis or a transplant, would be forced to close due to the application of the Facility PPA. The same commenter recommended that CMS make its low-volume exclusion based on an attestation that the ESRD facility is a low-volume facility.

Response: We thank the commenters for their feedback. Regarding the comment that the need to promote home dialysis outweighs the reasons CMS cited for proposing the low-volume exclusion for ESRD facilities, we must underscore that statistical reliability is essential for determining whether the financial incentives offered in this Model can significantly alter the provision of home dialysis. Further, CMS hopes that all ESRD facilities, regardless of participation in the ETC Model, will promote home dialysis and educate their patients regarding all renal replacement modalities, including home dialysis modalities. Moreover, creating a virtual group for small and low-volume ESRD facilities, as suggested by the commenter, would be unduly complex operationally, as described previously in this final rule. We are also concerned that it would be difficult to define virtual groups for purposes of the low-volume threshold for ESRD facilities without inadvertently giving either the virtual group, or those ESRD facilities not in the virtual group, an unfair advantage. In addition, as discussed later in this section of the final rule, CMS will calculate the low-volume threshold for ESRD facilities at the level of the aggregation group (as described in our regulation at § 512.365(e)(1)), under which CMS will aggregate all ESRD facilities that are not Subsidiary ESRD facilities with all other ESRD facilities that are not Subsidiary ESRD facilities located within the same HRR.

Because CMS is not aggregating independent or ESRD facilities that are not Subsidiary ESRD facilities, CMS will apply the low-volume threshold exclusion policy to ESRD facilities that are not Subsidiary facilities at the facility level. As described elsewhere in this final rule, an aggregation group pools the performance of several ESRD facilities in a particular HRR and thus strengthen their ability to perform in the Model. Applying the low-volume threshold exclusion policy at the aggregation group level, as discussed below, allows CMS to more precisely exclude ESRD facilities who may be unlikely to perform adequately under the Model due to low historical beneficiary attribution, while bolstering statistical reliability. CMS believes that this policy sufficiently addresses the concerns the commenter intended to address in recommending the virtual group policy.

While we agree with the commenter that volume alone may not be sufficiently nuanced to account for all ESRD facilities that serve an important access need but are unable to bear downside financial risk, part of CMS's reasoning for pursuing the low-volume exclusion is to bolster statistical reliability, which ultimately benefits ETC Participants. Similarly, even if CMS's proposed low-volume exclusion does not exclude from the application of the PPA all ESRD facilities operating with a near-zero or negative profit margin, (1) CMS reiterates its need to assure statistical reliability in the calculation of the PPA, and (2) the ETC Model offers such ESRD facilities an opportunity to increase revenue through the payment adjustments, depending upon their performance. Similarly, CMS believes that the commenter's concerns about rural ESRD facilities are unfounded, as the home dialysis rate measure captures the percentage of an ESRD facility's ESRD Beneficiaries who use a home dialysis modality. ESRD facilities currently operating with thin profit margins could see those margins grow by investing capital in creating or building upon home dialysis or self-dialysis programs, thus reducing their costs

associated with providing dialysis services in-center multiple days a week and potentially earning them a positive PPA or increasing the magnitude of the PPA earned. Similarly, while rural ESRD facilities may have high numbers of patients without support at home, the Model is designed to incent ESRD facilities to consider how to increase access to home dialysis modalities for their ESRD Beneficiaries, and CMS will be including self-dialysis in the home dialysis rate measure, as discussed elsewhere in this final rule. If an ESRD facility has many ESRD Beneficiaries lacking support at home, such an ESRD facility could prioritize training its ESRD Beneficiaries on self-dialysis rather than home dialysis, which would, like home dialysis, give the beneficiaries greater agency in their treatment and help the ESRD facility improve its performance under the Model. CMS believes that the proposed low-volume exclusion, with the modifications described in this section of the final rule, is sufficient to ensure beneficiary access to care and will not result in market consolidation, and that the Model, through the HDPA, will provide ESRD facilities that are not excluded from the application of the PPA with greater financial resources during the initial years of the Model to establish or build upon home dialysis programs, which will help position ESRD facilities to earn a higher PPA. While it is possible that an ESRD facility could have 12 ESRD Beneficiaries, all of whom are not appropriate candidates for either home dialysis or a transplant, CMS finds this situation to be highly unlikely. However, if an ESRD facility found itself in that situation, the ESRD facility could still perform well under the Model by focusing attention on educating its ESRD Beneficiaries on self-dialysis and transplantation, and encouraging and helping its ESRD Beneficiaries to register for a transplant waitlist.

Regarding the comment that CMS should provide an exclusion for low-volume ESRD facilities, this is what we proposed to do; however, we disagree with the alternative low-volume

thresholds recommended by the commenters. Regarding the comment suggesting that CMS make its low-volume exclusion for ESRD facilities based on an attestation that the facility is low-volume, CMS is concerned that such a policy would lead to gaming and abuse in the context of this Model. While CMS requires attestations from ESRD facilities that qualify as "low volume" under the ESRD PPS, the Model is using a different policy for identifying "low volume" than that used under the ESRD PPS, and operational limitations render attestations and subsequent confirmation by CMS or its Medicare Administrative Contractors (MACs), as is done under the ESRD PPS, unsuitable for this Model. CMS also finds its policy for identifying a low-volume ESRD facility under the Model to be more appropriate than the ESRD PPS definition for purposes of the Model, in light of the goals of the Model and CMS's need for statistically reliable data.

CMS also declines to include the commenter's recommended exclusion for ESRD facilities located more than 20 miles away from another ESRD facility at this time. While CMS understands the commenter's concern, an exclusion of this nature could give rise to gaming, insofar as ETC Participants that are newly building spaces for home dialysis training and self-dialysis could strategically position new ESRD facilities more than 20 miles away from other ESRD facilities. Finally, regarding the comment recommending that CMS apply positive PPAs to ESRD facilities otherwise excluded from the application of the PPA, but exclude such facilities from any negative PPAs, CMS believes this would not produce a strong enough financial incentive for such ESRD facilities to improve home dialysis and, ultimately, transplant rates.

After considering public comments, we are finalizing our proposed provisions on the low volume exclusion for ESRD facilities, with modification. Specifically, in an effort to limit the

scope of the low-volume exclusion in order to promote modality choice with the need for statistical reliability, CMS is modifying its proposal such that, under the ETC Model, CMS will exclude aggregation groups (as described in our regulation at § 512.365(e)(1)) of ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the application of the Facility PPA for the corresponding PPA Period. CMS will similarly exclude ESRD facilities that are not Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the application of the Facility PPA for the corresponding PPA Period. This policy is also consistent with our final policy for assessing ESRD facility performance for purposes of the MPS calculation, which will also occur at the aggregation group level. Because the low-volume threshold determination will generally be made at the aggregation group level (that is, across multiple Subsidiary ESRD facilities), under this final policy, fewer ESRD facilities will be excluded from the application of the Facility PPA as compared to the number that would have been excluded under the policy we proposed. This low-volume exclusion is also narrower than the ESRD PPS definition suggested by the commenter and accordingly better ensures that a greater number of ESRD Beneficiaries will receive the benefit of receiving care from an ESRD facility incentivized by the Model to provide home dialysis services, self-dialysis services, and a robust pathway to transplantation. By contrast, the ESRD PPS definition of "low-volume facility" is an ESRD facility that (1) furnished less than 4,000 treatments in each of the three "cost reporting years…preceding the payment year;" and (2) "[h]as not opened, closed, or received a new provider number due to a change of ownership" in the same time period. 42 CFR 413.232(b). This definition captures a larger number of ESRD facilities than does the low-volume facility provision in this final rule.

We are codifying the modified low-volume threshold for ESRD facilities in § 512.385(a) of our regulation.

(2) Managing Clinicians

We proposed excluding ETC Participants that are Managing Clinicians who fall below a specified low-volume threshold during an MY from the application of the PPA during the corresponding PPA Period. The low-volume exclusion would ensure that we would be adjusting payment based on reliable measurement of Managing Clinician performance. We noted that Managing Clinicians with sufficiently small attributed beneficiary populations may serve unique patient populations, such as children, such that we may not be able to produce statistically reliable transplant rates and home dialysis rates for these Managing Clinicians. We proposed that the low-volume threshold would be set at the bottom five percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinician billed the MCP during the MY. We stated in the proposed rule that we considered using 11 beneficiary-years as the low-volume exclusion for Managing Clinicians, to mirror the proposed exclusion for ESRD facilities. However, we recognized that ESRD facilities and Managing Clinicians are different in that Managing Clinicians are more diverse, as compared to ESRD facilities, in terms of both volume of services furnished to beneficiaries related to receiving dialysis and services furnished that are not related to dialysis. Therefore, we proposed using a percentile-based low-volume exclusion threshold for Managing Clinicians that would help to ensure statistical soundness while recognizing the diversity of the Managing Clinician population. In the proposed rule, we alternatively considered establishing the low-volume threshold based on the bottom five percent of Managing Clinicians who are ETC Participants in the total dollar value of Medicare claims paid. However, as Managing Clinicians are in a variety

of specialties and provide a wide range of services that are paid at a variety of rates, we concluded that a dollar-value threshold was not suitable for purposes of this proposed exclusion.

We invited public comment on this proposal for excluding certain Managing Clinicians from the application of the PPA during the applicable PPA Period based on our proposed low volume threshold, as well as the alternatives considered.

The following is a summary of the comments received on the proposed low-volume exclusion from the application of the PPA for Managing Clinicians and our responses.

Comment: A commenter expressed support for the proposed low-volume exclusion for Managing Clinicians. Another commenter expressed support for the proposed low-volume exclusion for Managing Clinicians, but suggested that CMS give otherwise excluded Managing Clinicians the option to opt in to the application of the PPA under Model.

Response: We thank the commenters for their feedback and support. Regarding the commenter's suggestion that CMS allow otherwise excluded Managing Clinicians to opt in to the application of the PPA under the Model, we decline to adopt this recommendation because Managing Clinicians who are ETC Participants must treat at least a minimum volume of ESRD Beneficiaries in order for CMS to produce statistically reliable transplant rates and home dialysis rates for purposes of calculating the Managing Clinicians' MPS and corresponding Clinician PPA. However, CMS determined, after publishing the NPRM, that the policy described in the NPRM would not exclude Managing Clinicians with adequate precision. In other words, our proposed policy would result in CMS applying the PPA to Managing Clinicians who have far fewer attributed beneficiary years than we expected and need for the purpose of achieving statistical reliability. Accordingly, CMS is modifying its proposal for the Managing Clinician low-volume threshold exclusion, as described below.

After considering public comments, we are modifying our proposed provisions on the low volume exclusion for Managing Clinicians. Specifically, we are changing the low-volume threshold for excluding Managing Clinicians from the application of the PPA during the applicable PPA Period from excluding Managing Clinicians in the bottom five percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years for which the Managing Clinicians billed the MCP during the MY, as proposed, to excluding Managing Clinicians in an aggregation group (as described in our regulation at § 512.365(e)(2)) with fewer than 11 attributed ESRD beneficiary-years during an MY. Determining the low-volume threshold for a Managing Clinician at the aggregation group level conforms to changes CMS made to the ESRD facility low-volume exclusion policy, described above, and also is consistent with our final policy for assessing ESRD facility performance for purposes of the MPS calculation, which will also occur at the aggregation group level. CMS is similarly changing its policy from setting the exclusion level at the bottom five percent of ETC Participants who are Managing Clinicians in terms of the number of beneficiary-years to fewer than 11 attributed ESRD beneficiary years. As with the modified low-volume exclusion policy for ESRD facilities described elsewhere in this section of the final rule, this modified low-volume exclusion policy for Managing Clinicians allows CMS to more precisely exclude groups of ETC Participants that have low historical beneficiary attribution from application of the PPA, while bolstering statistical reliability. CMS noted in the proposed rule that ESRD facilities and Managing Clinicians are different, in that Managing Clinicians are more diverse as compared to ESRD facilities, in terms of both volume of services furnished to beneficiaries related to receiving dialysis and services furnished that are not related to dialysis. While CMS still believes this to be true, CMS determined subsequent to publishing the NPRM that the Managing Clinician low-

volume threshold exclusion policy described in the NPRM would not precisely exclude Managing Clinicians with too few attributed ESRD beneficiary years to obtain statistical reliability. Accordingly, to obtain statistical reliability, CMS must modify its proposal to set the Managing Clinician low-volume threshold exclusion at 132 attributed ESRD beneficiary months, or 11 attributed ESRD beneficiary years. This modification will result in a higher number of Managing Clinicians being excluded from the Model. Finally, CMS is making the change from considering "beneficiary-years" to "attributed ESRD beneficiary-years" to conform to the low-volume threshold exclusion for ESRD facilities, as ESRD facilities will not have attributed Pre-emptive LDT Beneficiaries. We are codifying this low-volume exclusion in § 512.385(b) of our regulation.

g. Notification

Per the PPA schedule, we proposed that payment adjustments would be made during the PPA period that begins 6 months after the end of the MY. This 6-month period would allow for 3 months claims run-out to account for lag in claims processing, and for CMS to calculate and validate the MPS and the corresponding PPA for each ETC Participant. After we calculate ETC Participant MPSs and PPAs, we proposed to notify ETC Participants of their attributed beneficiaries, MPSs and corresponding PPAs. We proposed notification of ETC Participants no later than 1 month before the start of the PPA Period in which the PPA would go into effect. As stated in the proposed rule, we believe this notification period balances the need for sufficient claims run-out to ensure accuracy, as well as sufficient time for MPA and PPA calculation and validation by CMS, with our interest in providing sufficient advanced notification regarding the resulting payment adjustments to ETC Participants.

We proposed to conduct notifications in a form and manner determined by CMS. The following is a summary of the comment received on proposed notifications and our response.

Comment: A commenter expressed concern that providing reports regarding the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period only once per year would be insufficient and would not provide the information necessary for ETC Participants to measure their performance and take corrective action when necessary.

Response: We thank the commenter for the feedback. As described in the proposed rule and previously in this final rule, each PPA Period will be 6 months long and will begin 6 months after the last date of the corresponding MY. As a result, ETC Participants will receive notifications regarding beneficiary attribution, MPS, and PPA twice per year (that is, every six months)—one month prior to each PPA Period. We believe this notification schedule affords CMS the time needed collect data, attribute beneficiaries, calculate the MPS and PPA, validate those calculations, and distribute this information to ETC Participants in accordance with the requirements set forth in this final rule, while protecting the ETC Participant's interest in timely receiving the data, reviewing for suspected errors, and implementing performance improvement strategies for current and subsequent MYs.

After considering the public comment, we are finalizing our proposed notification provision in our regulation at § 512.390(a) without modification.

h. Targeted Review

We noted in the proposed rule that we believe that it would be advisable to provide a process according to which an ETC Participant would be able to dispute errors that it believes to have occurred in the calculation of the MPS. Therefore, we proposed a policy that would permit ETC Participants to contest errors found in their MPS, but not in the ETC Model home dialysis

rate calculation methodology, transplant rate calculation methodology, achievement and improvement benchmarking methodology, or MPS calculation methodology. We noted that, if ETC Participants have Medicare FFS claims or decisions they wish to appeal (that is, Medicare FFS issues experienced by the ETC Participant that occur during their participation in the ETC Model that do not involve the calculation of the MPS), then the ETC Participant should continue to use the standard CMS procedures through their MAC. Section 1869 of the Act provides for a process for Medicare beneficiaries, providers, and suppliers to appeal certain claims and decisions made by CMS.

We proposed that ETC Participants would be able to request a targeted review of the calculation of their MPS. ETC Participants would be able to request a targeted review for certain considerations, including, but not limited to, when: the ETC Participant believes an error has occurred in the home dialysis rate or transplant rate used in the calculation of the MPS due to data quality or other issues; or the ETC Participant believes that there are certain errors, such as misapplication of the home dialysis rate or transplant rate benchmark in determining the ETC Participant's achievement score, improvement score, or the selection of the higher score for use in the MPS. We noted in the proposed rule that the targeted review process would be subject to the limitations on administrative and judicial review as previously described. Specifically, an ETC Participant could not use the targeted review process to dispute a determination that is precluded from administrative and judicial review under section 1115A(d)(2) of the Act and our regulation at § 512.170.

To request a targeted review, we proposed that the ETC Participant would provide written notice to CMS of a suspected error in the calculation of their MPS no later than 60 days after we notify ETC Participants of their MPS, or at a later date as specified by CMS. We

proposed that this written notice must be submitted in a form and manner specified by CMS. The ETC Participant would be able to include additional information in support of its request for targeted review at the time the request is submitted.

We proposed that we would respond to each request for targeted review submitted in writing in a timely manner, and determine within 60 days of receipt of the request whether a targeted review is warranted. We proposed that we would either accept or deny the request for targeted review, or request additional information from the ETC Participant that we would deem necessary to make such a decision. If we were to request additional information from the ETC Participant, we would require that it be provided and received within 30 days of the request. Non-responsiveness to the request for additional information would potentially result in the closure of the targeted review request. If we were to find, after conducting a targeted review, that there had been an error in the calculation of the ETC Participant's MPS, we would notify the ETC Participant within 30 days of the finding. If the error in the MPS were such that it caused us to apply an incorrect PPA during the PPA Period associated with the incorrect MPS, we would notify the ETC Participant and resolve the payment discrepancy during the next PPA Period following notification of the MPS error. We proposed that decisions based on the targeted review process would be final, and there would be no further review or appeal.

In the proposed rule, we considered compressing the duration of the targeted review process such that it could be completed before the PPA Period for which the MPS in question sets the PPA. However, we stated that we believe that this would be an insufficient amount of time for ETC Participants to review their MPS, consider the possibility of a calculation or data error, request a targeted review, and provide additional information to CMS if requested.

The following is a summary of the comment received on the proposed targeted review process and our response.

Comment: We received one comment that 60 days would be insufficient time for ETC Participants to review their MPS, identify potential errors, and request a targeted review from CMS. The commenter suggested 90 days as an alternative.

Response: We thank the commenter for the feedback. After considering the comment, we will adopt a final policy that ETC Participants must provide written notice to CMS of a suspected error in the calculation of their MPS no later than 90 days after we notify ETC Participants of their MPS, or at a later date as specified by CMS. This modification would be an increase from the 60-day period discussed in the proposed rule.

After considering the public comment received, we are finalizing our targeted review proposal in our regulation at § 512.390(b), with modification. As noted previously in this section of the final rule, we are increasing the amount of time that an ETC Participant will have to request a targeted review from 60 days to 90 days after the ETC Participant is notified of their MPS. We are also modifying the regulatory text at § 512.390(b)(1) to specify that the ETC Participant may request a targeted review at a later date as specified by CMS to align with the proposed policy as described in the preamble to the proposed rule. In addition, we are modifying the regulatory text at § 512.390(b)(4) of our regulations to clarify that CMS must resolve any resulting discrepancy in payment that arises from the application of an incorrect PPA in a time and manner determined by CMS, as opposed to during the next PPA Period that begins after the notification of the ETC Participant, as we had proposed. We believe this flexibility will allow CMS to more quickly and effectively resolve PPA payment discrepancies than the more specific time frame described in the proposed rule.

6. Overlap with Other Innovation Center Models and CMS Programs

As proposed, the ETC Model would overlap with several other CMS programs and models, and we sought comment on our proposals to account for overlap:

• ESRD Quality Incentive Program (ESRD QIP) – The ESRD QIP reduces payment to a facility under the ESRD PPS for a calendar year by up to 2 percent if the facility does not meet or exceed the total performance score established by CMS for the corresponding ESRD QIP payment year with respect to measures specified for that payment year. We proposed that the ETC Model's Facility HDPA and Facility PPA would be applied prior to the application of the ESRD QIP payment adjustment to the ESRD PPS per treatment payment amount, as we were proposing that the Facility HDPA and the Facility PPA would adjust the Adjusted ESRD PPS per Treatment Base Rate, as previously discussed in the proposed rule and in section IV.C.4.b of this final rule.

• Merit-based Incentive Payment System (MIPS) – Under section 1848(q)(6) of the Act and 42 CFR 414.1405(e), the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) generally apply to the amount otherwise paid under Medicare Part B with respect to covered professional services furnished by a MIPS eligible clinician during the applicable MIPS payment year. We proposed that the Clinician HDPA and the Clinician PPA in the ETC Model would similarly apply to the amount otherwise paid under Medicare Part B, but would occur prior to the application of the MIPS payment adjustment factors. This was designed to ensure that the MIPS payment adjustment factors would still have a significant weight for Managing Clinicians.

• Kidney Care Choices (KCC) Model[155] – The KCC Model is an optional Innovation Center model for nephrologists, dialysis facilities, transplant providers, and other providers and suppliers that will be focused on beneficiaries with CKD and beneficiaries with ESRD. The KCC Model is scheduled to begin with an implementation period for a portion of 2020 and 2021, with the performance period of the model beginning on April 1, 2021, and continuing through December 31, 2023, with the option for the Innovation Center to extend the model by one or two additional performance years.[156] Thus, the KCC Model will have up to nearly five years of financial accountability overlap with the ETC Model beginning April 1, 2021. We proposed that the types of entities eligible to participate in the KCC Model as Kidney Care First (KCF) practices and Kidney Contracting Entities (KCEs) would be permitted to participate in the KCC Model within regions where the ETC Model would be in effect. We stated in the proposed rule that not allowing these entities to participate as KCF practices or KCEs in the KCC Model within the ETC Model's Selected Geographic Areas would limit participation in the KCC Model, and could prevent a sufficient number of KCF practices or KCEs from participating in the KCC Model, such that the KCC Model would not have sufficient participation to be evaluated. We explained that we believed it was important to test both models in order to evaluate payment incentives inside and outside the coordinated care context. As stated in the proposed rule, the ETC Model would allow for a broader scope of test due to its mandatory nature across half the country, while the KCC Model will test the effects on outcomes of higher levels of risk for a self-selected group of participants. We proposed that payment adjustments under the ETC

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[155] The KCC Model was referred to as the Comprehensive Kidney Care Contracting and Kidney Care First Models in the proposed rule, but has since undergone a rebranding. References in this final rule have been updated to reflect the name of the model in use as of the date of the publication of the final rule.

[156] This timing has been updated from what appeared in the proposed rule to reflect the current anticipated timeline for this model as of the date of publication of this final rule.

Model would be counted as expenditures for purposes of the KCC Model. We designed both models to include explicit incentives for participants when beneficiaries receive kidney transplants; and we proposed that a participant in both models would be eligible to receive both types of adjustments under the ETC Model (the HDPA and PPA), as well as a kidney transplant bonus payment under the KCC Model. Kidney transplants represent the most desired and cost effective treatment for most beneficiaries with ESRD, but providers and suppliers may currently have insufficient financial incentives to assist beneficiaries through the transplant process because dialysis generally results in higher reimbursement over a more extended period of time than a transplant.[157] As a result, we stated that we believed it would be appropriate to test incentives in both the ETC Model and KCC Model simultaneously to assess their effects on the transplant rate.

• Comprehensive ESRD Care (CEC) Model – The CEC Model is a voluntary model for ESRD dialysis facilities, nephrologists, and other providers and suppliers that focuses on beneficiaries with ESRD. We noted in the proposed rule that the CEC Model will end on December 31, 2020, and therefore, would overlap for one year with the proposed ETC Model, though the models will now only overlap for three months from January 1, 2021 to March 31, 2021 due to the updated timeline for the ETC and CEC Models. We proposed that ETC Participants could be selected from regions where there are participants in the CEC Model. Given the national distribution of CEC ESCOs, we noted in the proposed rule that we do not believe the overlap between the two Models would impact the validity of the ETC Model test, as ESCOs would be equally likely to be located in Selected Geographic Areas as in Comparison

[157] Abecassis M, Bartlett ST, Collins AJ, Davis CL, Delmonico FL, Friedewald JJ et al. Kidney transplantation as primary therapy for end-stage renal disease: a National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (NKF/KDOQITM) conference. Clinical Journal of the American Society of Nephrology. 2008;3(2):471–80.

Geographic Areas, creating a net neutral effect. We also stated that we do not believe that the proposed ETC Model would significantly affect the CEC Model because the payment incentives under the ETC Model would be smaller in 2020 when the CEC Model is active and because the CEC Model is focused on total cost of care, the majority of which is non-dialysis care. In the proposed rule we noted our belief that not allowing CEC ESCOs to participate in the CEC Model within the ETC Model's Selected Geographic Areas would require either terminating ESCOs that participate in the CEC Model in the ETC Model's Selected Geographic Areas, which we believe would negatively impact the CEC Model test, or altering ETC Model randomization to exclude regions in which CEC ESCOs are participating in the CEC Model, which we believe would negatively impact the ETC Model by interfering with the proposed randomization.

• All other APMs with Medicare– For other Medicare APMs, such as the Medicare Shared Savings Program or the Next Generation ACO Model, that focus on total cost of care, we proposed that any increase or decrease in program expenditures that is due to the ETC Model would be counted as program expenditures to ensure that the Medicare APM continues to measure the total cost of care to the Medicare program. The Medicare Shared Savings Program regulations include a policy for addressing payments under a model, demonstration, or other time-limited program. Specifically, in conducting payment reconciliation for the Medicare Shared Savings Program, CMS considers "individually beneficiary identifiable final payments made under a demonstration, pilot, or time limited program" (see, for example, § 426.610(a)(6)(ii)(B)). In the proposed rule we stated our belief that this existing policy sufficiently addresses overlaps that would arise between the Medicare Shared Savings Program and the proposed ETC Model. We also stated that CMS would review any other models where

this form of reconciliation may not be possible and make an assessment as to what changes, if any, may be necessary to account for the effects of testing the ETC Model.

We invited public comments on our proposals to account for overlaps with other CMS programs and models.

The following is a summary of the comments received on overlaps between the ETC Model and other CMS programs and models, and our responses.

Comment: We received several comments urging the Innovation Center to test potential methods to increase home dialysis and transplant rates solely through a voluntary model or coordinated care framework, rather than with the proposed framework of the ETC Model.

Response: We appreciate the feedback. However, as discussed in section IV.C.3.a of this final rule, we believe that both voluntary and mandatory frameworks can be used by the Innovation Center to test models and can accomplish different goals. As described in the proposed rule and previously in section IV.C.3.a of this final rule, for the ETC Model, we believe that a mandatory framework is critical to avoid selection bias and to ensure a broad representation of participants. Concurrent with the ETC Model test, we plan to test the voluntary KCC Model to test the efficacy of coordinated care for beneficiaries with advanced kidney disease.

Comment: We received several comments urging CMS to exclude from the ETC Model beneficiaries aligned to coordinated care models, particularly beneficiaries aligned to participants in the CEC Model or the KCC Model.

Response: We appreciate the feedback; however, we believe that these models are testing different policy questions and that beneficiaries should be aligned or attributed to participants in more than one model if such alignment or attribution is consistent with the

methodologies for the models. The CEC and KCC Models are focused around incentives for managing total cost of care and for managing beneficiary care across different providers, while the ETC Model is focused specifically on dialysis modality selection. While both the KCC and ETC Models include financial incentives around kidney transplantation, we believe that the incentives are different enough in structure, including with respect to the entity to whom the incentive payments are made, that both are worth testing. We view this payment overlap between the ETC Model and the KCC Model as similar to how an ESRD facility may both participate in the CEC Model and be subject to payment adjustments under the ESRD PPS based on the facility's performance under the ESRD QIP. Additionally, we are concerned about having a sufficiently large beneficiary population to be able to evaluate the results from the ETC Model if KCC Participants are excluded and are also concerned about a situation where ETC Participants could control whether a beneficiary is aligned to them under the ETC Model by taking steps to ensure that the beneficiary is aligned to an entity participating in either the CEC Model or the KCC Model.

Comment: We received comments urging that any payment adjustments under the ETC Model be excluded from the payment calculations under the Medicare Shared Savings Program or under models tested by the Innovation Center under section 1115A of the Act.

Response: We believe that excluding ETC Model payments from the payment calculations under these other initiatives would compromise the design of these other initiatives, many of which are focused on accountability for the total cost of care. For example, the Medicare Shared Savings Program considers all Medicare Part A and B expenditures, only excluding Inpatient Medical Education and Disproportionate Share Hospital payments, while explicitly including individually beneficiary identifiable final payments made under a

demonstration, pilot or time limited program when performing financial calculations under the program (see, for example, 42 CFR 425.601(c)(2)). We view the inclusion of payment adjustments made under the ETC Model as similar to how the payment adjustments for CMS quality programs, like the ESRD QIP, are incorporated into expenditure calculations under the Medicare Shared Savings Program and models tested by the Innovation Center under section 1115A.

Comment: We received a comment urging CMS to adopt quality measures around home dialysis and kidney transplants under the ESRD QIP, rather than testing the separate ETC Model.

Response: CMS is proposing to implement these payment adjustments in the ETC Model rather than the ESRD QIP because it is our intention to apply these incentives to Managing Clinicians in addition to ESRD facilities. The incentives in the ESRD QIP program apply to ESRD facilities, and not to Managing Clinicians, yet CMS believes that Managing Clinicians are a key part of supporting beneficiary modality choice and should also face payment incentives to increase utilization of home dialysis and transplants. Additionally, the maximum penalty for the ESRD QIP is 2 percent and we believe that increasing rates of home dialysis and the inclusion of beneficiaries on transplant waitlists are important enough areas to focus on that ETC Participants should have a larger potential downside and the potential for upside for succeeding in improving their rates in these areas.

Comment: We received a comment from a group representing physicians pointing out that Managing Clinicians who are MIPS eligible clinicians are already subject to MIPS and would be subject to a second set of payment adjustments under the ETC Model. They urged that nephrologist payments only be adjusted by MIPS.

Response: The MIPS program was designed to tie payments to quality and cost efficient care, drive improvement in care processes and health outcomes, increase the use of healthcare information, and reduce the cost of care, while the ETC Model has a narrower focus on kidney replacement modality choice. CMS believes that both are important focuses for Managing Clinicians. Accordingly, CMS believes it is appropriate for Managing Clinicians participating in the ETC Model to have their payments adjusted under both the MIPS program and the ETC Model.

After considering the public comments, we are finalizing the overlaps in policy as proposed without modification.

7. Medicare Program Waivers

We noted in the proposed rule our belief that it was necessary and appropriate to provide additional flexibilities to ETC Participants for purposes of testing the ETC Model. The purpose of such flexibilities would be to give ETC Participants additional access to the tools necessary to ensure ESRD Beneficiaries can select their preferred treatment modality, resulting in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, suppliers, and beneficiaries.

We proposed to implement these flexibilities using our waiver authority under section 1115A of the Act. Section 1115A(d)(1) of the Act provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive Medicare program requirements as necessary to test models under section 1115A of the Act.

The following is a summary of the comments we received suggesting that CMS issue additional waivers and our responses.

Comment: We received many comments urging CMS to waive other requirements. Many commenters requested CMS to waive requirements similar to those we have indicated that we intend to waive for purposes of testing the voluntary KCC Model, such as the requirements that will be waived for purposes of testing the Concurrent Care for Beneficiaries that Elect the Medicare Hospice Benefit Enhancement, the Home Health Benefit Enhancement, Telehealth Benefit Enhancement, and Post-Discharge Home Visits Benefit Enhancement under that Model, as well as requirements we have waived for purposes of testing the voluntary Next Generation Accountable Care Organization Model, including the waivers necessary for testing the Care Management Home Visits Benefit Enhancement. A commenter also specifically requested that CMS waive certain telehealth requirements as necessary to test allowing nurses to provide home dialysis visits via telemedicine under the Model.

Another commenter asked CMS to waive back-up arrangement requirements for certifications of home dialysis providers, and instead allow licensed home-dialysis providers to provide back-up hemodialysis in the space licensed for home dialysis. CMS also received a comment requesting to include a waiver to permit advanced practice providers under the general supervision of a Managing Clinician to manage a patient's home dialysis care. A commenter urged CMS include waivers necessary to allow renal dieticians to bill for services of nutrition education under this Model. According to the commenter, nutrition therapy and education provided by a renal dietician can improve the patient's quality of life and delay the progress of kidney disease. We received a comment suggesting that CMS issue a waiver to allow certified

dialysis technicians, without the physical presence of a licensed nurse, and clinicians providing remote monitoring to qualify as caregivers who may perform Medicare-covered home dialysis.

Response: We thank all of the commenters for their feedback. The suggested benefit enhancements and other waivers were not included in the proposed rule, and we therefore are not finalizing these benefit enhancements or other waivers suggested by the commenters in this final rule. CMS will take the commenters' feedback into consideration as we consider potential future changes to the model design.

a. Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA discussed in the proposed rule and in sections IV.C.4 and IV.C.5 of this final rule, respectively, we stated in the proposed rule that we believe we would need to waive certain Medicare program rules.

Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we proposed to waive requirements of the Act for the ESRD PPS and PFS payment systems only to the extent necessary to make these payment adjustments under this proposed payment model for ETC Participants selected in accordance with CMS's proposed selection methodology. Also, we proposed to waive the requirement in section 1881(h)(1)(A) of the Act that payments otherwise made to a provider of services or a renal dialysis facility under the system under section 1881(b)(14) of the Act for renal dialysis services be reduced by up to 2.0 percent if the provider of services or renal dialysis facility does not meet the requirements of the ESRD QIP for a payment year, as may be necessary solely for purposes of ensuring that the ESRD QIP payment reduction would be applied to ESRD PPS payments that have been adjusted by the HDPA and the PPA. In addition, we proposed that the payment adjustments made under

this Model would not change beneficiary cost sharing from the regular Medicare program cost sharing for the related Part B services that were paid for beneficiaries who receive services from ETC Participants. We proposed to make payment adjustments without impacting beneficiary cost sharing because, if beneficiary cost sharing changed as a result of the HDPA and the PPA, this would create a perverse incentive in which beneficiaries would pay less to receive services from ETC Participants with lower rates of home dialysis and transplants, potentially increasing beneficiary interest in receiving care from providers and suppliers performing poorly on the rates the ETC Model intends to improve, which would be contrary to the purpose of the Model.

Therefore, we proposed to waive the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act to the extent that these requirements otherwise would apply to payments made under the ETC Model. We sought comment on our proposed waivers of Medicare payment requirements related to the HDPA and PPA and beneficiary cost sharing.

The following is a summary of the comments we received on the proposed Medicare payment waivers and our responses.

Comment: We received comments supporting our proposal that beneficiary cost-sharing would be unaffected by the HDPA and the PPA.

Response: We thank the commenters for their feedback and support and will finalize this policy as proposed.

Comment: A commenter asked CMS to consider including a waiver for payment modifications for surgeons, hospitals, and surgery centers within the Model to bring reimbursement for PD catheter placement in-line with arteriovenous fistula reimbursement. Additionally, the commenter recommended adding a PD catheter placement diagnosis related

group payment to further incentivize surgeons, hospitals, and surgery centers to perform this procedure.

Response: We thank the commenter for these suggestions. This type of waiver was not included in the proposed rule, and we therefore are not finalizing a waiver of this nature in this final rule. Additionally, the commenter's recommendation to add a PD catheter placement diagnosis related group payment is outside the scope of this rulemaking. CMS will take the commenter's other recommendations into consideration for future potential changes to the model design.

After considering the public comments received, CMS will finalize the Medicare payment waivers, including our policy with respect to beneficiary cost-sharing, as proposed without modification in our regulation at 42 CFR 512.397(a).

b. Waiver of Select KDE Benefit Requirements

We stated in the proposed rule our belief that it is necessary for purposes of testing the ETC Model to waive select requirements of the KDE benefit authorized in section 1861(ggg)(1) of the Act and in the implementing regulation at 42 CFR 410.48. Medicare currently covers up to 6, 1-hour sessions of KDE services for beneficiaries that have Stage IV CKD. While the KDE benefit is designed to educate and inform beneficiaries about the effects of kidney disease, their options for transplantation, dialysis modalities, and vascular access, the uptake of this service has been low at less than 2 percent of eligible patients. As noted in the proposed rule, we believe that the KDE benefit is one of the best tools to promote treatment modalities other than in-center HD and that this waiver is necessary to test ways to increase its utilization from its current low rate as part of the model test.

We proposed to waive the following requirements for ETC Participants billing for KDE services:

• Currently, doctors, physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs) are the only clinician types that can furnish and bill for KDE services as required by section 1861(ggg)(2)(A)(i) of the Act and its implementing regulation at 42 CFR 410.48(a) and 42 CFR 410.48(c)(2)(i). However, the payment for KDE is lower than a typical evaluation and management (E/M) visit, so there may be limited financial incentive for these clinician types to conduct the KDE sessions. There are various other types of health care providers that also may be well-suited to educate beneficiaries about kidney disease, such as registered dieticians and nephrology nurses. In its 2015 report on home dialysis, GAO recommended allowing other types of health care providers to perform KDE to increase uptake of the benefit.[158] We proposed to waive the requirement that KDE be performed by a physician, PA, NP or CNS, to allow additional clinical staff such as dietitians and social workers to furnish the service under the direction of a Medicare-enrolled participating Managing Clinician. The staff would not need to be Medicare-enrolled, but would furnish these services incident to the services of a clinician authorized to bill Medicare for KDE services as specified in section 1861(ggg)(2)(B)(i). In the proposed rule, we considered also waiving the requirement under section 1861(ggg)(2)(B) of the Act and the implementing regulation at 42 CFR 410.48(c)(2)(ii) restricting ESRD facilities from billing for KDE directly, but decided not to, as we did not believe it is necessary for testing the Model. Moreover, ESRD facilities are already required to provide information to beneficiaries about their treatment modality options in the ESRD facility

[158] United States Government Accountability Office. 2015

conditions for coverage at § 494.70(a)(7); and to develop and implement a plan of care that addresses the patient's modality of care, at § 494.90(a)(7).

• KDE is now covered only for Medicare beneficiaries with Stage IV CKD as required by section 1861(ggg)(1)(A) of the Act and in the implementing regulations at 42 CFR 410.48(b)(1). As we noted in the proposed rule, we understood this prevents many beneficiaries in Stage V of CKD from receiving the benefits of KDE before starting dialysis or pursuing a transplant. In the proposed rule, we hypothesized that beneficiaries with ESRD could also benefit from this education in the first 6 months after an ESRD diagnosis. While CKD Stage V and early ESRD patients' disease may be more advanced and the prospect of dialysis or transplant more certain than for patients with Stage IV CKD, there is still opportunity to improve beneficiary knowledge to ensure the best patient-centered care and outcomes. GAO recommended covering the KDE benefit for beneficiaries with Stage V CKD.[159] We proposed to waive the requirement that KDE is covered only for Stage 4 CKD patients for purposes of testing the ETC Model and to permit beneficiaries with CKD Stage V and those in the first 6 months of receiving an ESRD diagnosis to receive the benefit, when billed by an ETC Participant who is a Managing Clinician.

• Under 42 CFR 410.48(d)(1), at least one of the KDE sessions must be dedicated to management of comorbidities, including delaying the need for dialysis. Because we proposed a waiver that would extend the KDE benefit to beneficiaries with CKD Stage V and ESRD in the first 6 months of diagnosis, this KDE topic may no longer be relevant to patients who are facing a more immediate decision to commence dialysis or arrange for a kidney transplant. We

[159] United States Government Accountability Office. 2015

proposed to waive the requirement that KDE include the topic of managing comorbidities and delaying the need for dialysis under the ETC Model, when furnishing KDE to beneficiaries with CKD Stage V and ESRD. We proposed further clarifying, however, that ETC Participants who are Managing Clinicians furnishing KDE (either personally or with clinical staff incident to their services) must still cover this topic if relevant to the beneficiary, for example, if the beneficiary has not yet started dialysis and can still benefit from education regarding delaying dialysis.

- Under 42 CFR 410.48(d)(5)(iii), an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment must be performed by a qualified clinician during one of the 6 sessions. This requirement presents two challenges; first that it may take away time from a session that could be dedicated exclusively to education, and second that if a beneficiary demonstrates inadequate knowledge, there may not be sufficient time in one session to address all areas in which a beneficiary might need assistance. If the outcomes assessment could be performed by qualified staff during a follow-up visit to the Managing Clinician, there would still be 6 full KDE sessions available to beneficiaries, and we believe there would be more flexibility for the qualified staff to reinforce what the beneficiary learned during the KDE sessions and fill in any gaps. We proposed to maintain the requirement that an outcomes assessment be performed by qualified staff in some manner within one month of the final KDE session, but to waive the requirement that it be conducted within a KDE session.

In the proposed rule, we also considered waiving the co-insurance requirement for the KDE benefit and certain telehealth requirements to allow the KDE benefit to be delivered via telehealth for beneficiaries outside of rural areas and other applicable limitations on telehealth originating sites, but did not believe those waivers were necessary for purposes of testing the Model.

The following is a summary of the comments received on the proposed waivers of select requirements of the KDE benefit for purposes of testing the ETC Model and the alternatives considered and our responses.

Comment: We received several comments, supporting CMS' proposal to waive select requirements of the KDE Benefit for the purposes of testing the ETC Model. However, many commenters asked CMS to further increase the scope of the KDE benefit under the proposed waivers, specifically in order to allow additional clinicians and health care sites provide the KDE benefit, including dieticians, social workers, ambulance providers, home health aides, and other clinicians who work in nursing homes or ESRD facilities. Additionally, a commenter asked CMS not to increase the scope of the KDE benefit to dialysis provider staff, while another requested that CMS issue additional waivers in order to provide more flexibility around the timeframe within which the KDE benefit could be provided. Finally, a commenter expressed concern that the KDE Benefit would permit health care providers to give beneficiaries incomplete information.

Response: We appreciate the commenters' support for our proposals to waive select requirements of the KDE benefit for purposes of testing the ETC Model. While we understand the commenter's interest in increasing even further the types of clinicians and entities that may provide the KDE benefit, we believe that our proposed policy provides the necessary flexibility to test the Model and will finalize the types of clinicians and entities that may provide the KDE benefit as proposed. We also understand the commenter's concern that the proposed waivers of certain KDE Benefit requirements would allow health care providers to give beneficiaries less information than is currently required. However, we proposed to waive the requirement to include managing comorbidities and delaying the need for dialysis as a required topic as part of a

KDE session because those topics may not be relevant to beneficiaries with CKD Stage V and ESRD, who will be able to receive the KDE Benefit under the ETC Model. We also will finalize our proposed clarification that ETC Participants who are Managing Clinicians furnishing KDE (either personally or with clinical staff incident to their services) must still cover this topic if relevant to the beneficiary, for example, if the beneficiary has not yet started dialysis and can still benefit from education regarding delaying dialysis.

Comment: We received comments urging CMS to waive additional categories of beneficiary cost sharing in this Model, including cost-sharing for the KDE benefit or home-dialysis treatments.

Response: We thank the commenters for their feedback. While we considered waiving the coinsurance for the KDE benefit, the ETC Model aims to test the use of financial incentives for ETC Participants (namely Managing Clinicians and ESRD facilities), rather than beneficiary incentives, and we are concerned that testing a financial incentive for ETC Participants in conjunction with additional behavioral incentives for beneficiaries could confound the Model test. Specifically, it would be difficult to determine whether the impacts observed in the Model are a result of the Model's financial incentives or beneficiary incentives. Additionally, CMS is concerned that including waivers for additional categories of beneficiary cost-sharing could influence beneficiaries to choose health care providers based on the lower cost of treatment, rather than the quality of care that the health care providers deliver. CMS will take the commenters' recommendations into consideration for future potential changes to the model design.

Comment: We received one comment asking CMS to change payment for KDE to "per treatment-hour reimbursement" to incentivize ESRD facilities to educate patients as early as

possible for transition to home dialysis. The commenter also suggested that "highly skilled, 24/7 centralized real-time equipment and clinical telephone support" must be in place after patients begin dialyzing at home.

Response: We thank the commenter for this feedback. We did not propose to change payment for the KDE benefit in the proposed rule, nor did we propose to require that "highly skilled, 24/7 centralized real-time equipment and clinical telephone support" be in place after patients begin dialyzing at home, and we therefore are not finalizing these policies in this final rule. CMS will take the commenter's recommendations into consideration for future potential changes to the model design.

Comment: A commenter recommended the commenter's proprietary tool for patient education programs for home dialysis and asked CMS to require ETC Participants to use this tool in all educational programs related to home dialysis.

Response: While we encourage innovation in both the private and public sectors, CMS is not permitted to endorse any particular product.

After considering the public comments, we are finalizing the proposed waivers of select requirements of the KDE Benefit for purposes of testing the ETC Model, with changes, in our regulation at § 512.397(b). Specifically, we will waive the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. Our regulation at § 512.397(b) will now list the Supplier and Non-Physician Practitioner types that will be able to furnish and bill for the KDE benefit under this waiver. This list does not exclude any supplier types that would otherwise have been permitted to furnish the KDE benefit. Specifically, the waiver will

allow the KDE benefit to be furnished and billed by a physician, as well as a clinical nurse specialist, licensed clinical social worker, nurse practitioner, physician assistant, registered dietician/nutrition professional, and supplier specialty listed as clinic/group practice to test greater use of the KDE benefit. We also will waive the requirement that KDE is covered only for Stage 4 CKD patients to permit beneficiaries with CKD Stage V and those in the first 6 months of starting dialysis to receive the KDE benefit. In the proposed rule, we stated that we would waive this requirement to permit beneficiaries with CKD Stage V and those in the first 6 months of an ESRD diagnosis to receive the KDE benefit. However, we have since determined that using ESRD diagnosis codes to identify beneficiaries in the first 6 months of an ESRD diagnosis in order to determine eligibility for the KDE benefit would be difficult to operationalize due to the potential for delays in reporting of the diagnosis, as well as incomplete reporting of diagnosis codes on Medicare claims. By contrast, CMS can use Medicare claims data to more quickly and accurately identify ESRD Beneficiaries based on the submission of claims for the initiation of dialysis, which is consistent with how Medicare FFS identifies ESRD Beneficiaries generally. We are therefore modifying our regulation at 512.397(b)(2) to permit KDE services to be furnished to beneficiaries in the first 6 months of starting dialysis (rather than the first 6 months of receiving an ESRD diagnosis). Therefore, in the final rule, we will waive this requirement to permit beneficiaries with CKD Stage IV, CKD Stage V, and those in the first 6 months of dialysis to receive the KDE benefit. Also, as we noted in the preamble to the proposed rule, we clarify that this waiver applies only when claims for such services are billed by an ETC Participant who is a Managing Clinician. We will also waive the requirement that the content of the KDE sessions include the topic of managing comorbidities and delaying the need for dialysis under the ETC Model, when such services are furnished to beneficiaries with CKD

Stage V or ESRD. However, we will require that ETC Participants who are Managing Clinicians furnishing KDE (either personally or with clinical staff incident to their services) must still cover this topic if relevant to the beneficiary, for example, if the beneficiary has not yet started dialysis and can still benefit from education regarding delaying dialysis. As proposed, we will waive the requirement that an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment be performed by qualified staff as part of one of the KDE sessions, provided that such outcomes assessment is performed in some manner within one month of the final KDE session by qualified staff.

8. Compliance with Fraud and Abuse Laws

The authority for the ETC Model is section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and certain provisions of section 1934 as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b). For this Model and consistent with this standard, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the SSA. However, CMS proposed that no fraud and abuse waivers would be issued for this Model. Thus, notwithstanding any other provision of this final regulation, all ETC Participants must comply with all applicable laws and regulations.

The following is a summary of the comments received on compliance with fraud and abuse laws and our responses.

Comment: We received several requests from commenters to include waivers of the physician self-referral law (commonly referred to as the "Stark law"), Federal Anti-Kickback

Statute, and the Beneficiary Inducements Civil Monetary Penalty to provide ETC Participants with the flexibilities found in other models tested under the authority of section 1115A of the Act. Commenters asserted that these fraud and abuse waivers are necessary to improve care coordination, population health management, patient education on home dialysis, and post-transplant care.

Response: We appreciate the commenters' interest in this matter. However, as we stated in the proposed rule (84 FR 34563), no fraud and abuse waivers are being issued for this Model. At this time, we believe that the arrangements contemplated by this Model can be executed in a manner that complies with existing fraud and abuse laws and that fraud and abuse waivers are not necessary to test this Model. Thus, notwithstanding any other provisions of this final regulation, all ETC Participants must comply with all applicable laws and regulations.

9. Beneficiary Protections

As we discussed in the proposed rule and in section IV.C.4.b of this final rule, we proposed to attribute non-excluded ESRD Beneficiaries and, as applicable, pre-emptive transplant beneficiaries to the ETC Participant that furnishes the plurality of the beneficiary's dialysis and other ESRD-related services. Although the ETC Model would not allow ESRD Beneficiaries to opt out of the payment adjustment methodology being applied to the Medicare payments made for their care, the Model would not affect beneficiaries' freedom to choose their dialysis services provider or supplier, meaning that beneficiaries may elect to see any Medicare-enrolled provider or supplier including those selected and not selected to participate in the Model based on geography. In addition, the general beneficiary protections described in the proposed rule and section II.B.2.a.(8) of this final rule would apply to the ETC Model; accordingly, ETC Participants would be prohibited from restricting beneficiary freedom of choice or access to

medically necessary covered services, which includes the beneficiary's choice regarding the appropriate modality to receive covered services. ETC Participants also would be prohibited from using or distributing descriptive model materials and activities that are materially inaccurate or misleading. We proposed to prohibit ETC Participants from offering or paying any remuneration to influence a beneficiary's choice of renal replacement modality, unless such remuneration complied with all applicable law. We stated in the proposed rule that we believed this policy is necessary to help ensure that beneficiary modality selection is based on the care of the beneficiary and the beneficiary's needs and preferences, rather than financial or other incentives the beneficiary may have received or been offered.

Furthermore, we explained in the proposed rule, beneficiaries with disabilities who receive care from ETC Participants, including dementia and cognitive impairments, remain protected under Federal disability rights laws including, but not limited to, section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, as amended, and section 1557 of the Patient Protection and Affordable Care Act. These beneficiaries cannot be denied access to home dialysis or kidney transplant due to their disability. We stated that ETC Participants may not apply eligibility criteria for participation in programs, activities, and services that screen out or tend to screen out individuals with disabilities; nor may ETC Participants provide services or benefits to individuals with disabilities through programs that are separate or different, excepting those separate programs that are necessary to ensure that the benefits and services are equally effective.

In addition, as described in the proposed rule and in sections IV.C.4.c and IV.C.5.e.(2) of this final rule, we proposed to apply the Clinician HDPA and the Clinician PPA to the amount otherwise paid under Medicare Part B and furnished by the Managing Clinician during the CY

subject to adjustment, which would mean that beneficiary cost sharing would not be affected by the application of the Clinician HDPA and the Clinician PPA. Similarly, as described in the proposed rule and section IV.C.7.a. of this final rule, we proposed to use our waiver authority under section 1115A(d)(1) of the Act to issue certain payment waivers, pursuant to which beneficiaries would be held harmless from any model-specific payment adjustments made to Medicare payments under this Model.

We proposed to specify in our regulations at § 512.330(a) that ETC Participants would be required to prominently display informational materials in each of their offices or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. This notification would serve to inform a beneficiary that his or her provider or supplier is participating in a model that incentivizes the use of home dialysis and kidney transplants and who to contact if they have questions or concerns. As we stated in the proposed rule, we proposed this notification to further non-speculative government interests including transparency and beneficiary freedom of choice. So as not to be unduly burdensome, we stated in the proposed rule that CMS intends to provide a template for these materials to ETC Participants, which would identify required content that the ETC Participant must not change and places where the ETC Participant may insert its own original content. This template would include information for beneficiaries about how to contact the ESRD Network Organizations with any questions or concerns regarding participation in the ETC Model by their health care provider(s). (The 18 ESRD Network Organizations serve distinct geographical regions and operate under contract to CMS; their responsibilities include oversight of the quality of care to ESRD Beneficiaries, the collection of data to administer the national Medicare ESRD program, and the provision of technical assistance to ESRD providers and patients in areas related to

ESRD). We noted in the proposed rule that all other ETC Participant communications with beneficiaries that are descriptive model materials and activities would be subject to the requirements for such materials and activities included in the general provisions, as discussed in the proposed rule and section II.D.3 of this final rule.

The following is a summary of the comments received on the proposed beneficiary protections and our responses.

Comment: We received multiple comments expressing concern that the structure and incentives of the Model could produce unintended consequences that would be contrary to beneficiary freedom of choice and access to medically necessary covered services. Many commenters stressed that the criteria for ESRD Beneficiaries to be excluded from attribution to ETC Participants under the ETC Model, described in § 512.360(b) of the regulatory text, should include an exclusion for patient treatment choice. Additionally, a commenter recommended that beneficiaries be allowed to opt of out the Model. The rationale for these suggestions was that patients could choose other treatment modalities or supportive care due to religious reasons, patients' need or desire to travel for work or leisure, or reliance on inpatient facilities due to other confounding co-morbidities or factors. Several commenters acknowledged that patients may choose other treatment modalities besides home dialysis or transplant despite adequate education on treatment choices. Accordingly, a commenter suggested adding in a quality measure for physician-patient relationship and the shared decision making process.

Response: CMS appreciates the feedback to include additional provisions regarding patient choice in the design of the model, but believes patient choice is adequately protected in the provision to be finalized in our regulation at § 512.120. As applied to the ETC Model, this provision prohibits ETC Participants from inhibiting a beneficiary's freedom to choose the

provider and supplier from which they receive care. The ETC Model would not restrict beneficiaries from choosing in-center dialysis as their treatment choice.

We are, however, making certain modifications to our proposed beneficiary notification requirements in light of the comments received. As proposed, each ETC Participant will be required to prominently display informational materials in each of their office or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. Also as proposed, CMS will provide a template for these materials, which will include information for beneficiaries about how to contact the ESRD Network Organizations with any questions or concerns regarding participation in the ETC Model by their health care provider(s). To promote CMS's interest in ensuring that beneficiaries are not mislead into believing that the Model in any way restricts their freedom of choice, the CMS-provided template for the beneficiary notification materials will also include an affirmation of a beneficiary's protections under Medicare, including the freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice. We have revised our regulation at § 512.330(a) to specify that the CMS-provided template for the beneficiary notification will include, without limitation, this information.

Additionally, ETC Participants must continue to make medically necessary covered services available to beneficiaries and cannot target or avoid treating beneficiaries on the basis of their income levels or other factors that would render a beneficiary an at-risk beneficiary as that term is defined for purposes of the Medicare Shared Savings Program, and similarly may not selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the ETC Participant's financial or quality performance in the ETC Model. We address comments related to beneficiary exclusions under section IV.C.B.1 of this final rule.

Beneficiaries are not Model participants and while they cannot opt out of the ETC Model's payment methodology, attributed beneficiaries retain all existing beneficiary rights and protections regarding Medicare Parts A and B services, including choice of providers, suppliers and treatment modality.

Comment: We received one comment requesting that we create an Alternative Payment Models Beneficiary Ombudsman to cast a wide net for beneficiary issues.

Response: We disagree that a Beneficiary Ombudsman is necessary for the testing of the ETC Model. As previously noted, beneficiaries are not Model participants and while they cannot opt out of the ETC Model's payment methodology, attributed beneficiaries retain all existing beneficiary rights and protections regarding Medicare Parts A and B services, including choice of providers, suppliers and treatment modality. In addition, as described elsewhere in this final rule, we plan to conduct the monitoring activities described in our regulation at § 512.150 to determine whether the Model is resulting in unintended consequences, including impact on beneficiary choice. We thank the commenter for this feedback and are finalizing the rule without the addition of a Beneficiary Ombudsman.

Comment: We received two comments in support of the beneficiary protection provisions identified in § 512.120 of the proposed rule and their application to the ETC Model. Multiple commenters appreciated CMS proposals to protect beneficiaries' freedom to choose services providers and suppliers by applying the general beneficiary protection provisions identified in § 512.120 to the ETC Model and the proposed requirement for ETC Participants to notify beneficiaries of such participation under proposed § 512.330(a).

Response: We thank the commenters for their feedback and support.

Comment: A commenter recommended that beneficiaries be provided optional assistance in transferring to a provider or supplier not participating in the ETC Model without undue hardship, including assistance with any transportation barriers. Some commenters asked for beneficiaries to have the ability to formally indicate they are not interested in home dialysis or kidney transplantation and, as a result, to be excluded from the home dialysis rate and transplant rate calculations for purposes of the ETC Model.

Response: We disagree with these recommendations and will finalize the rule without this modification. Nothing in this final rule prohibits a practice from offering beneficiaries the optional assistance described by the commenter, as long as the assistance complies with all applicable laws and regulations, including the Federal anti-kickback statute and the civil monetary penalty provision prohibiting inducements to beneficiaries. To the extent the commenter is advocating that the Secretary waive one or more laws pursuant to section 1115A(d)(1) of the Act to enable the provision of transportation or other assistance, we note that the statutory standard for issuance of such a waiver would not be satisfied because we have determined that offering transportation or other assistance to beneficiaries is not necessary to test the ETC Model. The Model would not affect beneficiaries' freedom to choose their dialysis services provider or supplier, meaning that beneficiaries may elect to see any Medicare-enrolled provider or supplier including those selected and not selected to participate in the Model based on geography. We decline to modify the Model terms to permit beneficiaries to opt out of the Model payment adjustment methodology being applied to the Medicare payments made for their care because their attribution and inclusion are necessary to determine if Model payment adjustments can achieve the Model's goals of increasing rates of home dialysis utilization and kidney transplantation and, as a result, improving or maintaining the quality of care while

reducing Medicare expenditures among all types of ESRD facilities and for a full representation of beneficiaries receiving services at those ESRD facilities. In addition, while payment adjustments to the Managing Clinicians and ESRD facilities are being tested under the Model, the health care services available to Beneficiaries likely will not change since the Beneficiary will retain their existing Medicare right to choose their providers and suppliers, as identified in § 512.120 of the final rule. The notification required under § 512.330 will also include an affirmation of the ESRD Beneficiary's protections under Medicare, including the beneficiary's freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

Comment: A commenter recommended that we require ETC Participants to inform beneficiaries about all available coverage options and disclose relevant information about payments to patients and insurers.

Response: We disagree that beneficiary notifications beyond those identified in §§ 512.330 and 512.120 of the final rule are necessary for the testing of this Model. As noted in the proposed rule and elsewhere in this final rule, beneficiaries will retain all existing beneficiary rights and protections regarding Medicare Parts A and B services, including choice of providers, suppliers, and treatment modality.

After considering the public comments, we are finalizing the proposed beneficiary notification requirements in our regulation at § 512.330 with modification. In § 512.330(b) of the final rule, we are making a change to the applicability of our regulation at §512.120(c) (regarding descriptive model materials and activities) to the CMS-provided templates for the informational materials required to be displayed in the office or facilities of ETC Participants where beneficiaries receive treatment described in our regulation at §512.330(a). In the

proposed rule, we had proposed that the entirety of §512.120(c) would not apply to such CMS-provided materials. However, this was a drafting error. We had intended to refer only to the requirement in 512.120(c)(2), such that the requirement to include the disclaimer that "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 & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document" would not apply to those CMS-provided materials. Because the purpose of these materials is to educate beneficiaries about the Model and because our regulation at §512.330(a) will permit an ETC Participant to insert its own original content to the CMS-provided templates, where indicated by CMS, we believe that it is important that the other requirements of §512.120(c) apply to those materials, including the requirement that such materials not be materially inaccurate or misleading, that ETC Participants retain copies of such materials, and that CMS reserve the right to review such materials to determine whether the content added by the ETC Participant is materially inaccurate or misleading. Also, we have revised §512.330(a) of our regulations to specify that the CMS-provided template for the beneficiary notification will include, without limitation, a notification that the ETC Participant is participating in the ETC Model; instructions on how to contact the ESRD Network Organizations with any questions or concerns about the ETC Participant's participation in the Model; and an affirmation of the ESRD beneficiary's protections under Medicare, including the beneficiary's freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

10. Monitoring

a. Monitoring Activities

We proposed that the general provisions relating to monitoring described in the proposed rule and in section II.I of this final rule would apply to ETC Participants, including but not limited to cooperating with the model monitoring activities under § 512.150, granting the government the right to audit under § 512.135(a), and retaining and providing access to records under §§ 512.135(c) and 512.135(b), respectively. CMS would conduct the model monitoring activities in accordance with the proposed § 512.150. We stated in the proposed rule that we believed that we must closely monitor the implementation and outcomes of the ETC Model throughout its duration. As described in the proposed rule, the purpose of monitoring would be to ensure that the Model is implemented safely and appropriately; that ETC Participants comply with all the terms and conditions of the ETC Model; and to protect beneficiaries from potential harms that may result from the activities of an ETC Participant. All monitoring activities under the ETC Model would focus exclusively on Medicare FFS beneficiaries.

Consistent with proposed § 512.150, we proposed that monitoring activities may include documentation requests sent to the ETC Participant; audits of claims data, quality measures, medical records, and other data from the ETC Participant; interviews with members of the staff and leadership of the ETC Participant; interviews with beneficiaries and their caregivers; site visits to the ETC Participant; monitoring quality outcomes and clinical data; and tracking patient complaints and appeals. Specific to the ETC Model, we would use the most recent claims data available to track utilization of certain types of treatments, beneficiary hospitalization and Emergency Department use, and beneficiary referral patterns to make sure the utilization and beneficiary outcomes are in line with the Model's intent. We stated in the proposed rule that we

believe this type of monitoring is important because as ETC Participants adapt to new payment incentives, we want to ensure to the greatest extent possible that the Model is effective and Medicare beneficiaries continue to receive high quality, low cost, and medically appropriate care.

In the proposed rule, we recognized that one of the likely outcomes of this Model would be an increase in utilization of home dialysis. However, in testing payment incentives aimed at increasing utilization of this modality, there may be a risk of inappropriate steering of ESRD Beneficiaries who are unsuitable for home dialysis. As described in the proposed rule and section IV.C.5.b.(1) of this final rule, we proposed to exclude from beneficiary attribution certain categories of beneficiaries not well suited to home dialysis, including beneficiaries with a diagnosis of dementia. We proposed these eligibility criteria to exclude certain categories of beneficiaries from attribution up front so Managing Clinicians and ESRD facilities that are ETC Participants do not attempt or believe that it is wise to attempt to place these particular beneficiaries on home dialysis. In addition, we proposed that CMS would monitor for inappropriate encouragement or recommendations for home dialysis through the proposed monitoring activities. We stated in the proposed rule that instances of inappropriate home dialysis would show up through increases in patient hospitalization, infection, or incidence of peritonitis. For example, multiple incidences of peritonitis would be a good indicator that the patient should not be on PD. If claims data show unusual patterns, we proposed to review a sample of medical records for indicators that a beneficiary was not suited for home dialysis. In the proposed rule, we discussed using patient surveys and interviews to look for instances of coercion on beneficiary choice of modality against beneficiary wishes. If such instances of coercion were found, we stated that we would take one or more remedial action(s) as described

at § 512.160 against the ETC Participant and refer the case to CMS for further investigation and/or remedial action.

Additionally, we noted in the proposed rule that we would employ longer-term analytic strategies to confirm our ongoing analyses and detect more subtle or hard-to-determine changes in care delivery and beneficiary outcomes. Some determinations of beneficiary outcomes or changes in treatment delivery patterns may not be able to be built into ongoing claims analytic efforts and may require longer-term study. We stated in the proposed rule that we believe it is important to monitor the transplant and home dialysis trends over a longer period of time to make sure the incentives are not adversely affecting the population of beneficiaries included in the Model.

We also stated in the proposed rule that we would examine the extent of any unintended consequences, including any increase in adverse clinical events such as graft failures, returns to dialysis, peritonitis and other health incidents due to home dialysis, fluctuations in machine and supplies markets, lemon-dropping clinically complex patients, cherry-picking of less clinically complex patients, increase in referrals to home dialysis for patients that are not physically or cognitively able to safely handle the responsibility of dialyzing at home, or an increase in referrals to Comparison Geographic Areas. Specifically, we would monitor the rate at which back-up in-center dialysis (Claim Code 76) and ESRD self-care retraining (Claim Code 87) are used for home dialysis beneficiaries. The use of back-up dialysis for a home dialysis beneficiary can also be an indicator of equipment malfunction. Under the Innovation Center's authority in 42 CFR 403.1110, and built upon in our regulation at § 512.130, we would seek to obtain clinical data for home dialysis patients such as an increase in instances of fever, abnormal bleeding,

access point issues, and changes in vitals or weight, from ETC Participants for monitoring purposes and also would use applicable Medicare claims data.

In the proposed rule, we welcomed input about how to best track issues with home dialysis equipment and machines and the format of any proposed documentation for any incidents that occur, and how CMS should share any information about incidents that occur.

For those beneficiaries attributed to ETC Participants who have received a kidney transplant, we proposed to monitor transplant registry data from the SRTR, Medicare claims data available for life of transplant, post-transplant rates of hospitalization and ED visits, infection and rejection rates, and cost of care compared to the beneficiaries who have received a kidney transplant and are not included in the ETC Model test.

We stated in the proposed rule that a key pillar of our monitoring strategy for both transplant, pre-emptive transplant and home dialysis beneficiaries would be stakeholder engagement, and we would continue conversations and relationships with patient-advocate groups and closely monitor patient surveys to uncover any of the unintended consequences listed earlier or others that may be unforeseen. We noted in the proposed rule that we believe beneficiary and/or care partner feedback would be a tremendous asset to help CMS determine and resolve any issues directly affecting beneficiaries.

In addition, we sought comment on how the payment adjustments under the ETC Model may influence delivery-oriented interventions among participating ESRD facilities and Managing Clinicians (for example, increased Managing Clinician knowledge of dialysis modalities, greater patient education, increased investment in equipment and supplies), as well as how the Model's financial incentives may affect the resourcing of these endeavors, and what are

the barriers to change. The following is a summary of the comments received on monitoring and our responses.

Comment: We received multiple comments expressing support for our proposed monitoring plan for the ETC Model.

Response: We thank the commenters for their support and are finalizing this monitoring policy for the ETC Model without modification.

Comment: We received multiple comments recommending additional events and conditions for monitoring under the ETC Model. A commenter recommended that we monitor for frequent hospitalizations, patient non-compliance and non-adherence, tracheotomy, patients who have a catheter in certain cases, acute blood loss due to surgical intervention, unknown acute blood loss including gastrointestinal bleeds, heart failure exacerbation, endocarditis, stroke, sepsis, septic shock, surgical procedures (for example, heart surgery, amputations, etc.), active malignancies, diabetic ketoacidosis, Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-susceptible Staphylococcus aureus (MSSA), ulcers (for example, decubitus or foot ulcers), open wounds (for example, bed sores), abscess (stump or other diabetic-related abscess), peri-anal abscess, osteomyelitis, bowel perforation, cardiac arrest, cellulitis, leg and hip fractures, cholecystitis, ulcerative colitis, substance abuse, active lupus, active Polycystic Kidney Disease (PKD), behavioral problems, especially those associated with mental illness diagnosis, bariatric issues, especially those patients with weighing in excess of 500 lbs., and chronic hypertension related to cardiac disease such as cardiomyopathy. Another commenter recommended that we look for blood stream infections for beneficiaries receiving HHD and peritonitis for beneficiaries receiving PD. Another commenter recommended that we monitor for resource shifting between the Comparison Geographic Areas and Selected Geographic Areas,

lemon-dropping and cherry-picking patients who are more likely to receive a transplant, market exits and reduction of in-center chairs in small and low-volume facilities serving a critical need, rates of peritonitis, bloodstream infections in home HD patients, and attrition from home dialysis.

Response: We thank the commenters for their feedback, which will be informative and helpful as we further develop our monitoring strategy for the ETC Model. We note that hospitalizations, infections and peritonitis were identified in the preamble to the proposed rule as items for monitoring and we intend to monitor for these events under the ETC Model.

Comment: A commenter expressed concern that the monitoring approach described in the proposed rule is too vague and requested that CMS provide additional information on our plans to monitor for beneficiary choice and medical appropriateness under the Model.

Response: We thank the commenter for the feedback and are finalizing our monitoring policy for the ETC Model without modification. We disagree with the comment that our monitoring policy for the ETC Model is too vague. In the proposed rule, we provided a list of monitoring activities we would plan to implement in the ETC Model. We identified a number of areas of ETC Model-specific risk and provided specific examples of data, documentation and activities that we would monitor to address that risk. Within a broad outline of monitoring activities described in the regulatory text and preamble of the final rule, we will retain discretion and flexibility as to the specific risks, subject matter, timing, items to be reviewed and mechanics of our monitoring strategy and activities during the model test to be responsive and devote resources to areas of high priority as they become identified. In the proposed rule, we also identified that we may review medical records and clinical data, perform interviews with beneficiaries, caregivers, and ETC Participant leadership and staff, implement surveys, review

complaints and appeals, and engage with stakeholders and including patient advocacy groups. We believe these activities will support our monitoring for restrictions on beneficiary choice and medical appropriateness.

Comment: A commenter recommended that we consider whether monitoring could be accomplished through an existing network or survey rather than a separate, model-specific monitoring process and, in the alternative, requested clarification on how the ETC Model monitoring process would align with existing monitoring processes.

Response: As noted in the proposed rule and previously in this final rule, the ETC Model is aimed at increasing utilization of home dialysis and thus may create a risk of inappropriate steering ESRD Beneficiaries who are unsuitable for home dialysis. This unique risk created under this Model requires model-specific monitoring activities, in addition to the existing CMS monitoring processes to protect ESRD Beneficiaries. We thank the commenter for the feedback and are finalizing our proposed monitoring strategy without modification.

Comment: A commenter expressed concern that peritonitis is not included in hospital acquired infection reporting and is not accounted for in hospital payment, and asked that facilities that accept PD patients and place PD catheters be accountable for clinical competency and infections.

Response: We thank the commenter for this feedback and note this specific item is beyond the scope of this rulemaking. The ETC Model, as described in the final rule, would not change or modify hospital quality reporting or payment methodology to account for incidences of peritonitis that occur in their facility or otherwise.

Comment: A commenter expressed concern that our proposed monitoring plan would be too retrospective and would not identify issues quickly enough. The commenter cited the timing

for the availability of claims data as an example. In addition, the commenter expressed concern that certain risks are difficult or impossible to identify through claims data, including peritonitis and partner burnout.

Response: We thank the commenter for the feedback. However, we note that in addition to reviewing claims data, we also may review medical records and clinical data, perform interviews with beneficiaries, caregivers, and ETC Participant leadership and staff, implement surveys, review complaints and appeals, and engage with stakeholders including patient advocacy groups. We believe these monitoring strategies will provide us timely feedback and will supplement the information made available through claims data.

After consideration of the public comments, we are finalizing the monitoring policy for the ETC Model as proposed, without modification.

b. Quality Measures

In addition to the monitoring activities discussed previously, we proposed two ESRD facility quality measures for the ETC Model:

- 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.

- 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.

We explained in the proposed rule that SMR and SHR measures are currently calculated and displayed on Dialysis Facility Compare, a public reporting tool maintained by CMS. The SHR is also included in the ESRD QIP measure set as a clinical measure on which ESRD

facilities' performance is scored.[160] Because data collection and measure reporting are ongoing, there would be no additional burden to ETC Participants to report data on these measures for the ETC Model. We stated in the proposed rule that, although CMS has in a previous rule acknowledged concerns that the SMR might not be adequately risk adjusted (78 FR 72208), we believe this measure is appropriate for purposes of the ETC Model, under which the SMR would not be used for purposes of determining payment. Mortality is a key health care outcome used to assess quality of care in different settings. We noted in the proposed rule that while we recognize that the ESRD population is inherently at high risk for mortality, we believe that mortality rates are susceptible to the quality of care provided by dialysis facilities, and note that the measure is currently being used in the CEC Model. The SMR is NQF endorsed, indicating that it serves as a reliable and valid measure of mortality among ESRD Beneficiaries who receive dialysis at ESRD facilities.

We stated in the proposed rule that we considered including the In-Center Hemodialysis (ICH) CAHPS® survey to monitor beneficiary perceptions of changes in quality of care as a result of the ETC Model. However, the ICH CAHPS survey includes only beneficiaries who receive in-center dialysis. The survey specifically excludes the two beneficiary populations that the ETC Model would focus on, namely beneficiaries who dialyze at home and beneficiaries who receive transplants and, therefore, we did not propose to use this measure for purposes of the ETC Model.

We noted in the proposed rule that we considered including quality measures for Managing Clinicians that are reported by Managing Clinicians for MIPS or other CMS

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[160] For the specifications for these measures, see "CMS ESRD Measures Manual for the 2018 Performance Period/2020 Payment Year", June 20, 2018, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRD-Manual-v30.pdf

programs. However, whereas all ESRD facilities are subject to the same set of quality measures under the ESRD QIP, there is no analogous source of quality measure data for Managing Clinicians. We stated that Managing Clinicians may be subject to MIPS, or they may be participating in a different CMS program – or an Advanced APM – which has different quality requirements. In addition, most Managing Clinicians participating in MIPS select the quality measures on which they report. Taken together, these factors mean that we would be unable to ensure that all Managing Clinicians in the ETC Model are already reporting on a given quality measure, and therefore would be unable to compare quality performance across all Managing Clinicians without imposing additional burden.

We proposed that the SHR and SMR measures would not be tied to payment under the ETC Model. However, we stated in the proposed rule that we believe that the collection and monitoring of these measures would be important to guard against adverse events or decreases in quality of care that may occur as a result of the performance-based payment adjustments in the ETC Model. We noted that we believe we would be able to observe changes over time in individual ESRD facility level scores on these measures, as well as comparing change over time for ESRD facilities that are ETC Participants against change over time in those that are not ETC Participants. In the aggregate, these measures should capture any increase in adverse events, particularly for patients on home dialysis, as home dialysis patients are included in both the numerators and denominators of these measures. We stated in the proposed rule that home dialysis patients primarily receive care through ESRD facilities, and barring beneficiaries excluded from the measures per the measure specifications, the majority of ESRD Beneficiaries attributed to an ETC Participant would be captured in these measures. These measures also

include ESRD Beneficiaries before they receive a kidney transplant; however, beneficiaries post-transplant would not be included, per the measure specifications.

We invited public comment on the proposed quality measures and whether their proposed use would enable CMS to sufficiently monitor for adverse conditions for ESRD Beneficiaries, in combination with the monitoring activities previously described. We also invited other suggestions as to measures that would support monitoring beneficiary health and safety under the Model, while minimizing provider burden.

Additionally, as described in the proposed rule and in section IV.C.6 of this final rule, we proposed that ETC Participants that are ESRD facilities would still be included in the ESRD QIP and required to comply with that program's requirements, including being subject to a sliding scale payment reduction if an ESRD facility's total performance score does not meet or exceed the minimum total performance score specified by CMS for the payment year. We explained that ETC Participants who are Managing Clinicians and are MIPS eligible clinicians would still be subject to MIPS requirements and payment adjustment factors, and those in a MIPS APM would be scored using the APM scoring standard. ETC Participants who are Managing Clinicians and who are in an Advanced APM would still be assessed to determine whether they are Qualifying APM Participants (QPs) who, as such, would earn the APM incentive payment and would not be subject to the MIPS reporting requirements or payment adjustment. We did not propose to waive any of these requirements for purposes of testing the ETC Model.

The following is a summary of the comments received on the quality measures included in the Model and our responses.

Comment: CMS received supportive comments for our proposal to use the two quality measures and not tie them to payment. However, a commenter stated that the measures incentivize increase utilization rather than performance improvement.

Response: CMS appreciates the feedback from these commenters. Both the SMR and the SHR are NQF-endorsed outcome measures for patients who receive dialysis at a given ESRD facility. The measures were chosen for the purpose of monitoring for adverse events that may occur as an unintended consequence of performance-based payment adjustments for home dialysis and transplant. While there are currently no measures of adverse events for beneficiaries who dialyze at home, CMS believes that adverse events at ESRD facilities is a suitable proxy, as the measures include both beneficiaries who dialyze at home and beneficiaries who dialyze in-center for a given ESRD facility.

Comment: We received several comments emphasizing the importance of beneficiary experience and requesting that CMS include a formal measure of beneficiary experience in this Model. A couple comments suggested that CMS develop a CAHPS measure for home dialysis.

Response: CMS considered the inclusion of ICH CAHPS to monitor beneficiary perceptions of change in quality of care as a result of the ETC Model. However, as we stated in the proposed rule, because the ICH CAHPS survey includes only beneficiaries who receive in-center dialysis, and specifically excludes the beneficiary populations that this Model is specifically focused on, namely beneficiaries moving away from in-center hemodialysis to alternative renal replacement therapies, ICH CAHPS does not reach the target beneficiary population. Because there is no equivalent CAHPS or other survey for home dialysis patients, or for post-transplant patients, CMS intends to develop a beneficiary experience measure, similar to the CAHPS survey, that could influence Model payments to participants as early as the third year

of the Model. We intend to propose and incorporate a beneficiary experience measure in the ETC Model in the near future.

The Model's evaluation will examine the effect of the ETC Model on such key outcomes as improved quality of care and quality of life. Data collection activities performed for purposes of the evaluation may include patient surveys and beneficiary focus groups.

Comment: Multiple commenters encouraged CMS to add additional quality measures. The commenters suggested measures including: ED utilization; peritonitis in hospital acquired infections; provision of supportive care services; behavioral and mental health; care coordination; safety and reliability; provider engagement; and Advanced Care Plans. In addition, commenters recommended that CMS develop a measure for referrals into the transplantation process as well as hospice. A commenter noted the burden of manual data collection and the impact on patient care.

Response: CMS chose the SMR and SHR measures, essential indicators for the ESRD population, because they are already reported in Dialysis Facility Reports and the ESRD QIP, respectively. These are programs run by CMS/CCSQ that produce dialysis facility-level quality data annually and, therefore, impose no additional administrative burden on ESRD facilities. We appreciate commenters suggestions about other potential quality measures that we could include in the ETC Model that may benefit the patient population. However, we believe that the two quality measures we have included are sufficient for the purposes of monitoring to guard against adverse events or decreases in quality of care that may occur as a result of the performance-based payment adjustments in the Model. All ETC Participants remain subject to other applicable CMS quality programs unless otherwise exempt, so we believe that other potential aspects of quality of care are sufficiently captured and incentivized by those quality programs. In addition,

the purpose of the measures is solely for monitoring for adverse events that may occur as an unintended consequence of performance-based payment adjustments for home dialysis and transplant, and will have no impact on the payment adjustments under the ETC Model. Therefore, CMS believes these two measures are adequate and no additional measures are needed at this time.

Comment: CMS received one comment urging CMS to use mortality and hospitalization rates rather than ratios because ratio measures have wide confidence intervals that potentially lead to incorrect information about facility performance being reported. In addition, the commenter recommended that CMS work with NQF to develop social-demographic adjusters.

Response: CMS appreciates the feedback. Both of the proposed measures are NQF-endorsed measures for renal conditions and are already reported through CMS reporting systems, Dialysis Facility Compare for SHR and SMR, and ESRD QIP for SHR. We believe it is appropriate to use the ratio measures for the purposes of the Model because they align with existing CMS programs. Additionally, we do not believe that the statistical features of these ratio measures referenced, namely the wide confidence intervals, contributes to incorrect information about facility performance being reported. These measures are already reported publicly at the facility level through Dialysis Facility Compare and the ESRD QIP, with explanation of the statistical properties of the ratios. Additionally, the measures are being used in the Model for monitoring purposes, and are not intended to convey specific information about individual facility performance to the public.

Comment: A commenter requested that CMS acknowledge that palliative dialysis is a patient-preference option that should not result in penalties under the ESRD QIP.

Response: CMS appreciates the feedback from our stakeholders. However, the comment pertains to the ESRD QIP generally and is therefore not within the scope of this final rule.

Based on the comments received, we are finalizing the quality measures as proposed without modification.

11. Evaluation

As we described in the proposed rule, an evaluation of the ETC Model would be conducted in accordance with section 1115A(b)(4) of the Act, which requires the Secretary to evaluate each model tested by the Innovation Center. We noted in the proposed rule that we believe an independent evaluation of the Model is necessary to understand its impacts of the Model on quality of care and Medicare program expenditures and to share with the public. We would select an independent evaluation contractor to perform this evaluation. As specified in the proposed rule and section II.E of this final rule, all ETC Participants would be required to cooperate with the evaluation.

We stated in the proposed rule that research questions addressed in the evaluation would include, but not be limited to, 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 ESRD Beneficiaries in Selected Geographic Areas in relation to Comparison Geographic Areas. The evaluation would also explore qualitatively what changes Managing Clinicians and ESRD facilities implemented in response to the ETC Model, what challenges they faced, and lessons learned to inform future policy developments.

We proposed that the ETC Model evaluation would employ a mixed-methods approach using quantitative and qualitative data to measure both the impact of the Model and implementation effectiveness. The impact analysis would examine the effect of the ETC Model

on key outcomes, including improved quality of care and quality of life, and decreased Medicare expenditures and utilization. The implementation component of the evaluation would describe and assess how ETC Participants implement the Model, including barriers to and facilitators of change. We noted in the proposed rule that findings from both the impact analysis and the implementation assessment would be synthesized to provide insight into what worked and why, and to inform the Secretary's potential decision regarding model expansion.

We would use multi-pronged data collection efforts to gather the quantitative and qualitative data needed to understand the context of the Model implemented at participating ESRD facility and Managing Clinician locations and the perspectives of different stakeholders. Data for the analyses would come from sources including, but not limited to, payment and performance data files, administrative transplant registry data, beneficiary focus groups, and interviews with ETC Participants.

As described in the proposed rule, the quantitative impact analysis would compare performance and outcome measures over time, using a difference-in-differences or a similar approach to compare beneficiaries treated by ETC Participants to those treated by ESRD facilities and Managing Clinicians in Comparison Geographic Areas. We would examine both cumulative and year-over-year impacts. The quantitative analyses conducted for the evaluation would take advantage of the mandatory nature of the ETC Model for ESRD facilities and Managing Clinicians located in Selected Geographic Areas.

We explained in the proposed rule that, while the model design would control for the selection bias inherent in voluntary models, a comparison group would still be necessary to determine if any changes in outcomes are due to the ETC Model or to secular trends in CKD and ESRD care. The comparison group would be those Managing Clinicians and ESRD facilities

located in Comparison Geographic Areas which would not be subject to the ETC Model payment adjustments. The evaluator would match Managing Clinicians and ESRD facilities located in Comparison Geographic Areas with Managing Clinicians and ESRD facilities that are located in Selected Geographic Areas (that is, ETC Participants) using propensity scores or other accepted statistical techniques. Beneficiaries who receive care from ESRD facilities and Managing Clinicians in these Selected Geographic Areas and Comparison Geographic Areas would be identified using the ETC Model claims-based eligibility criteria, and would be attributed using the same claims-based beneficiary attribution methods we proposed to use for purposes of calculating the MPS.

We stated in the proposed rule that the evaluation would account for any interaction with other CKD- and ESRD-related initiatives at CMS, such as the ESRD QIP, the CEC Model, and the KCC Model (formerly the CKC Model). For example, the evaluator would look for disparate outcomes that could arise in the ESRD QIP between facilities that are also participating in the ETC Model and facilities that are not participating in the ETC Model and also assess whether performance in the ETC Model varies for Managing Clinicians and ESRD Facilities who are also participating in the CEC or KCC Models.

We invited public comment on our proposed approach related to the evaluation of the ETC Model.

Comment: A commenter noted that CMS did not specify the timing of the ETC Model evaluation.

Response: We thank the commenter for this feedback. The evaluation will be active during and after the Model test period to allow for data collection and analysis. We expect the

evaluation will have annual reports covering the assessment of the Model using available data, including a summative report following the conclusion of the model test.

Comment: A commenter recommended that the evaluation take into account any possible negative impacts or lack of impact of the Model. Should the latter occur, the commenter suggested that the Model should be terminated.

Response: We agree with the commenter regarding the need to assess potential negative impacts of the Model. We clarify here that the evaluation will account for potential impacts of the Model including positive, negative, or a lack thereof, in terms of both Medicare expenditures and the quality of care and we would determine the appropriate actions, including potential termination of the Model, based upon an analysis of the evaluation findings.

Comment: A commenter noted that the Model evaluation should measure the impact of concurrent hospice dialysis access; specifically, patient and family experience with care satisfaction and costs at the end of life.

Response: We appreciate this comment suggesting a measure to assess in evaluating the Model. The Model evaluation's questions around quality of care and quality of life and expenditures include questions regarding patient and family experience and costs at the end of life, and we will analyze these questions to the extent feasible.

Comment: Several commenters expressed concern that 50 percent of the 306 HRRs in the US is larger than is necessary to evaluate a change in the transplantation rate as a result of the Model.

Response: As previously noted, we performed a power calculation to determine the minimum sample size of the participant and comparison groups in the Model in order to produce robust and reliable results. We determined from these tests that 30 percent of the HRRs are

needed to minimize the risk of false positive and false negative results, and the minimum detectable effect of a two percentage point increase or decrease in the rate of transplant wait listing and a one and one-half percentage point increase or decrease in home dialysis  Since this approach provides sufficient statistical power, we are finalizing our evaluation approach as proposed.

12. Learning System

We proposed that in conjunction with the ETC Model, CMS would operate a voluntary learning system focused on increasing the availability of deceased donor kidneys for transplantation. The learning system would work with, regularly convene, and support ETC Participants and other stakeholders required for successful kidney transplantation, such as transplant centers, OPOs, and large donor hospitals. We proposed that these ETC Participants and stakeholders would utilize learning and quality improvement techniques to systematically spread the best practices of highest performers. The application of broad scale learning and other mechanisms for rapid and effective transfer of knowledge within a learning network would also be used. Quality improvement approaches would be employed to improve performance by collecting and analyzing data to identify the highest performers, and to help others to test, adapt and spread the best practices of these high performers throughout the entire national organ recovery system. We stated in the proposed rule that we believed that implementation of the learning system would help to increase the supply of transplantable kidneys, which would help ETC Participants achieve the goals of the Model.

Comment: We received several comments in this area, all supporting CMS's proposal to implement the proposed learning system. A commenter proposed working with the Quality Improvement Organizations (QIOs) to help implement the learning system and branding the

learning collaborative as the "Transplant First" initiative. Another commenter proposed delaying implementation of the transplant component of the PPA until the learning collaborative has been implemented for multiple years.

Response: We appreciate the commenters' support for the proposed learning system and are finalizing our proposal to implement it as proposed. We plan to refer to the learning system as the ETC Learning Collaborative as it is a part of the ETC Model test and we do not wish to confuse ETC Participants or the public by giving the learning system a name with no clear connection to the Model. We appreciate the suggestion about the QIOs, but we do not believe that QIO involvement is necessary given their other priority areas that they are working on. In terms of the comment recommending that CMS delay implementation of the transplant component of the PPA until the learning collaborative has been implemented for multiple years, while we hope that the ETC Learning Collaborative will be successful at improving utilization of available kidneys, such a delay is not necessary because, as previously described in section IV.C of this final rule, we are now assessing ESRD facilities and Managing Clinicians based on their ability to impact transplant rates calculated as the sum of the transplant waitlist rate and the living donor transplant rate, rather than overall transplant rates including deceased donor transplants, for purposes of the ESRD PPA and Managing Clinician PPA, respectively.

After considering the public comments, we are implementing the learning system under this Model as proposed.

13. Remedial Action

As described in the proposed rule and in section 512.160 of this final rule, the remedial actions outlined in the general provisions in § 512.160 would apply to the ETC Model. Accordingly, if CMS determines that an ETC Participant has engaged in one or more of the

actions listed under § 512.160(a) (Grounds for Remedial Action), CMS may take one or more of the remedial actions listed under § 512.160(b).

We did not receive comments on our proposals relating to remedial action in the ETC Model. Therefore, we are finalizing these proposals without modification.

14. Termination of the ETC Model

As described in the proposed rule, the general provisions relating to termination of the Model that CMS proposed in the proposed rule and discussed in section II.J of this final rule would apply to the ETC Model. Consistent with these provisions, in the event we terminate the ETC Model, we would provide written notice to ETC Participants specifying the grounds for termination and the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act and § 512.170, termination of the Model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

We did not receive comments on the proposals relating to termination of the ETC Model. Therefore, we are finalizing our proposals without modification.

## V. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing, evaluation, and expansion of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated information collection requirements in section VI.C.4. of this final rule.

## VI. Regulatory Impact Analysis

We have examined the impact of this final rule as required by Executive Order 12866 and other laws and Executive Orders, requiring economic analysis of the effects of final rules. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold and also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, reflects the economic impact of the policies contained in this final rule.

### A. Statement of Need

#### 1. Need for the Radiation Oncology (RO) Model

Radiotherapy (RT) services represent a promising area of health care for payment and service delivery reform. First, RT services are furnished in both freestanding radiation therapy centers paid under the Medicare Physician Fee Schedule (PFS) and the Outpatient Prospective Payment System (OPPS). There are site-of-service payment differentials between the OPPS and PFS payment systems, which can result in financial incentives to offer care in one setting over another. Second, as in other health care settings, health care providers are financially incentivized to provide more services to patients because they are paid based on the volume of

care they provide, not value. We believe that these incentives are misaligned with evidence-based practice, which is moving toward furnishing fewer radiation treatments for certain cancer types. Third, difficulties in coding and setting payment rates for RT services have led to volatility in Medicare payment for these services under the PFS and increased coding complexity and administrative burden. As part of the RO Model's design, we will examine whether the model leads to higher quality care by encouraging improved adherence to clinical guidelines and by collecting information related to quality performance and clinical practice. The RO Model aims to incentivize RO participants to maintain high quality care with the opportunity to earn back a withheld payment amount through successful quality outcomes and clinical data reporting.

As described in detail in section III.C.8. of this final rule, RO participants are required to collect and submit 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.

We refer readers to section III.B. of this final rule for more information on our research and rationale for the RO Model, including summaries of stakeholder comments on this rationale and our response. We refer readers to section III.C for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy.

2. Need for End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model

Beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. One of CMS' goals in designing the ETC Model is to test ways to incentivize home dialysis and kidney transplants, so as to enhance beneficiary choice of modality for renal replacement therapy, and improve or maintain quality of care while reducing

Medicare program expenditures. The substantially higher expenditures, mortality, and hospitalization rates for dialysis patients in the U.S. compared to those for individuals with ESRD in other countries indicate a population with poor clinical outcomes and potentially avoidable expenditures. We anticipate preservation or improvement in quality of care for beneficiaries and reduced expenditures under the ETC Model inasmuch as the Model will create incentives for beneficiaries, along with their families and caregivers, to choose the optimal kidney replacement modality.

In section IV.B of this final rule, we describe how current Medicare payment rules and a deficit in beneficiary education result in a bias toward in-center hemodialysis, which is often not preferred by patients or physicians relative to home dialysis or kidney transplantation. We provide evidence from published literature to support the projection that higher rates of home dialysis and kidney transplants will reduce Medicare expenditures, and, not only enhance beneficiary choice, independence, and quality of life, but also preserve or enhance the quality of care for ESRD beneficiaries.

As described in detail in sections II. and IV. of this final rule, ETC Participants will be subject to payment adjustments under the ESRD Prospective Payment System (ESRD PPS) and Physician Fee Schedule (PFS), as applicable, and will be required to comply with certain requirements, including to cooperate with CMS's monitoring and evaluation activities, for the duration of the ETC Model.

3. Impact of RO Model and ETC Model

In the proposed rule (84 FR 34567), we estimated, as detailed in Table 16A of the proposed rule, a net impact of $260 million in net savings to the Medicare program due to the RO Model from January 1, 2020 through December 31, 2024, with a range of impacts between

$50 million and $460 million in net Medicare savings. Alternatively, as detailed in Table 16B of the proposed rule, we estimated a net impact of $250 million in net savings to the Medicare program due to the RO Model from April 1, 2020 through December 31, 2024, with a range of impacts between $40 million and $450 million in net Medicare savings.

As detailed in Table 17 of the proposed rule, we estimated the Medicare program would save a net total of $185 million from the PPA and HDPA, which would be applied under the ETC Model between January 1, 2020 through June 30, 2026. We also stated our expectation that the ETC Model would cost an additional $15 million, resulting from increases in education and training costs. Therefore, we estimated the net impact to Medicare spending to be $169 million in savings as a result of the ETC Model.

We solicited comment on the assumptions and analysis presented throughout the regulatory impact section of the proposed rule.

Comment: A few commenters stated that the RO Model's estimates of $250-$260 million in savings over a 5-year period are understated. One commenter suggested that total savings would be closer to $320 million over 5 years based on volume and intensity (V&I) calculations of the bundled services per episode, which remain unchanged between the period used for rate setting and when payments are made.

Response: We thank these commenters for expressing their concerns. Policy impact estimates may vary depending on a number of factors. Our estimate reflects a net Medicare Part B financial impact. Therefore, our impact analysis includes changes to Medicare Trust Fund payments and other Medicare financing interaction effects such as changes in Part B Trust Fund revenue, MA capitation rates, APM incentive payments, and the BBA 1999 IPPS Part A deductible cap. Moreover, the impact estimate excluded changes in beneficiary cost sharing

liability to the extent it is not shifted to being a Federal outlay by the policy. Our estimate also assumed the V&I of the bundled services per episode remains unchanged between the period used for rate setting and when payments are made. We estimated that if V&I were to decrease by 1.0 percent annually for the bundled services absent the model, then Medicare would reduce net outlays by $50 million ($40 million with an April 1, 2020 start date) between 2020 and 2024. Similarly, if V&I increases by 1.0 percent annually then net outlays would be reduced by $460 million ($450 million with an April 1, 2020 start date) for the projection period. While we noted in the proposed rule that although V&I growth from 2014 through 2017 fell within this 1.0 percent range and did not exhibit a secular trend, actual experiences may vary. We are finalizing a different Model performance period and Model geographic scope than proposed, and have updated assumptions and estimates in VI.C of this final rule.

Based on the finalized policy, we have updated our net estimate of the RO Model impact and now expect a savings of $230 million for Medicare. We have also updated our net estimate of the ETC Model impact and now expect a savings of $23 million for Medicare. We discuss our analysis in greater detail in sections VI.C.1(a) and VI.C.2.a(3) of this final rule.

B. Overall Impact

We have examined the impacts of this final rule as 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), the Congressional Review Act (5 U.S.C. 804(2)), and

Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. As stated previously in this final rule, this final rule triggers these criteria.

C. Anticipated Effects

1. Scale of the Model

As we stated in the proposed rule (84 FR 34569 through 34570), there is no one-size-fits-all approach to designing, implementing, and evaluating models. Each payment and service delivery model tested by the Innovation Center is unique in its goals, and thus its design. Models vary in size in order to accommodate various design features and satisfy a variety of priorities. Decisions made regarding the features and design of the model strongly influence the extent to

which the evaluation will be able to accurately assess the effect of a given model test and produce clear and replicable results.

The Innovation Center conducts analyses to determine the ideal number of participants for each model for evaluation purposes. This analysis considers a variety of factors including the target population (for example, Medicare beneficiaries with select medical conditions), model eligibility (for example, beneficiary eligibility criteria for inclusion in the model), participant enrollment strategy (for example, mandatory versus voluntary) and, the need to test effects on subgroups. Model size can also be influenced by the type and size of hypothesized effect on beneficiary outcomes, such as quality of care, or the target level of model savings. The smaller the expected impact a model is hypothesized to achieve, the larger a model needs to be for CMS to have confidence in the observed impacts.

An insufficient number of participants increases the risk that the evaluation will be imprecise in detecting the true effect of a model, potentially leading, for example, to a false negative or false positive result. The goal is to design a model that is sufficiently large to achieve adequate precision but not so large as to waste CMS's limited resources. These decisions affect the quality of evidence CMS is able to present regarding the impacts of a model on quality of care, utilization, and spending.

a. Radiation Oncology (RO) Model

In the case of the RO Model, in the proposed rule we determined the sample size necessary for a minimum estimated savings impact of 3 percent (84 FR 34568). While a savings higher than 3 percent would require a smaller sample size from an evaluation perspective, if we were to reduce the size of the RO Model and if the actual savings are at or just below the 3 percent level, then we would increase the risk of being unable to detect whether the RO Model

resulted in savings.

We refer readers to the proposed rule where we proposed that the RO Model would include 40 percent of radiation oncology episodes in eligible geographic areas and our simulation based on this proposal. In section III.C.3.c of this final rule, we finalized our policy to include 30 percent of radiation oncology episodes and a low-volume exception. We performed a simulation based on our finalized policies. Based on this simulation, we expect to have approximately 500 physician group practices (PGPs) (of which 275 are freestanding radiation therapy centers) and 450 HOPDs furnishing RT services in those simulated selected CBSAs. We further expect the RO Model to include approximately 348,000 episodes, 309,000 beneficiaries, and $5.3 billion in total episode spending of allowed charges over the Model performance period. To determine the number of PGPs, we counted the number of TINs that furnished at least one professional or technical component in 2018 in one of the CBSAs selected for Model participation as recorded in the 2016—2018 episode file. To determine the number of HOPDs, we counted the number of facility CCNs that furnished at least one technical component in 2018 in the CBSAs selected for Model participation as recorded in the 2016-2018 episode file. Similarly, to determine episode count, beneficiary count, and total spending estimates, we drew upon the historical data of RO participants simulated into CBSAs selected for participation. These estimates represent the Model size of 30 percent of RO episodes in eligible geographic areas

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

The ETC Model will include approximately 30 percent of ESRD beneficiaries, through the ESRD facilities and Managing Clinicians selected for participation in the Model. The Innovation Center will randomly select 30 percent of HRRs, stratified by region, and include

separate from randomization all HRRs for which at least 20 percent of the component zip codes are located in Maryland. All ESRD facilities and Managing Clinicians in selected HRRs, referred to as Selected Geographic Areas, will be required to participate in the Model. There are currently 7,196 ESRD facilities and 2,286 Managing Clinicians enrolled in Medicare, distributed across 306 HRRs and providing care for 383,057 ESRD beneficiaries that meet the eligibility criteria for attribution to ETC Participants under the Model. Only approximately 10 percent of beneficiaries on dialysis received home dialysis in 2017. The ETC Model will apply the payment adjustments described in section IV. of this final rule to claims with "claim service dates" between January 1, 2021 through June 30, 2027, and over that time period, will randomize 30 percent of the HRRs that the ESRD facilities and Managing Clinicians align with and generate $23 million in net Medicare savings. See Table 2 for an annual breakdown.

c. Aggregate Effects on the Market

As we noted in the proposed rule, there may be spillover effects in the non-Medicare market, or in non-ESRD areas of the Medicare market because of the implementation of these models. Testing changes in Medicare payment policy may have implications for non-Medicare payers. As an example, non-Medicare patients may benefit if participating providers and suppliers introduce system-wide changes that improve the coordination and quality of health care. Other payers may also be developing payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS' evaluations of payment models. Because there is uncertainty whether and how this evidence applies to a test of these new payment models, our analyses assume that spillover effects on non-Medicare payers will not occur, although this assumption is subject to considerable uncertainty. We solicited comments

on this assumption and evidence on how this rulemaking would impact non-Medicare payers and patients.

Comment: A couple of commenters expressed concern that the RO Model payment methodology could the impact practices where commercial payers use Medicare rates as a proxy.

Response: As stated in the proposed rule for the RO Model (84 FR 34568), although we assume that spillover effects on non-Medicare payers will not occur, we understand that considerable uncertainty surrounds this assumption. However, no evidence has been found to support this assumption that that the RO Model will impact non-Medicare payers either. In our analyses, we assume growth of FFS Medicare Part B enrollment as projected in the 2018 Medicare Trustees Report. We also assume that providers and suppliers would not change payer mix as a response to the RO Model. However, we hope that, at the end of the RO Model's evaluation, information learned can move Medicare and non-Medicare payment to more accurately and appropriately reimburse high-value RT services.

2. Effects on the Medicare Program

a. Radiation Oncology Model

(1) Overview

Under the current FFS payment system, RT services are paid on a per service basis to both PGPs (including freestanding radiation therapy centers) and HOPDs through the PFS and the OPPS, respectively. The RO Model will be a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during episodes initiated between January 1, 2021 and December 31, 2025.

The RO Model will test differences in payment from traditional FFS Medicare by paying RO participants two equal lump-sum payments, once at the start of the RO episode and again at

the end, for episodes of care. RO episode means the 90-day period that, as set forth in § 512.245, begins on the date of service that a Professional participant or a Dual participant furnishes an initial treatment planning service to an RO beneficiary in a freestanding radiation therapy center or an HOPD, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service. RO episodes include all Medicare items and services described in § 512.235 that are furnished to an RO beneficiary described in § 512.215. Once an RO episode is initiated, RO participants will no longer be allowed to separately bill other HCPCS codes or APC codes for activities related to radiation treatment for the RO beneficiary in that RO episode.

For each participating entity, the participant-specific professional episode payment and participant-specific technical episode payment amounts would be determined as described in detail in section III.C.6. of this final rule.

The RO Model is not a total cost of care model. RO participants will still bill traditional FFS Medicare for services not included in the episode payment and, in some instances, for less common cancers not included in the model and other exclusion criteria. A list of cancer types that meet the criteria for inclusion in the RO Model and associated FFS procedure codes are included in section III.C.5. of this final rule.

(2) Data and Methods

Similar to the analysis performed for regulatory impact analysis for the proposed rule (84 FR 34571), a stochastic simulation based on the finalized policies was created to estimate the financial impacts of the RO Model relative to baseline expenditures. The simulation relied upon statistical assumptions derived from retrospectively constructed RT episodes between 2016 and

2018 (updated from the 2015-2017 episodes used in the proposed rule to reflect finalized policy). This information was reviewed and determined to be reasonable for the estimates.

To project baseline expenditures, traditional FFS payment system billing patterns are assumed to continue under current law. Forecasts of the Medicare Part A and Part B deductibles were obtained from the 2019 Medicare Trustees Report and applied to simulated episode payments to estimate interactions of lump sum payments with the HOPD line item cap as described in section 1833(t)(8)(C)(i) of the Act. We assumed that the current relative value units under the PFS and relative payment weights under the OPPS in the updated episode data from 2016 through 2018 would continue into the future, which is consistent with the updates we made for the payment methodology in section III.C.6 of this final rule. Similarly, conversion factors in both the PFS and OPPS were indexed to the appropriate update factors under current law. Payment rate updates to future PFS conversion factors are legislated at 0.25 percent in 2019 and 0.0 percent for 2020 through 2025 under the Medicare Access and CHIP Reauthorization Act of 2015. OPPS conversion factors are updated by the productivity-adjusted inpatient hospital market basket update in our simulation. We forecast that net OPPS updates will outpace the PFS by 3.0 percent on average annually between 2019 and 2025.

(3) Medicare Estimate

Table 1 summarizes the estimated impact of the RO Model. The estimated impact reflects the finalized policies, which are different than some of the proposed rule policies. For instance, we are finalizing policies for reduced discount factors, a smaller Model size of 30 percent of RO episodes in eligible geographic areas, a low volume opt-out option, a stop-loss policy for RO participants with fewer than 60 episodes during 2016-2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of

this final rule, and a Model performance period of January 1, 2021 through December 31, 2025. Thus, we are now estimating that on net the Medicare program will save $230 million over the Model performance period. As in the proposed rule, this is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy.

On net, we project a lower spending reduction per RO episode and that slightly more RO episodes (2,000 more RO episodes) would be paid through the RO Model. As for the stop-loss policy, it applies only to RO participants with fewer than 60 episodes during 2016-2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of this final rule. Under the stop-loss policy, if payments under the Model resulted in more than 20 percent loss as compared to the amount the RO participant would have received under FFS, then CMS owes the RO participant the amount that exceeds that 20 percent. Recall that RO participants with fewer than 60 episodes during 2016-2018 do not receive a historical experience adjustment. The stop-loss payments for these RO participants were projected under the assumption that similar qualification rates and FFS claims volatility for these eligible providers experienced during 2016-2018 would occur within no-pay claims submitted during the Model test. The RO participants eligible for the stop-loss policy are projected to account for 1.2 percent of the Model episode spending, and we estimate the five-year cost of this policy to be $0.3 million, an immaterial impact on the savings estimate as displayed in Table 1. Revisions to the projected impacts primarily reflect the net effects of changes to the Model start and end dates, refinements to the randomization procedures used for CBSA selection, and a reduction in the proposed discount factors by 0.25 percent.

We project that 83 percent of physician participants (measured by unique NPI) would receive the APM incentive payment under the Quality Payment Program at some point (at least one QP Performance Period) during the model performance period. This assumption is based on applying the 2020 QPP final rule qualification criteria to simulated billing and treatment patterns for each QPP performance year during the RO Model test. Episode-initiating physicians were assumed to form an APM entity with the TIN(s) under which they bill for RT services. For each APM entity, counts of total treated patients and spending for covered physician services under the RO Model were estimated and applied to QPP qualification criteria based on CY2018 provider billing patterns.

As explained in section III.C.9 of this final rule, the APM incentive payment will apply only to the professional episode payment amounts and not the technical episode payment amounts and that APM incentive payments will be paid based on participation in the RO Model during 2021 and 2022. Due to the 2-year lag between the QPP performance and payment periods, these APM incentive payments are therefore assumed to be made during 2023 and 2024.

Complete information regarding the data sources and underlying methodology used to determine amounts for reconciliation were not available at the time of this forecast. In the case of the incomplete payment withhold, we assumed CMS retains payment only in the event that offsetting payment errors were made elsewhere. Past CMS experience in other value-based payment initiatives that included a penalty for not reporting have shown high rates of reporting compliance. Given the limited spending being withheld, scoring criteria, and specified timeframes involved, we assume that quality and patient experience withholds, on net, have a negligible financial impact to CMS.

A key assumption underlying of the impact estimate 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 by 1.0 percent annually for the bundled services absent the RO Model, then we estimate the impact of the RO Model to Medicare spending to be approximately budget neutral between January 1, 2021 and 2025. Similarly if V&I increases by 1.0 percent annually then net outlays would be reduced by $470 million for the projection period. Although V&I growth from 2014 through 2018 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ. Please also note that due to the current public health crisis caused by the COVID-19 virus, the forecasted impacts for the RO Model are subject to an additional level of uncertainty. The duration of the current COVID-19 pandemic, its severity, and the policy measures taken as a response are variables that are significant but unknown at this time. This forecast assumes that Medicare FFS billing and treatment patterns for beneficiaries observed during the 2016-2018 baseline period resume by the start of 2021. To the extent that this assumption does not hold, actual experience may vary significantly.

This table summarizes our estimated impacts of this final rule:

**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.

b. ESRD Treatment Choices Model

(1) Overview

Under the ESRD Prospective Payment System (PPS) under Medicare Part B, a single per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. Under the Physician Fee Schedule, medical management of an ESRD beneficiary receiving dialysis by a physician or other practitioner is paid through the MCP. The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in section IV. of this final rule, for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021 to June 20, 2027.

Under the ETC Model, there will be two payment adjustments designed to increase rates of home dialysis and kidney transplants through financial incentives. The HDPA is an upward payment adjustment on certain home dialysis claims for ESRD facilities, as described in §§ 512.340 and 512.350, and to certain home dialysis-related claims for Managing Clinicians, as described in §§ 512.345 and 512.350, during the initial 3 years of the ETC Model.

The PPA is an upward or downward payment adjustment on certain dialysis and dialysis-related claims submitted by ETC Participants, as described in §§ 512.375(a) and 512.380 for ESRD facilities and §§ 512.375(b) and 512.380 for Managing Clinicians, which will apply to claims with claim service dates beginning on July 1, 2022 and increase in magnitude over the duration of the Model. We will assess each ETC Participant's home dialysis rate, as described in § 512.365(b), and ETC Participant's transplant rate, as described in § 512.365(c), for each

Measurement Year. The ETC Participant's transplant rate, which is calculated as the sum of the risk adjusted transplant waitlist rate and living donor transplant rate, will be aggregated, as described in 512.365(e), and the ETC Participant's home dialysis rate will be aggregated, as described in § 512.365(e). The ETC Participant will receive a Modality Performance Score (MPS) based on the weighted sum of the higher of the ETC Participant's achievement score or improvement score for the home dialysis rate and the higher of the ETC Participant's achievement score or improvement score for the transplant rate, as described in §512.370(d). The achievement scores will be calculated in relation to a set of benchmarks based on the historical rates of home dialysis and inclusion on the transplant waitlist among ESRD facilities and Managing Clinicians located in Comparison Geographic Areas. As discussed in the proposed rule and section IV.C.5.d. of this final rule, we intend to increase these benchmarks over time. Any such changes would be made through subsequent notice and comment rulemaking. The improvement score will be calculated in relation to a set of benchmarks based on the ETC Participant's own historical performance. The ETC Participant's MPS for a MY will determine the magnitude of its PPA during the corresponding 6-month PPA Period, which will begin 6 months after the end of the MY. An ETC Participant's MPS will be updated on a rolling basis every 6 months.

The ETC Model will not be a total cost of care model. ETC Participants will still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments will continue to be paid as they would in the absence of the Model.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the Model relative to baseline expenditures. The simulation relied upon statistical assumptions derived

from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims and transplant waitlist data reported during 2016 and 2017, the most recent years with complete data available. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary.

The ESRD facilities and Managing Clinicians datasets were restricted to the following eligibility criteria. Beneficiaries must be residing in the United States, 18 years of age or older, and enrolled in Medicare Part B. Beneficiaries enrolled in Medicare Advantage or other cost or Medicare managed care plans, who have elected hospice, receiving dialysis for acute kidney injury (AKI) only, is residing in or receiving dialysis in a skilled nursing facility (SNF) or nursing facility, or has a diagnosis of dementia were excluded. In addition, the HRR was matched to the claim service facility zip code or the rendering physician zip code for ESRD facility and Managing Clinician, respectively.

For the modeling exercise used to estimate changes in payment to providers and suppliers and the resulting savings to Medicare, OACT maintained the previous method proposed to identify ESRD facilities with common ownership, the low-volume exclusion threshold, and the aggregation assumptions as these proposed changes are unlikely to have a significant impact in terms of our modeling. To clarify OACT's methodology, the ESRD facilities data were aggregated to the CMS Certification Number (CCN) level for beneficiaries on dialysis identified by outpatient claims with Type of Bill 072X to capture all dialysis services furnished at or through ESRD facilities. Beneficiaries receiving home dialysis services were defined as condition codes 74, 75, 76, and 80. Beneficiaries receiving in-center dialysis services were defined using condition codes 71, 72, and 73. For consistency with the exclusion in § 512.385(a), after grouping within each HRR, aggregated ESRD facilities with less than 132 total

attributed beneficiary months during a given MY were excluded. When constructing benchmarks, for consistency with the methodology for aggregating performance for purposes of the PPA calculation, we aggregated all ESRD facilities owned in whole or in part by the same dialysis organization located in the same HRR.

The Managing Clinicians' performance data were aggregated to the TIN level (for group practices) and the individual NPI level (for solo practitioners). For purposes of calculating the home dialysis rate, beneficiaries on home dialysis and were identified using outpatient claims with CPT® codes 90965 and 90966. Beneficiaries receiving in-center dialysis were identified by outpatient claims with CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962. Similar to our decision for the ESRD facilities, we did not expect the proposed changes to the low-volume threshold for the Managing Clinicians to have a significant impact on the model's estimate. To clarify, within each HRR, OACT applied a low-volume exclusion to Managing Clinicians in the bottom 5 percent in terms of beneficiary-years for which the Managing Clinician billed the MCP during the year. The aggregation method may vary when the ETC Model is executed.

The Scientific Registry of Transplant Recipients (SRTR) transplant waitlist data were obtained from the Center for Clinical Standards and Quality (CCSQ). To construct the transplant waitlist rate, the numerator was based on per-patient counts and included every addition to the waitlist for a patient in any past year. The waitlist counts for the numerator included waitlists for kidney transplants, alone or with another organ, active and inactive records, multi-organ listings, and patients that have subsequently been removed from the waitlist. The denominator was a unique count of prevalent dialysis patients as of the end of the year. Only patients on dialysis as of December 31st for the selected year were included. Facility attribution was based on the facility the patient was admitted to on the last day of the year.

The effects of the living donor transplants are described in two sections of this RIA. First, we provide a sensitivity estimate in the "Effects on Kidney Transplantation" section that includes the impact of living donor transplants. Since the sensitivity estimate is not part of the main model's calculations, the overall savings to Medicare estimate was not impacted. Second, we describe the modified transplant rate that includes two parts, the transplant waitlist rate and the living donor transplant rate in the "Effects of the Revised Transplant Rate" section. OACT's conclusion of the modified transplant rate was that the preemptive and living donor transplants are limited in frequency among the Medicare primary payer population; therefore, their inclusion in the transplant waitlist scores is not estimated to significantly impact overall payments under the Model.

The home dialysis score and transplant waitlist score for the PPA were calculated using the following methodology for the ESRD facilities and Managing Clinicians. ETC Participant behavior for each year was simulated by adjusting the ETC Participant's baseline home dialysis (or transplant waitlist) rate for a simulated statistical fluctuation and then summing with the assumed increase in home dialysis (or transplant waitlist) rate multiplied by a randomly generated improvement scalar. The achievement and improvement scores were assigned by comparing the ETC Participant's simulated home dialysis (or transplant waitlist) rate for the MY to the percentile distribution of home dialysis (or transplant waitlist) rates in the prior year. Last, the MPS was calculated using the weighted sum of the higher of the achievement or improvement score for the home dialysis rate and the transplant waitlist rate. The home dialysis rate constituted two -thirds of the MPS, and the transplant waitlist rate one-third of the MPS.

In addition, the waitlist benchmarks were annually inflated by approximately 2 percentage points growth observed during years 2017 through 2019 in the CCSQ data, to project

rates of growth. The annual growth rate was from the median transplant waitlist rate across HRR condensed facilities growing from 8 percent in 2017 to 10 percent in 2018 to 13 percent in 2019 (that is, not a growth rate of 1.02 percent per year).

To assess the impact of COVID-19 on the kidney transplant waitlist, we analyzed data from the United Network for Organ Sharing (UNOS)[161]. The UNOS data suggest that the number of new patients added to the kidney transplant waitlist steadily decreased between the weeks of March 15, 2020 through May 3, 2020, when between 16 to 81 percent of patients listed on the weekly kidney transplant waitlist became inactive due to COVID-19 precautions. During June and July 2020, the number of new patients added to the kidney transplant waitlist increased to near pre-pandemic levels with an average of less than 4 percent of patients listed as inactive due to COVID-19. Therefore, we assume that the number of new patients added to the waitlist will not decrease as a result of the pandemic and the linear 2 percentage point growth rate for the transplant waitlist calculated using years 2017 through 2019 CCSQ data does not need to be revised to account for COVID-19.

The HDPA calculation required a simplified methodology, with home dialysis and home dialysis-related payments adjusted by decreasing amounts (3, 2, and 1 percent) during each of the first 3 years of the Model.

The Kidney Disease Education (KDE) benefit utilization and cost data were identified by codes G0420 and G0421, to capture face-to-face individual and group training sessions for chronic kidney disease beneficiaries on treatment modalities. The home dialysis training costs for incident beneficiaries on home dialysis for Continuous Ambulatory Peritoneal Dialysis

[161] UNOS. 2020. COVID-19 and Solid Organ Transplants. Transplant and Waitlist Data Visualizations. https://unos.org/covid/

(CAPD) or Continuous Cycler-Assisted Peritoneal Dialysis (CCPD) were defined using CPT® codes 90989 and 90993 for complete and incomplete training sessions, respectively.

Data from calendar year 2017 were used to project baseline expenditures and the traditional FFS payment system billing patterns were assumed to continue under current law.

(3) Medicare Estimate – Primary Specification, Assume Rolling Benchmark

Table 2 summarizes the estimated impact of the ETC Model when assuming 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. We estimate the Medicare program will save a net total of $32 million from the PPA and HDPA between January 1, 2021 and June 30, 2027 less $9 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $23 million in savings. In Table 2, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results were generated from an average of 500 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. The projections do not include the Part B premium revenue offset because the payment adjustments under the ETC Model will not affect beneficiary cost-sharing. Any potential effects on Medicare Advantage capitation payments were also excluded from the projections. This approach is consistent with how CMS has previously conveyed the primary Fee-For-Service effects anticipated for an uncertain model without also assessing the potential impact on Medicare Advantage rates.

As anticipated, the expected Medicare program savings were driven by the net effect of the Facility PPA; a reduction in Medicare spending of $57 million over the period from July 1, 2022 through June 30, 2027. In comparison, the net effect of the Clinician PPA was only $1

million in Medicare savings. This estimate was based on an empirical study of historical home dialysis utilization and transplant waitlist rates for Medicare FFS beneficiaries that CMS virtually attributed to ESRD facilities and to Managing Clinicians based on the plurality of associated spending at the beneficiary level. We analyzed the base variation in those facility/practice level measures and simulated the effect of the payment policy assuming providers and suppliers respond by marginally increasing their share of patients utilizing home dialysis. Random variables were used to vary the effectiveness that individual providers and suppliers might show in such progression over time and to simulate the level of year-to-year variation already noted in the base multi-year data that was analyzed. The uncertainty in the projection was illustrated through an alternate scenario assuming that the benchmarks against which ETC Participants are measured were to not be updated as well as a discussion of the 10th and 90th percentiles of the actuarial model output. These sensitivity analyses are described in sections VII.C.2.b.(3)(a) and VII.C.2.b.(3)(b) of this final rule, respectively. KDE sessions on treatment modalities and home dialysis (HD) training for incident dialysis beneficiaries are relatively small outlays and were projected to represent only relatively modest increases in Medicare spending each year.

The key assumptions underlying the impact estimate are that each consolidated ESRD facility or Managing Clinician's share of total maintenance dialysis provided in the home setting was assumed to grow by up to an assumed maximum growth averaging 3 percentage points per year. Factors underlying this assumption about the home dialysis growth rate include: known limitations that may prevent patients from being able to dialyze at home, such as certain common disease types that make peritoneal dialysis impractical (for example, obesity); current equipment and staffing constraints; and the likelihood that a patient new to maintenance dialysis starts

dialysis at home compared to the likelihood that a current dialysis patient who dialyzes in center switches to dialysis at home. The 3 percentage point per year max growth rate will, in effect, move the average market peritoneal dialysis rate (about 10 percent) to the highest market baseline peritoneal dialysis rate (for example, Bend, Oregon HRR at about 25 percent), which we believe is a reasonable upper bound on growth over the duration of the ETC Model for the purposes of this actuarial model.

Consolidated ESRD facilities at the HRR level or Managing Clinicians were assumed to achieve anywhere from zero to 100 percent of such maximum growth in any given year. Thus, the average projected growth for the share of maintenance dialysis provided in the home was 1.5 percentage points per year. Projected forward, this will result in home dialysis ultimately representing approximately 19 percent of overall maintenance dialysis in Selected Geographic Areas by the end of 2027. In contrast, we do not include an official assumption that the overall number of kidney transplants will increase and provide justification for this assumption in section VII.C.2.b.(4). of this final rule. However, as part of the sensitivity analysis for the savings calculations for the model, we lay out different savings scenarios if the incentives under the ETC Model were to cause an increase in living donation and if the ETC Learning Collaborative described in section IV.C.12 of this final rule were to be successful in decreasing the discard rate of deceased donor kidneys and increasing the utilization rate of deceased donor kidneys that have been retrieved.

**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** |
| | | | | | | | | |
| 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. The KDE Benefit Costs are less than $1M each year, but are rounded up to $1M to show what years they apply to. Similarly, the HD Training Costs are less than $1M for years 2021-2024, but are rounded up to $1M to indicate that costs were applied those years.

(a) Sensitivity Analysis: Medicare Estimate – Assume Fixed Benchmark for Home Dialysis and Fixed Benchmark for Transplants

An alternative model specification was analyzed where benchmarks remain *fixed* at baseline year 0 over time (results available upon request). Both the rolling and fixed benchmark assumptions projected $12 and $11 million, respectively, in increased overall HDPA Medicare payments to ESRD facilities and Managing Clinicians in the first year of the Model. We project about $1 million in additional HD training add-on payments. This will represent $13 and $12 million in increased Medicare expenditures in the first year of the Model overall. The rolling and fixed specifications of the benchmark also projected the net impact of approximately $7 and $8 million, respectively, in increased Medicare expenditures in the second year of the Model.

The two scenarios diverge after the second year of the Model, with large differences

observed in overall net PPA and HDPA savings/losses. Table 2 illustrates that when benchmarks are rolled forward, using the methodology described in section VII.C.2.b.(3). of this final rule, the overall *savings* in PPA net and HDPA increase each year during the 2022-2026 period. Peak savings of $15 million occurs in 2026, followed by a slight deceleration in 2027 to $7 million in savings. In contrast, when benchmark targets are fixed, losses are projected for the net impact to Medicare spending (net of education and training but before administrative cost) in years 2022-2026 of $4, $7, $22, $39, and $26 million, respectively. The fixed benchmark will allow the ESRD facilities and Managing Clinicians to have more favorable achievement and improvement scores over time compared to the rolling benchmark method. In summary, the total of overall net PPA and HDPA from January 1, 2021 through June 30, 2027, with the fixed benchmark, was $102 million in losses, compared to a total of $32 million in savings with the rolling benchmark method. The net impact on Medicare spending for the PPA and HDPA using the fixed benchmark method is $117 million in *losses*.

(b) Sensitivity Analysis: Medicare Estimate – Assume Rolling Benchmark for Home Dialysis and Fixed Benchmark for Transplants in Response to COVID-19

At the time of writing, there were only six months of data available on COVID-19 in the United States. A few recent publications cite advantages of home dialysis in combination with telehealth in comparison to in-center dialysis by reducing the vulnerable ESRD population's exposure to COVID-19. In July 2020, CMS proposed expanding the transitional add-on payment adjustment for new and innovative equipment and supplies, or TPNIES, to include certain capital-related assets that are home dialysis machines, which would make it easier to get them to Medicare beneficiaries. If finalized, this policy would take effect January 1, 2021. Since we have not been able to observe the impact of this rule on potential changes to the home dialysis rates,

we propose to keep the benchmark for home dialysis as rolling.

The UNOS data show that after the first wave of COVID-19, the number of new patients being added to the kidney transplant waitlist was approaching pre-pandemic levels by July 2020. Specifically, the number of kidney transplants experienced a slight decline starting April 12, 2020 in response to fewer living donor transplants; however, the overall kidney transplant rate remained stable when comparing the slope for the same dates in 2019. It is unknown how future waves of COVID-19 may affect the kidney transplant waitlist and the transplant rate. To address this uncertainty, we tested the actuarial model by setting the benchmark to be *rolling* for home dialysis and *fixed* for transplants and did not find the model to be sensitive to incremental changes in the transplant rate because most of the weighting is determined by the home dialysis score.

(c) Sensitivity Analysis: Medicare Savings Estimate – Results for the 10$^{th}$ and 90$^{th}$ Percentiles

Returning to the primary specification used for the Medicare estimate with rolling benchmarks for home dialysis and transplants, we compare the results (available upon request) for the top 10$^{th}$ and 90$^{th}$ percentiles of the 500 individual simulations to the average of all simulation results reported in Table 2. Since the impact on Medicare spending for the ETC Model using the rolling benchmark method is estimated to be in savings rather than losses, the top 10$^{th}$ and 90$^{th}$ percentiles represent the most optimistic and conservative projections, respectively. The overall net PPA and HDPA for the top 10$^{th}$ and 90$^{th}$ percentiles using the rolling benchmark method are $79 million in savings and $7 million in losses (encompassing the mean estimate of $32 million in savings in Table 2).

(4) Effects on Kidney Transplantation

Kidney transplantation is considered the optimal treatment for most ESRD beneficiaries. However, while the PPA includes a one-third weight on the ESRD facilities' or Managing Clinician's transplant rate, calculated as the sum of the transplant waitlist rate and living donor transplant rate, with the ultimate goal of increasing the rate of kidney transplantation including from deceased donors, we decided to not include an assumption that the overall number of kidney transplants will increase. The number of ESRD patients on the kidney transplant waitlist has for many years far exceeded the annual number of transplants performed. Transplantation rates have not increased to meet such demand because of the limited supply of deceased donor kidneys. The United States Renal Data System[162] reported 20,161 kidney transplants in 2016 compared to an ESRD transplant waiting list of over 80,000. Living donor kidney transplantation (LDKT) has actually declined in frequency over the last decade while deceased donor kidney transplantation (DDKT) now represent nearly three out of four transplants as of 2016.

The PPA's transplant incentive will likely increase the share of ESRD beneficiaries who join the transplant waitlist but is unlikely to impact the deceased donor kidney supply limitation. There is evidence that the overall quantity of transplants could be positively impacted by reducing the discard rate for certain DDKT with lower quality, high-Kidney Donor Profile Index (KDPI) organs. However, while such transplantation has been shown to improve the quality of outcomes for patients, kidney transplant centers have reported barriers to their use including a higher cost of providing care in such relatively complex transplant cases relative to Medicare's

[162] United States Renal Data System. 2018. "ADR Reference Table 6 Renal Transplants by Donor Type."

standard payment. Because the PPA will not impact payment to transplant centers, the ETC Model will not mitigate the barrier to increased marginal kidney transplantations. Furthermore, even to the extent that marginal DDKT were somehow improved because of PPA incentives, evidence also suggests that the impact of DDKT with high-KDPI organs may not reduce overall spending despite improving the quality of outcomes for patients.

It is possible that the ETC Model could generate additional living donor kidney donations for which significant Medicare program savings could be realized. given that the living donor transplant rate is a component of the transplant rate used in calculating the PPA. In addition, additional patient education could lead more beneficiaries to find donors by tapping into resources already available to remove financial disincentives to donors (for example, payment for travel, housing, loss of wages, and post-operative care).[163] [164] The ETC Model does not include a policy to assist with minimizing disincentives to living donors for their kidney donation; however, qualified donors may apply for financial assistance through the National Living Donor Assistance Center (NLDAC), which administers federal funding received from HRSA under the federal Organ Donation Recovery and Improvement Act.[165] All applicants under this Act are means tested, with preference given to recipients and donors who are both below 300 percent of the federal poverty line (FPL). Approved applicants can receive up to $6,000 to cover travel, lodging, meals, and incidental expenses. In 2017, only 8.38 percent of

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[163] Salomon DR, Langnas AN, Reed AI, et al. 2015. "AST/ASTS Workshop on Increasing Organ Donation in the United States: Creating an `Arc of Change' From Removing Disincentives to Testing Incentives." *American Journal of Transplantation* 15: 1173–1179.

[164] Tong A, Chapman JR, Wong G, Craig JC. 2014. "Perspectives of Transplant Physicians and Surgeons on Reimbursement, Compensation, and Incentives for Living Kidney Donors." *American Journal of Kidney Disorders* 64(4):622-632.

[165] Public Law 108-216 (section 377 of the Public Health Service (PHS) Act, 42 U.S.C. 274f).

the approximate 6,000 total living kidney donations [166]received NLDAC support, resulting in up to $3 million in paid expenses per year. Additional methods are necessary to decrease financial disincentives for kidney donors and their recipients who exceed the means testing criteria of the NLDAC.

The costs/savings incurred by kidney transplantation vary by donor type. Axelrod et al. (2018) used Medicare claims data with Medicare as the primary payer linked to national registry and hospital cost-accounting data provides evidence for the cost-savings of kidney transplantations by donor type compared to dialysis.[167] The authors estimated ESRD expenditures to be $292,117 over 10 years per beneficiary on dialysis. LDKT was cost-saving at 10 years, reducing expected expenditures for ESRD treatment by 13 percent ($259,119) compared to maintenance dialysis. In contrast, DDKT with low-KDPI organs was cost-equivalent at $297,286 over 10 years compared to dialysis. Last, DDKT with high-KDPI organs resulted in increased spending of $330,576 over 10 years compared to dialysis.

The approximately $33,000 in savings per beneficiary over 10 years for LDKT compared to maintenance dialysis is likely a lower bound since living donation will help reduce the number of beneficiaries under the age of 65 who will be eligible for Medicare enrollment. The lower bound conditional savings can be adjusted to account for additional savings through reduced Medicare enrollment by considering the share of potential new live donations across three main scenarios.

The LDKT expected cost of $259,119 over 10 years per beneficiary projected by Axelrod

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[166] OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. https://www.srtr.org/reports-tools/srtroptn-annual-data-report/

[167] Axelrod DA, Schnitzler MA, Xiao H, *et al*. 2018. "An Economic Assessment of Contemporary Kidney Transplant Practice." *American Journal of Transplantation* 18: 1168-1176.

et al. (2018) assumes Medicare primary payer status. For roughly 25 percent of LDKTs, Medicare can be assumed to be the primary payer regardless of transplant success; therefore, the projected spending need not be adjusted. For the next 25 percent of LDKTs, we assumed the beneficiary is on dialysis and Medicare is the primary payer, but they will eventually leave Medicare enrollment if they had a transplant. We adjusted the expected Medicare spending for these cases downward by 33 percent. This projected a savings of approximately $119,000 over 10 years relative to the baseline spending projection of $292,117 over 10 years for beneficiaries on dialysis. The third scenario – covering the remaining 50 percent of LDKTs– assumes Medicare is not the primary payer when the transplant occurs. In this case, we assumed that Medicare spending is nominal relative to baseline spending and we adjust downward by 33 percent (that is, the beneficiary will take up to 30 months to become a Medicare primary payer enrollee absent the transplant), which projected a savings of approximately $195,000 over 10 years. The projected weighted average program savings for LDKT is $136,000 over 10 years per beneficiary.

Therefore, a 20 percent increase in the rate of LDKT in model markets in a single year, representing about 300 new transplants mainly from relatives of recipients, will produce approximately $41 million in program savings over 10 years (and multiples thereof for each successive year the living donor transplant rate were thusly elevated).

The model also includes an investment in learning and diffusion for improving the utilization of deceased donor kidneys that are currently discarded at a rate of approximately 19 percent nationally.[168] Similar to the previously discussed estimate on the average impact to

[168] OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. https://www.srtr.org/reports-tools/srtroptn-annual-data-report/

Medicare spending for LDKT, we estimated an average marginal savings to Medicare for DDKT by adjusting costs reported by Axelrod et al. (2018) for DDKT with high-KDPI to account for effects on Medicare payer status. We include three scenarios based on type of payer.

First, we assumed 50 percent of newly harvested deceased-donor kidneys will be for beneficiaries enrolled in Medicare, regardless of ESRD status. This scenario aligns with the Medicare primary payer estimates from the study, approximately $38,000 higher spending for DDKT with high-KDPI over 10 years relative to maintenance dialysis. Second, we assumed 30 percent of marginal DDKT will be for beneficiaries with Medicare as their primary coverage where the transplant spending was adjusted downward by 33 percent to account for reduced liability for patients returning to non-Medicare status. Third, we assumed 20 percent of DDKT with high-KDPI will involve beneficiaries not yet under Medicare as their primary payer. For this scenario, we adjusted the baseline dialysis spending downward by 33 percent to account for initial non-Medicare status during the waiting period and for the transplant spending we assumed 25 percent of baseline Medicare spending will still be present due to early graft failure before the end of the 10-year window (recognizing the shorter lifespan high-KDPI organs tend to offer recipients).

Combining these assumptions produced an average 10-year savings to Medicare of approximately $32,000 per beneficiary for DDKT with high-KDPI. Overall, we found 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, representing approximately 2,360 additional transplants and an estimated $76 million in federal savings.

For both living and deceased donor transplants, the illustrated potential effect of the model will reduce long run program spending by $116 million. Costs for this effort include a

learning and diffusion investment of $15 million in section 1115A administrative funds over the model testing period and a potential increase in PPA adjustments to clinician and facility payments of approximately $20 million. The projected increase in transplantation is estimated to produce a net savings of $81 million – a net return on investment of approximately 2.3.

(5) Effects of the Revised Transplant Rate

This final rule includes a modified transplant rate that includes two parts, the "transplant waitlist rate" and the "living donor transplant rate." The ESRD facility transplant rate is calculated as the sum of the transplant waitlist rate for ESRD facilities, risk adjusted based on age strata, and the living donor transplant rate for ESRD facilities. For purposes of calculating the transplant waitlist rate for ESRD facilities, the sum of the attributed ESRD beneficiary waitlist years is divided by the total attributed ESRD beneficiary dialysis treatment years. For purposes of calculating the living donor transplant rate for ESRD facilities, the living donor transplant years for attributed ESRD beneficiaries is divided by the total attributed ESRD beneficiary dialysis treatment years. The Managing clinician transplant rate is calculated as the sum of the transplant waitlist rate for Managing clinicians, risk adjusted based on age strata, and the living donor transplant rate for Managing clinicians. For purposes of calculating the transplant waitlist rate for Managing clinicians, the sum of the attributed ESRD beneficiary waitlist years is divided by the total attributed ESRD beneficiary dialysis treatment years. For purposes of calculating the living donor transplant rate for Managing clinicians, the living donor transplant years for attributed ESRD beneficiaries is divided by the total attributed ESRD beneficiary dialysis treatment years.

The goal of these revised formulas is to give credit to model participants with beneficiaries who are on the kidney transplant waitlist and who receive a transplant from a living

donor transplant. Data from the SRTR show that in 2018, 1.8 percent of all living donor transplant recipients had a preemptive transplant and 62.3 percent had a wait time of less than 1 year[169]. The SRTR data also report that only 39.7 percent of all living donor transplants (including preemptive) had Medicare as the primary payer. We also used the SRTR data to confirm that year 2018, the most recent year with data available, was not an anomaly and we found that years 2016 – 2018 had similar rates of wait time for living donor transplants. In addition, we calculated total member months from the Medicare data in the IDR and found that in 2018, all living donor transplant member months (regardless of wait time) accounted for only 0.6 percent of total member months among beneficiaries on dialysis.

Because the living donor transplants and pre-emptive living donor transplants (variables "d" and "c" in the proposed formulas) are limited in frequency among the Medicare primary payer population, their inclusion in the transplant waitlist scores is not estimated to significantly impact overall payments under the model. This is partly due to limited effects expected for the transplant waitlist score at the clinician and facility levels, but also because model payments are more heavily weighted on the home dialysis measure.

(6) Effects on the KDE Benefit and HD Training Add-ons

The KDE benefit has historically experienced very low uptake, with less than 2 percent of eligible Medicare beneficiaries utilizing this option. A recent report summarized barriers to adequate education on home dialysis.[170] According to this report, kidney disease education may: not be provided at all, be done only once, not be appropriate for patient's literacy level or not

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[169] SRTR 2018 Annual Report. Section KI Kidney Transplants. https://srtr.transplant.hrsa.gov/annual_reports/2018/Kidney.aspx#KI_8_char_adult_tx_dem

[170] Chan CT, Wallace E, Golper TA, *et al*. 2018. "Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report." *American Journal of Kidney Disease* 73(3): 363-371.

provided in patient's native language, not be done until after patient starts in-center hemodialysis, and/or not be provided to caregivers.

The ETC Model will incorporate waivers of select KDE benefit requirements that should make these educational sessions on treatment modality options more accessible to beneficiaries targeted by the model and address some of the barriers previously described. We assume the KDE benefit utilization rate to increase from 2.2 in 2021 to 3.2 in 2027. To arrive at this assumption, we began with the current low utilization of the benefit. The utilization rate of the KDE benefit during the first year of the Model was set to 2 percent of beneficiaries eligible to use the KDE benefit, which is consistent with the current rate of utilization of the benefit. We set the utilization growth rate to increase by 0.2 percentage points each year from 2021 to 2027. This results in a projected doubling of the costs attributed to the KDE benefit to approximately $1 million in 2027. Although the ETC Model will allow different types of health care providers to furnish the KDE benefit to beneficiaries, there is no direct evidence that this will cause an increase in the utilization growth rate that differs significantly from the historical rate. Challenges to increasing the utilization rate include: the beneficiary's Managing Clinician may not inform the beneficiary of the option to seek KDE benefit sessions for a variety of reasons (for example – the Managing Clinician is unaware of the KDE benefit, alternative treatment modalities are not feasible for the beneficiary, or the clinician believes that the beneficiary will not be able to make an informed choice about dialysis modality after receiving the KDE benefit); if informed of the KDE benefit option, the beneficiary may prefer to rely on their Managing Clinician's recommendation rather than receive education about their treatment options; and the beneficiary may not want to have an additional one to six sessions with a health care provider for the provision of the KDE benefit, as beneficiaries with late stage CKD and ESRD are medically

fragile and already in frequent contact with the health care system.

The impacts of increased utilization of the home dialysis (HD) training add-on payment adjustment under the ESRD PPS are expected to be larger than the KDE benefit costs as these trainings will be required for all incident beneficiaries on home dialysis. Assuming a stable 3 percent growth rate in home dialysis per year, the 7-year total in HD training costs is projected to be $10 million.

3. Effects on Medicare Beneficiaries

a. Radiation Oncology Model

We anticipate that the RO Model will modestly reduce the cost to beneficiaries receiving RT services on average. 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 MPFS, respectively). This policy will remain the same under the RO Model. More specifically, beneficiaries will be responsible for 20 percent of each of the PC and TC episode payments made under the RO Model. Since we are finalizing our proposal to take a percentage "discount" off of the total payment to participants for both PC and TC episode payment amounts (this discount representing savings to Medicare), the total allowed charge for services furnished by HOPDs and physicians is expected to decrease. Thus, beneficiary cost-sharing, on average, should be reduced relative to what typically would be paid under traditional Medicare FFS for an episode of care. In addition, the limit on beneficiary cost-sharing in the HOPD setting to the inpatient deductible will continue under the RO Model.

In addition, we note that, because episode payment amounts under the RO Model will include payments for RT services that will be provided over multiple visits, individual

beneficiary coinsurance payments will be higher than they would otherwise be for an individual RT service visit. We encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments.

We received a few comments regarding the application of coinsurance. Summaries of these comments, our response, and the details on our final policy related to coinsurance are available in section III.C.6.i. of this final rule.

b. ESRD Treatment Choices Model

We anticipate that the ETC Model will have a negligible impact on the cost to beneficiaries receiving dialysis. Under current policy, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain the same under the ETC Model. However, we will waive certain requirements of title XVIII of the Act as necessary to test the PPA and HDPA under the Model and to hold beneficiaries harmless from any effect of these payment adjustments on cost sharing. We received a few comments regarding the application of cost sharing under the ETC Model. Summaries of these comments, our response, and the details of our final policy related to cost sharing are available in section IV.C.7.a of this final rule. In addition, the Medicare beneficiary's quality of life has the potential to improve if the beneficiary elects to have home dialysis as opposed to in-center dialysis. Studies have found that home dialysis patients experienced improved quality of life as a result of their ability to continue regular work

schedules or life plans[171]; as well as better overall, physical, and psychological health[172,173] in comparison to other dialysis options.

4. Effects on RO Participants and ETC Participants

RO participants will be given instructions on how to bill for patients, using RO Model-specific HCPCS codes. We expect it will take medical coding staff approximately 0.72 hours [(((~36 pages*300 words/per page)/250 words per minute)/60 minutes)= 0.72][174] to read and learn the payment methodology and billing sections of the rule. In addition, we estimate an additional 1 hour to review the relevant MLN Matters publication, 1 hour to read the RO Model billing guide, 1 hour to attend the billing guidance webinar, and 1 hour to review the pricing methodology training materials for a total of 4.72 hours. We estimate the median salary of a Medical Records and Health Information Technician is $19.40 per hour, at 100 percent fringe benefit for a total of $38.80, using the wage information from the BLS.[175] The total cost of learning the billing system for the RO Model thus is $183.14 per participant, or approximately $173,983.00 in total (950 expected participants x $183.14/participant = $173,983 total).

The ETC Model will not alter the way ETC Participants bill Medicare. Therefore, we believe that there will be no additional burden for ETC Participants related to billing practices.

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[171] Dąbrowska-Bender M, Dykowska G, Zuk W, et al. 2018. "The impact on quality of life of dialysis patients with renal insufficiency." *Patient Prefer Adherence* 12: 577–583.

[172] Makkar V, Kumar M, Mahajan R, Khaira NS. 2015. "Comparison of Outcomes and Quality of Life between Hemodialysis and Peritoneal Dialysis Patients in Indian ESRD Population." *J Clin Diagn Res*. 9(3): OC28–OC31

[173] Van Eps CL, Jeffries JK, Johnson DW, et al. 2010. "Quality of life and alternate nightly nocturnal home hemodialysis." *Hemodial Int*.14(1):29-38.

[174] https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf

[175] For the RO Model, we use the estimated median hourly wage of $19.40 per hour, plus 100 percent overhead and fringe benefits. Estimating the hourly wage is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate to estimate total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.
https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm

We believe the audit and retention policies of the RO Model and ETC Model are generally consistent with existing policies under Medicare. Additionally, the monitoring requirements for the RO Model and ETC Model are consistent with the monitoring and evaluation requirements already in place under 42 CFR 405.1110(b) for participants in models tested under section 1115A of the Act. Therefore, we believe the audit and retention policies and the monitoring and evaluation requirements do not add additional regulatory burden on participants.

The model evaluation for both the RO Model and the ETC Model will include beneficiaries and providers completing surveys. Burden for these surveys will depend on the length, complexity, and frequency of surveys administered as needed to ensure confidence in the survey findings. We will make an effort to minimize the length, complexity, and frequency of the surveys. A typical survey on average would require about 20 minutes of the respondent's time. In other evaluations of models where a survey is required, the frequency of surveys varies from a minimum of one round of surveys to annual surveys.

We believe the burden estimate for quality measure and clinical data element reporting requirements that is provided for Small Businesses in section VII.C.5.a. of this final rule apply to RO participants that are not considered small entities. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which we estimate to be approximately $1,743.07per entity per year. We estimate approximately 950 RO participants, then total burden estimate for collecting and reporting quality measures and clinical data was approximately $1,655,916.50

Additionally, the ETC Model does not require any additional quality measure or clinical data element reporting by ETC Participants. Therefore, we believe that there is no additional burden for ETC Participants related to quality measures or clinical data reporting.

Finally, we believe the burden estimate for reading and interpreting this final rule that is provided for Small Businesses apply to RO participants and ETC Participants that are not considered small entities. The burden estimate for reading and interpreting this final rule may be equal to or less than that for small businesses. We estimate that cost of reading the rule for RO participants would be approximately $1,093.26 per entity with a total cost of approximately $3,170,454.00 (2,900 eligible entities x $1,093.269/participant). In sum, we estimate that reading the RO Model rule, learning the RO billing system, the pricing methodology and submitting quality measures and clinical data to the RO Model will cost approximately $3,019.47 per RO participant ($1,093.26 to read the rule, $183.14 to attend and learn the billing guidance, and $1,743.07 to submit quality measure and CDE information), and collectively cost approximately $2,868,496.50 across the 950 RO participants, and an additional $2,131,350.00 for those providers and suppliers who read the rule, but are not ultimately selected as RO participants, for a total cost $4,999,846.50. Similarly, we base our estimate for the cost of reading the final rule for ETC Participants on the same cost per participant as used for the RO Model, that is, $1,093.26 per entity. We assume that all ESRD facilities and Managing Clinicians will read the rule, even though only a subset of each category will participate in the

Model. Therefore, the collective cost will be $6,714,000 (14,380 entities reading the rule (7,097 ESRD facilities plus 7,283 Managing Clinicians) times $466.89).

5. Regulatory Flexibility Act (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. As discussed in sections VII.5.a and VII.5.b. of this final rule, the Secretary has considered small entities and has determined and certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

a. Radiation Oncology Model

This final rule affects: (1) radiation oncology PGPs that furnish RT services in both freestanding radiation therapy centers and HOPDs; (2) PGPs that furnish RT services only in HOPDs; (3) PGPs that are categorized as freestanding radiation therapy centers; and (4) HOPDs. The majority of HOPDs and other RT providers and RT suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (defined as having minimum revenues of less than $12 million to $41.5 million[176] in any 1 year, depending on the type of provider; the $41.5 million per year threshold is for hospitals, whereas the $12 million per year threshold is for other entities). (*https://www.sba.gov/document/support--table-size-standards*). States and individuals are not included in the definition of small entity.

HHS uses an RFA threshold of at least a 5 percent impact on revenues of small entities to

[176] Please note these numbers are updated from the proposed rule due to an update on SBA categorizations. The small business revenue numbers were previously $11.5 million and 38.5 million, respectively.

determine whether a final rule is likely to have "significant" impacts on small entities.[177] Throughout the rule we describe how the changes to a prospective episode payment may affect PGPs and HOPDs.

In the proposed rule, we provided an analysis for the RO Model's impact on small businesses based on the proposed policies and following analysis (84 FR 34575 through 34577). Our analysis was based on the assumption that the RO Model would include only Medicare FFS beneficiaries receiving RT services by selected PGPs (including freestanding radiation therapy centers) and HOPDs. During 2018, 39 percent of Medicare beneficiaries with both Part A and B coverage on average are estimated to have enrolled in Medicare Advantage plans.[178] PGPs and HOPDs also serve patients with other coverage, for example, through Medicare or commercial insurance. We believed that on average, Medicare FFS payments to PGPs would be reduced by 5.9 percent and Medicare FFS payments to HOPDs would be reduced by 4.2 percent and would not change with an April 1 start date. Given that this Model is limited to only Medicare FFS beneficiaries, not other payers including Medicare Advantage and commercial insurance, which combined we expect to be about 50 to 60 percent of total HOPD and PGP revenue for RT services, we expected that the anticipated average impact of revenue based solely on Medicare FFS payments to be less than 1 percent. Therefore, we determined that the proposed rule would not have a greater than 5 percent impact on total revenues on a substantial number of small entities (84 FR 34577). We estimated the administrative costs of adjusting to and complying with the quality measure and clinical data element reporting requirements for RO Model for

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[177] Office of Advocacy, Small Business Administration. (2012). A Guide for Government Agencies, How to Comply with the Regulatory Flexibility Act, Implementing the President's Small Business Agenda and Executive Order 13272, Retrieved from www.sba.gov/sites/default/files/rfaguide_0512_0.pdf (accessed March 18, 2019).

[178] This figure comes from the 2018 Medicare Trustees Report, Table IV.V1, p151 from the footnote that has the A and B share.

small entities to be approximately $388.00 per entity per year. To estimate the costs per small entity, we assumed that a Medical Records & Health Information Technician with an Hourly salary (from BLS) plus 100 percent fringe benefits would cost $38.80/hour[179] and would report the information on quality measures and clinical data elements. We expected submission of the 4 quality data measures would take approximately 8 hours and would require submission once a year, ($38.80 x 8.0 hours x 1 submission) = $310.40. In the proposed rule, also we estimated that the submission of clinical data elements would take up to an hour, but occur twice a year, that is, ($38.80 x 1-hour x 2 submission) = $77.60 per year (84 FR 34577).

Based on the final design of the RO Model, we believe that on average, Medicare FFS payments to PGPs will be reduced by 6.0 percent and Medicare FFS payments to HOPDs will be reduced by 4.7 percent. We believe that this impact would be less for small providers that provide fewer than 20 episodes in the previous year and choose to opt out of the Model under the low volume opt out policy (see section III.C.3.c. of this final rule) because they would continue to bill FFS for RT services furnished during their opt out year(s). In response to commenter feedback, we are updating our estimate for the administrative costs of adjusting to and complying with the quality measure and clinical data element reporting requirements for RO Model for small entities to be approximately $1,743.06 per entity per year. We assume that our estimate for the submission of quality measures remains an accurate estimate at $310.40 per year. We revisited our clinical data element estimates and now expect the total cost of submission of the clinical data elements would be approximately $1,432.67 per entity ($38.80 x 18.5 hours x 2 submissions) per year. Our estimate was updated based on our review of the

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179 https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm

potential list of the clinical data elements which may be included across the five cancer types (prostate, breast, lung, bone and brain) finalized in section III.C.8. of this final rule. We note that the final list will be communicated prior to the start of PY1, so our estimate may slightly overstate or understate the final number of CDEs (and thus may slightly understate or overstate the burden) and each RO participant's experience may vary. We still expect the burden costs per small entity associated with measure and data reporting to be small because three of the four measures for the RO Model are already in use in other CMS programs; and compliance with the Treatment Summary Communication (the measure not currently in use) is a best practice that should already be the standard of care across PGPs and HOPDs.

In the proposed rule, we further estimated the administrative cost of reading and interpreting this final rule per small entity at approximately $446.89 (84 FR 34577). We are updating our estimate to approximately $1,093.26 for reading the rule and an additional $183.14 to learn the billing system. We expect that a medical health service manager reading 250 words per minute could review the rule in approximately 11.4 hours [(approximately 569 pages*300 words/per page)/250 words per minute)[180]/60 minutes)]. We estimated the salary of a medical and health service manager is $95.90 per hour, using the wage information from the BLS including overhead and fringe benefits.[181] Assuming an average reading speed for pages relevant to the RO Model, we estimated that it would take approximately 11.4 hours for the staff to review the RO portion of this final rule. For each provider that reviews the rule, the estimated cost based on the expected time and salary of the person reviewing the rule ($1,093.26 = ($95.90

[180] https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf

[181] For the RO Model, we use an estimated median hourly wage of $47.95 per hour, plus 100 percent overhead and fringe benefits. https://www.bls.gov/oes/current/oes119111.htm

* 11.4 hrs). RO participants would also review the billing guidance, which we would expect to cost approximately $183.14 as discussed in section VI.C.4. of this final rule.

We solicited public comments on our estimates and analysis of the impact of the final rule on those small entities.

Comment: A commenter expressed concern with the RO Model's payment rates estimates based on their belief that Medicare is a material payer for the majority of providers. The commenter added that Medicare is, or may exceed, 46 percent of their payer mix and that this coupled with episode payment amounts that would reduce payment by up to 50 percent from what participants would have received under FFS, makes furnishing RT services under the Model unsustainable.

Response: We thank this commenter for their feedback. First, as we stated in section III.C.6. of this final rule, we disagree that episode payment amounts would be reduced by 50 percent as compared to non-participants. This might be true for some participants if the case mix and historical experience adjustments were removed from the Model's pricing methodology. We designed the pricing methodology so that episode payment amounts for Professional participants, Dual participants, and Technical participants are largely based on what each participant has been paid historically under FFS and trended forward based on latest payment rates under FFS. In particular, we refer readers to section III.C.6.e.(2). of this final rule for more information regarding the blend used to determine how much participant-specific historical payments and national base rates figure into payment. Second, RT services furnished under the RO Model were assumed to grow with FFS Medicare Part B enrollment as projected in the 2018 Medicare Trustees Report. We assume that participants do not change payer mix as a response to the RO

Model. No explicit assumptions were made about the relative amount of RT services paid through private or other forms of insurance.

Comment: A commenter stated that providers and suppliers chosen for the Model will see reductions to their payments under the Hospital Outpatient PPS or PFS, respectively, between 3.9 percent and 4.4 percent (PC) and between 5.7 and 5.1 percent (TC) on average, with participants furnishing RT services in freestanding radiation therapy centers experiencing a higher reduction than those furnishing RT services in the HOPD setting. According to this commenter, the combined effect of the discount factor and efficiency factor, now termed, "blend," will reduce payments by 6.6 percent in the fifth year and the commenter expressed concern that this reduction would not be offset by the APM bonus incentive for technical payments, and even so, this is waived under the Model as proposed.

Response: We appreciate the commenters concerns regarding the combined effect of the discount factor and blend. We believe that the commenters' estimates are consistent with our analysis, though we note, we are finalizing policies that reduce the discount factor by 0.25 percent for both the PC and TC, so that the discount rates are 3.75 percent and 4.75 percent for the PC and TC, respectively as we discussed in section III.C.6. We are also finalizing the Model performance period to begin January 1, 2021 in order to give RO participants the necessary time to prepare for implementation.

Comment: A few of commenters stated their belief that the regulatory impact analysis severely underestimates burden on participants. A commenter estimated that the cost of adjusting to the Model could be well over $400,000 in PY1 and $350,000 in each successive PY. Another commenter estimated that 0.3 FTEs per physician would be needed to account for the newly created workflow related to the revenue cycle processes as well as quality metric and data

documentation, collection and reporting that will exist alongside the current workflow already established for patients outside of the RO Model.

To better account for cost, a couple of commenters suggested that CMS consider the following: the additional administrative tasks and requirements that the Model imposes, the use of certified EHR technology, the need to prepare multiple billings and participate in a radiation oncology-specific AHRQ patient safety organization, and the need to participate in CMS site visits and medical record audits. A few commenters recommended a review of OCM's cost and utilization reports, which they believe would show that manual data abstraction alone represents 45-90 minutes per patient and requires thousands of dollars in human resources to implement. Another commenter claimed that OCM practices also spend tens of thousands of dollars each year to meet the clinical data element and quality measure reporting requirements under that model, as captured in the OCM cost and resource utilization reports that are submitted to CMS.

Response: We thank these commenters for explaining their concerns. First, we believe the administrative, monitoring, and compliance requirements for the RO Model will not substantially diverge from general monitoring requirements for Medicare Part B providers. RO participants are already subject to site visits and record audits as part of their participation in Medicare, so we do not expect the Model requirements to create additional burden. Second, we disagree that the use of EHR technology should be included in the regulatory impact analysis as part of the cost of the Model. An entity's EHR has many uses within the clinical setting and is not solely used for RO Model measures reporting. The cost of the EHR system should not be reflected in the burden estimates developed specifically for the RO Model. We also note that American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) and Meaningful Use require providers to use EHRs to avoid Medicare payment reductions, which is independent

of any proposals in the RO Model. Third, and as we stated in section III.C.7. of this final rule, we believe that we have created a billing process that will be easily implemented within current systems, because it is based on how FFS claims are submitted today and may reduce the amount of time spent billing because coding will be submitted at the beginning and end of the episode. Lastly, we believe that the 45-60 minutes per patient file that one stakeholder estimates is an overestimate of the time it will take to review a chart and submit quality measures for the RO Model, nor do we believe the cost and utilization reports of OCM are comparable to that of the RO Model. The RO Model does not mandate the same OCM reporting requirements. We also believe that we have included measures that are commonly used in the field and reflect common treatment practices. However, as discussed earlier in this section, we are updating our estimates for the burden associated with quality measure and clinical data element submission and our estimates of the cost it would take to read the rule and learn the billing.

We believe that on average the updated policies contained in this final rule will result in reductions of 5.9 percent to underlying fee schedules for RT services over the course of the model test, which is similar to the proposed rule. The final rule payment reduction was estimated by simulating RT episodes using 2018 claims and assuming that the relative value units under the PFS and relative payment weights under the OPPS by providers would remain unchanged in the future. Another key assumption is that the distribution of provider efficiency as defined in (section III.C.1. of this final rule) during 2018 would remain unchanged in future years under the current FFS payment system. Although discounts were reduced by 0.25 percent between the proposed and final rule, this was approximately offset by an additional year of data underlying the distribution of provider efficiency. Moreover, these estimated fee schedule reductions do not include APM bonuses payable to participants. APM bonuses to providers were forecasted to be

0.5 percent of RO episode allowed charges. Please note that for any individual provider a range of potential outcomes may occur due to the RO model and that actual experience may vary.

We expect the anticipated average impact of revenue based solely on Medicare FFS payments to be less than 1 percent. We therefore expect that this final rule would not have a greater than 5 percent impact on total revenues on a substantial number of small entities.

b. ESRD Treatment Choices Model

This final rule includes as ETC Participants Managing Clinicians and ESRD facilities required to participate in the Model pursuant to § 512.325(a). We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians are small entities and that the greater majority of ESRD facilities are not small entities. Throughout the final rule we describe how the adjustments to certain payments for dialysis services and dialysis-related services furnished to ESRD beneficiaries may affect Managing Clinicians and ESRD facilities participating in the ETC Model. The great majority of Managing Clinicians are small entities by meeting the SBA definition of a small business (having minimum revenues of less than $11 million to $38.5 million in any 1 year, varying by type of provider and highest for hospitals) with a minimum threshold for small business size of $38.5 million (*https://www.sba.gov/document/support--table-size-standardshttp://www.sba.gov/content/small-businesssize-standards*). The great majority of ESRD facilities are not small entities, as they are owned, partially or entirely by entities that do not meet the SBA definition of small entities.

The HDPA in the ETC Model would be a positive adjustment on payments for specified home dialysis and home dialysis-related services. The PPA in the ETC Model, which includes both positive and negative adjustments on payments for dialysis services and dialysis-related services, excludes aggregation groups with fewer than 132 attributed beneficiary-months during

the relevant year.

For the remaining small entities that are above the low-volume exclusion threshold and randomly selected for participation, the design of the ETC Model will incorporate a risk adjustment of the transplant waitlist rate and aggregation of the home dialysis rate and transplant waitlist rate to allow for the calculation of home dialysis rates and transplant waitlist rates for both small entities that may be owned in whole or in part by another company. The transplant waitlist rate is risk adjusted based on age, as described in section IV.C.5.b.(3). of the final rule. The aggregation methodology groups ESRD facilities owned in whole or in part by the same dialysis organization within a Selected Geographic Area and Managing Clinicians billing under the same TIN within a Selected Geographic Area. This aggregation policy increases the number of beneficiary months, and thus statistical reliability, of the ETC Participant's home dialysis and transplant rate for ESRD facilities that are owned in whole or in part by the same dialysis organization and for Managing Clinicians that share a TIN with other Managing Clinicians.

Taken together, the low volume threshold exclusions, risk adjustments of the transplant rate, and aggregation policies previously described, coupled with the fact that the ETC Model will affect Medicare payment only for select services furnished to Medicare FFS beneficiaries; we have determined that the provisions of this final rule will not have a significant impact on spending for a substantial number of small entities (defined as greater than 5 percent impact). No comments were received regarding the impact of the ETC Model that were not addressed elsewhere.

5. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This

analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that the RO Model and ETC Model will not have a significant impact on the operations of a substantial number of small rural hospitals.

We received a number of comments regarding the impact of certain RO Model policies on rural hospitals. We direct readers to section III of this final rule and in the policy sections to which they applied where addressed these comments. We also note that in response to stakeholder feedback, we are finalizing a low volume opt out policy, described in section III.C.3.(c). of this final rule.

6. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that is approximately $168 million. This final rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

7. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has

Federalism implications.

This rule would not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication because both the RO Model and ETC Model are Federal payment programs impacting Federal payments only and do not implicate local governments or state law. Therefore, the requirements of Executive Order 13132 are not applicable.

D. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is not expected to be subject to the requirements of E.O. 13771 because it is estimated to result in no more than *de minimis* costs.

E. Alternatives Considered

Throughout this final rule, we have identified our policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and the rationale for each of our policies. We solicited comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these.

This final rule contains a model specific to radiation oncology. It provides descriptions of the requirements that we will waive, identifies the payment methodology to be tested, and presents rationales for our decisions and, where relevant, alternatives that we considered. We carefully considered the alternatives to this final rule, including whether the RO Model should be implemented by all RT providers and RT suppliers nationwide. We concluded that it would be best to test the model using a subset of all RT providers and RT suppliers in order to compare them to the RT providers and RT suppliers that would not be participating in the RO Model.

This final rule also contains a model specific to ESRD. It provides descriptions of the requirements that we will waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our decisions, and where relevant, alternatives that we considered. We carefully considered the alternatives to this final rule, including whether the model should be implemented to include more or fewer ESRD facilities and Managing Clinicians. We concluded that it would be best to test the model with approximately 30 percent of ESRD facilities and Managing Clinicians in the U.S. in order to have an effective comparison group and to provide the best opportunity for an accurate and thorough evaluation of the model's effects.

We solicited comments on our proposals and on any Model alternatives and consequent policies that should be considered. We refer readers to section III.C and IV.C of this final rule for more information on policy-related stakeholder comments, our responses to those comments, and statements of final policy.

F. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a4*) in Tables E3 and E4, we have prepared an accounting statement showing the classification of transfers which represent savings associated with the provisions in this final rule. The accounting statement is based on estimates provided in this regulatory impact analysis.

**TABLE 3: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR THE RADIATION ONCOLOGY MODEL**

| Category | Estimates | Units | | |
|---|---|---|---|---|
| | | Year Dollar | Discount Rate | Period Covered |
| **Transfers** | | | | |
| Annualized Monetized ($million/year) | -$40 million | 2020 | 7% | Jan 1, 2021 – December 31, 2025 |
| | -$42 million | 2020 | 3% | Jan 1, 2021 – December 31, 2025 |
| **From Whom to Whom** | From the federal government to healthcare providers | | | |

**TABLE 4: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR END STAGE RENAL DISEASE (ESRD) TREATMENT CHOICES MODEL**

| Category | Estimates | Units | | |
|---|---|---|---|---|
| | | Year Dollar | Discount Rate | Period Covered |
| **Transfers** | | | | |
| Annualized Monetized ($million/year) | -$2 million | 2020 | 7% | Jan 1, 2021 – June 30, 2027 |
| | -$3 million | 2020 | 3% | Jan 1, 2021 – June 30, 2027 |
| **From Whom to Whom** | From the Federal government to ESRD facilities and Managing Clinicians. | | | |

Note: Negative spending reflects a reduction in Medicare spending.

G. Conclusion

This analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this final rule, we estimate that the financial impact of the Radiation Oncology Model and ESRD Treatment Choices Model will net a federal savings of $253 million over a 6.5-year performance period (2021 through 2027).

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

**List of Subjects in 42 CFR Part 512**

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble and under the authority at 42 U.S.C. 1302, 1315a, and 1395hh, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV by adding part 512 to read as follows:

**PART 512 – RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL**

**Subpart A – General Provisions Related to Innovation Center Models**

Sec.

512.100 Basis and scope.

512.110 Definitions.

512.120 Beneficiary protections.

512.130 Cooperation in model evaluation and monitoring.

512.135 Audits and record retention.

512.140 Rights in data and intellectual property.

512.150 Monitoring and compliance.

512.160 Remedial action.

512.165 Innovation center model termination by CMS.

512.170 Limitations on review.

512.180 Miscellaneous provisions on bankruptcy and other notifications.

**Subpart B – Radiation Oncology Model**

**General**

512.200 Basis and scope of subpart.

512.205 Definitions.

**RO Model Participation**

512.210 RO participants and geographic areas.

512.215 Beneficiary population.

512.217 Identification of individual practitioners.

512.220 RO participant compliance with RO Model requirements.

512.225 Beneficiary notification.

**Scope of RO Episodes Being Tested**

512.230 Criteria for determining cancer types.

512.235 Included RT services.

512.240 Included modalities.

512.245 Included RO episodes.

**Pricing Methodology**

512.250 Determination of national base rates.

512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

**Billing and Payment**

512.260 Billing.

512.265 Payment.

512.270 Treatment of add-on payments under existing Medicare payment systems.

**Data Reporting**

512.275 Quality measures, clinical data, and reporting.

**Medicare Program Waivers**

512.280 RO Model Medicare program waivers.

**Reconciliation and Review Process**

512.285 Reconciliation process.

512.290 Timely error notice and reconsideration review process.

**Subpart C – ESRD Treatment Choices Model**

**General**

512.300 Basis and scope.

512.310 Definitions.

**ESRD Treatment Choices Model Scope and Participants**

512.320 Duration.

512.325 Participant selection and geographic areas.

512.330 Beneficiary notification.

**Home Dialysis Payment Adjustment**

512.340 Payments subject to the facility HDPA.

512.345 Payments subject to the clinician HDPA.

512.350 Schedule of home dialysis payment adjustments.

**Performance Payment Adjustment**

512.355 Schedule of performance assessment and performance payment adjustment.

512.360 Beneficiary population and attribution.

512.365 Performance assessment.

512.370 Benchmarking and scoring.

512.375 Payments subject to adjustment.

512.380 PPA amounts and schedule.

512.385 PPA exclusions.

512.390 Notification and targeted review.

**Quality Monitoring**

512.395 Quality measures.

**Medicare Program Waivers**

512.397 ETC Model Medicare program waivers.

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

**Subpart A – General Provisions Related to Innovation Center Models**

**§ 512.100 Basis and scope.**

(a) *Basis*. This subpart implements certain general provisions for the Radiation Oncology Model implemented under subpart B (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model implemented under subpart C (ETC Model), collectively referred to in this subpart as Innovation Center models. Except as specifically noted in this part, the regulations do not affect the applicability of other provisions affecting providers and suppliers under Medicare Fee-For-Service (FFS), including provisions regarding payment, coverage, or program integrity.

(b) *Scope*. The regulations in this subpart apply to model participants in the RO Model (except as otherwise noted in § 512.160(b)(6)) and to model participants in the ETC Model. This subpart sets forth the following:

(1) Basis and scope.

(2) Beneficiary protections.

(3) Model participant requirements for participation in model evaluation and monitoring, and record retention.

(4) Rights in data and intellectual property.

(5) Monitoring and compliance.

(6) Remedial action and termination by CMS.

(7) Limitations on review.

(8) Miscellaneous provisions on bankruptcy and notification.

**§ 512.110 Definitions.**

For purposes of this part, the following terms are defined as follows unless otherwise stated:

*Beneficiary* means an individual who is enrolled in Medicare FFS.

*Change in control* means any of the following:

(1) The acquisition by any "person" (as this term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the model participant by any individual or entity.

(3) The sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant.

(4) The approval and completion of a plan of liquidation of the model participant, or an agreement for the sale or liquidation of the model participant.

*Covered services* means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

*Days* means calendar days.

*Descriptive model materials and activities* means general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the model participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding the Innovation Center model. The following communications are not descriptive model materials and activities: communications that do not directly or indirectly reference the Innovation Center model (for example, information about care coordination generally); information on specific medical conditions; referrals for health care items and services; and any other materials that are excepted from the definition of "marketing" as that term is defined at 45 CFR 164.501.

*Downstream participant* means an individual or entity that has entered into a written arrangement with a model participant under which the downstream participant engages in one or more Innovation Center model activities.

*Innovation Center model* means the RO Model implemented under subpart B or the ETC Model implemented under subpart C.

*Innovation Center model activities* means any activities impacting the care of model beneficiaries related to the test of the Innovation Center model under the terms of this part.

*Medically necessary* means reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

*Model beneficiary* means a beneficiary attributed to a model participant or otherwise included in an Innovation Center model under the terms of this part.

*Model participant* means an individual or entity that is identified as a participant in the Innovation Center model under the terms of this part.

*Model-specific payment* means a payment made by CMS only to model participants, or a payment adjustment made only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers.

*Provider* means a "provider of services" as defined under section 1861(u) of the Act and codified in the definition of "provider" at § 400.202 of this chapter.

*Supplier* means a supplier as defined in section 1861(d) of the Act and codified at **§** 400.202 of this chapter.

*US Territories* means 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.

**§ 512.120 Beneficiary protections.**

(a) *Beneficiary freedom of choice*. (1) The model participant and its downstream model participants must not restrict beneficiaries' ability to choose to receive care from any provider or supplier.

(2) The model participant and its downstream model participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any provider or supplier or from any health care provider who has opted out of Medicare. The model participant and its downstream model participants may

communicate to model beneficiaries the benefits of receiving care with the model participant, if otherwise consistent with the requirements of this part and applicable law.

(b) *Availability of services*. (1) The model participant and its downstream participants must continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law. Model beneficiaries and their assignees retain their rights to appeal claims in accordance with part 405, subpart I of this chapter.

(2) The model participant and its downstream participants must not take any action to select or avoid treating certain Medicare beneficiaries based on their income levels or based on factors that would render the beneficiary an "at-risk beneficiary" as defined at § 425.20 of this chapter.

(3) The model participant and its downstream participants must not take any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the model participant's or downstream participant's financial or quality performance, a practice commonly referred to as "cherry-picking."

(c) *Descriptive model materials and activities*. (1) The model participant and its downstream participants must not use or distribute descriptive model materials and activities that are materially inaccurate or misleading.

(2) The model participant and its downstream participants must include the following statement on all descriptive model materials and activities: "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 & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document."

(3) The model participant and its 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).

(4) CMS reserves the right to review, or have a designee review, descriptive model materials and activities to determine whether or not the content is materially inaccurate or misleading. This review takes place at a time and in a manner specified by CMS once the descriptive model materials and activities are in use by the model participant.

**§ 512.130 Cooperation in model evaluation and monitoring.**

The model participant and its downstream participants must comply with the requirements of § 403.1110(b) of this chapter and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate the Innovation Center model in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under § 512.150, including producing such data as may be required by CMS to evaluate or monitor the Innovation Center model, which may include protected health information as defined in 45 CFR 160.103 and other individually-identifiable data.

**§ 512.135 Audits and record retention.**

(a) *Right to audit.* 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 regarding implementation of an Innovation Center model.

(b) *Access to records*. The model participant and its downstream participants must maintain and give the Federal government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit,

evaluation, inspection, or investigation of the implementation of the Innovation Center model, including without limitation, documents and other evidence regarding all of the following:

(1) The model participant's and its downstream participants' compliance with the terms of the Innovation Center model, including this subpart.

(2) The accuracy of model-specific payments made under the Innovation Center model.

(3) The model participant's payment of amounts owed to CMS under the Innovation Center model.

(4) Quality measure information and the quality of services performed under the terms of the Innovation Center model, including this subpart.

(5) Utilization of items and services furnished under the Innovation Center model.

(6) The ability of the model participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Patient safety.

(8) Other program integrity issues.

(c) *Record retention.* (1) The model participant and its downstream participants must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of six years from the last payment determination for the model participant under the Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless--

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the model participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(2) If CMS notifies the model participant of the special need to retain records in accordance with paragraph (c)(1)(i) of this section or there has been a termination, dispute, or allegation of fraud or similar fault against the model participant or its downstream participants described in paragraph (c)(1)(ii) of this section, the model participant must notify its downstream participants of this need to retain records for the additional period specified by CMS.

**§ 512.140 Rights in data and intellectual property.**

(a) CMS may --

(1) Use any data obtained under §§ 512.130, 512.135, and 512.150 to evaluate and monitor the Innovation Center model; and

(2) Disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. Data disseminated may include patient--

(i) De-identified results of patient experience of care and quality of life surveys, and

(ii) De-identified measure results calculated based upon claims, medical records, and other data sources.

(b) Notwithstanding any other provision of this part, for all data that CMS confirms to be proprietary trade secret information and technology of the model participant or its downstream participants, CMS or its designee(s) will not release this data without the express written consent of the model participant or its downstream participant, unless such release is required by law.

(c) If the model participant or its downstream participant wishes to protect any proprietary or confidential information that it submits to CMS or its designee, the model participant or its downstream participant must label or otherwise identify the information as proprietary or confidential. Such assertions are subject to review and confirmation by CMS prior to CMS' acting upon such assertions.

**§ 512.150 Monitoring and compliance.**

(a) *Compliance with laws*. The model participant and each of its downstream participants must comply with all applicable laws and regulations.

(b) *CMS monitoring and compliance activities*. (1) CMS may conduct monitoring activities to ensure compliance by the model participant and each of its downstream participants with the terms of the Innovation Center model including this subpart; to understand model participants' use of model-specific payments; and to promote the safety of beneficiaries and the integrity of the Innovation Center model. Such monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the model participant and its downstream participants, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the model participant and its downstream participants.

(iii) Interviews with members of the staff and leadership of the model participant and its downstream participants.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the model participant and its downstream participants, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and clinical data, if applicable.

(vii) Tracking patient complaints and appeals.

(2) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to model beneficiaries.

(c) *Site visits*. (1) In a manner consistent with § 512.130, the model participant and its downstream participants must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of the Innovation Center model and the monitoring of the model participant's compliance with the terms of the Innovation Center model, including this subpart.

(2) CMS or its designee provides, to the extent practicable, the model participant or downstream participant with no less than 15 days advance notice of any site visit. CMS--

(i) Will attempt, to the extent practicable, to accommodate a request for particular dates in scheduling site visits.

(ii) Will not accept a date request from a model participant or downstream participant that is more than 60 days after the date of the CMS initial site visit notice.

(3) The model participant and its downstream participants must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) Additionally, CMS may perform unannounced site visits at the office of the model participant and any of its downstream participants at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(5) Nothing in this part shall be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) *Reopening of payment determinations.* (1) CMS may reopen a model-specific payment determination on its own motion or at the request of a model participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter).

(2) CMS may reopen a model-specific payment determination at any time if there exists reliable evidence (as defined in § 405.902 of this chapter) that the determination was procured by fraud or similar fault (as defined in § 405.902 of this chapter).

(3) CMS's decision regarding whether to reopen a model-specific payment determination is binding and not subject to appeal.

(e) *OIG authority*. Nothing contained in the terms of the Innovation Center Model or this part limits or restricts the authority of the HHS Office of Inspector General or any other Federal government authority, including its authority to audit, evaluate, investigate, or inspect the model participant or its downstream participants for violations of any Federal statutes, rules, or regulations.

**§ 512.160 Remedial action.**

(a) *Grounds for remedial action*. CMS may take one or more remedial actions described in paragraph (b) of this section if CMS determines that the model participant or a downstream participant:

(1) Has failed to comply with any of the terms of the Innovation Center Model, including this subpart.

(2) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(3) Has taken any action that threatens the health or safety of a beneficiary or other patient.

(4) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the Innovation Center model.

(5) Has undergone a change in control that presents a program integrity risk.

(6) Is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(7) Is subject to investigation or action by HHS (including the HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal government has intervened, or similar action.

(8) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(b) *Remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the model participant and, if appropriate, require the model participant to notify its downstream participants of the violation.

(2) Require the model participant to provide additional information to CMS or its designees.

(3) Subject the model participant to additional monitoring, auditing, or both.

(4) Prohibit the model participant from distributing model-specific payments, as applicable.

(5) Require the model participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to the Innovation Center model.

(6) In the ETC Model only, terminate the ETC Participant from the ETC Model.

(7) Require the model participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS.

(8) Discontinue the provision of data sharing and reports to the model participant.

(9) Recoup model-specific payments.

(10) Reduce or eliminate a model-specific payment otherwise owed to the model participant.

(11) Such other action as may be permitted under the terms of this part.

**§ 512.165 Innovation center model termination by CMS.**

(a) CMS may terminate an Innovation Center model for reasons including, but not limited to, the following:

(1) CMS determines that it no longer has the funds to support the Innovation Center model.

(2) CMS terminates the Innovation Center model in accordance with section 1115A(b)(3)(B) of the Act.

(b) If CMS terminates an Innovation Center model, CMS provides written notice to the model participant specifying the grounds for model termination and the effective date of such termination.

**§ 512.170 Limitations on review.**

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for all of the following:

(a) The selection of models for testing or expansion under section 1115A of the Act.

(b) The selection of organizations, sites, or participants, including model participants, to test the Innovation Center models selected, including a decision by CMS to remove a model participant or to require a model participant to remove a downstream participant from the Innovation Center model.

(c) The elements, parameters, scope, and duration of such Innovation Center models for testing or dissemination, including without limitation the following:

(1) The selection of quality performance standards for the Innovation Center model by CMS.

(2) The methodology used by CMS to assess the quality of care furnished by the model participant.

(3) The methodology used by CMS to attribute model beneficiaries to the model participant, if applicable.

(d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.

(e) The termination or modification of the design and implementation of an Innovation Center model under section 1115A(b)(3)(B) of the Act.

(f) Determinations about expansion of the duration and scope of an Innovation Center model under section 1115A(c) of the Act, including the determination that an Innovation Center model is not expected to meet criteria described in paragraph (a) or (b) of such section.

**§ 512.180 Miscellaneous provisions on bankruptcy and other notifications.**

(a) *Notice of bankruptcy*. If the model participant has filed a bankruptcy petition, whether voluntary or involuntary, the model participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the model participant under the terms of each model tested under section 1115A of the Act in which the model participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number), and a list of all models tested under section 1115A of the Act in which the model participant is participating or has participated. This list need not identify a model tested under section 1115A of the Act in which the model participant participated if final payment has been made under the terms of the model and all administrative or judicial review proceedings regarding model-specific payments between the model participant and CMS have been fully and finally resolved with respect to that model. The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3-01-24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(b) *Notice of legal name change*. A model participant must furnish written notice to CMS at least 30 days after any change in its legal name becomes effective. The notice of legal name change must be in a form and manner specified by CMS and must include a copy of the legal document effecting the name change, which must be authenticated by the appropriate State official.

(c) *Notice of change in control.* (1) A model participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before any change in control becomes effective.

(2)(i) If CMS determines, in accordance with § 512.160(a)(5), that a model participant's change in control would present a program integrity risk, CMS may take remedial action against the model participant under § 512.160(b).

(ii) CMS may also require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

**Subpart B – Radiation Oncology Model**

**General**

**§ 512.200 Basis and scope of subpart.**

(a) *Basis.* This subpart implements the test of the Radiation Oncology (RO) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart do not affect the applicability of other regulations affecting providers and suppliers under Medicare FFS, including the applicability of regulations regarding payment, coverage, and program integrity.

(b) *Scope*. This subpart sets forth the following:

(1) RO Model participation.

(2) Episodes being tested under the RO Model.

(3) Methodology for pricing.

(4) Billing and payment under the RO Model.

(5) Data reporting requirements.

(6) Medicare program waivers.

(7) Payment reconciliation and review processes.

(c) RO participants are subject to the general provisions for Innovation Center models specified in subpart A of this part 512 and in subpart K of part 403 of this chapter.

**§ 512.205 Definitions.**

For purposes of this subpart, the following definitions apply:

*Aggregate quality score (AQS)* means the numeric score calculated for each RO participant based on its performance on, and reporting of, quality measures and clinical data. The AQS is used to determine an RO participant's quality reconciliation payment amount.

*APM* means Alternative Payment Model.

*ASC* means Ambulatory Surgery Center.

*Blend* means the weight given to an RO participant's historical experience adjustment relative to the geographically-adjusted trended national base rate in the calculation of its participant-specific episode payment amounts.

*CAH* means Critical Access Hospital.

*CEHRT* means Certified Electronic Health Record Technology.

*Clean period* means the 28-day period after an RO episode has ended, during which time an RO participant must bill for medically necessary RT services furnished to the RO beneficiary in accordance with Medicare FFS billing rules.

*Core-Based Statistical Area (CBSA)* means a statistical geographic area, based on the definition as identified by the Office of Management and Budget, 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).

*Discount factor* means the set percentage by which CMS reduces payment of the professional component and technical component.

(1) 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.

(2) The discount factor does not vary by cancer type.

(3) The discount factor for the professional component is 3.75 percent; the discount factor for the technical component is 4.75 percent.

*Dual participant* means an RO participant that furnishes both the professional component and technical component of RT services of an RO episode through a freestanding radiation therapy center, identified by a single TIN.

*Duplicate RT service* means 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. Such services are furnished in addition to the RT services furnished by the RO participant that initiated the PC or TC and continues to furnish care to the RO beneficiary during the RO episode.

*Episode* means the 90-day period of RT services that begins on the date of service that an RT provider or RT supplier that is not an RO participant furnishes an initial treatment planning service to a beneficiary, provided that an RT provider or RT supplier furnishes a technical component RT service to the beneficiary within 28 days of such initial treatment planning service. Additional criteria for constructing episodes to be included in determining the national base rates are set forth in § 512.250.

*EOE* stands for "end of episode" and means the end of an RO episode.

*HCPCS* means Healthcare Common Procedure Coding System.

*HOPD* means hospital outpatient department.

*Included cancer types* means the cancer types determined by the criteria set forth in § 512.230, which are included in the RO Model test.

*Included RT services* means the RT services identified at § 512.235, which are included in the RO Model test.

*Incomplete episode* means an RO 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 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.

*Individual practitioner* means a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and has reassigned his or her billing rights to the TIN of an RO participant.

*Individual practitioner list* means a list of individual practitioners who furnish RT services under the TIN of a Dual participant or a Professional participant, which is annually compiled by CMS and which the RO participant must review, revise, and certify in accordance

with § 512.217. The individual practitioner list is used for the RO Model as a Participation List as defined in § 414.1305 of this chapter.

*Initial reconciliation* means the first reconciliation of a PY that occurs as early as August following the applicable PY.

*MIPS* means Merit based Incentive Payment System.

*Model performance period* means, January 1, 2021, through December 31, 2025, the last date on which an RO episode may end under the RO Model. No new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

*National base rate* means the total payment amount for the relevant component of an RO episode, before application of the trend factor, discount factor, adjustments, and applicable withholds, for each of the included cancer types.

*NPI* means National Provider Identifier.

*OPPS* means outpatient prospective payment system.

*Participant-specific professional episode payment* means a payment which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Professional participant or Dual participant as set forth in § 512.265, for the provision of the professional component to an RO beneficiary during an RO episode.

*Participant-specific technical episode payment* means a payment which is calculated by CMS as set forth in § 512.255 and which is paid by CMS to a Technical participant or Dual participant in accordance with § 512.265, for the provision of the technical component to an RO beneficiary during an RO episode.

*Performance year (PY)* means the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period.

*PGP* means physician group practice.

*PPS* means prospective payment system.

*Professional component (PC)* means the included RT services that may only be furnished by a physician.

*Professional participant* means an RO participant that is a Medicare-enrolled PGP identified by a single TIN that furnishes only the PC of an RO episode.

*PSO* means patient safety organization.

*PY* means performance year.

*QP* means Qualifying APM Participants.

*Reconciliation payment* means a payment made by CMS to an RO participant, as determined in accordance with § 512.285.

*Repayment amount* means the amount owed by an RO participant to CMS, as determined in accordance with § 512.285.

*Reconciliation report* means the annual report issued by CMS to an RO participant for each PY, which specifies the RO participant's reconciliation payment amount or repayment amount.

*RO beneficiary* means a Medicare beneficiary who meets all of the beneficiary inclusion criteria at § 512.215(a) and whose RO episode meets all the criteria defined at § 512.245.

*RO episode* means the 90-day period that, as set forth in § 512.245, begins on the date of service that a Professional participant or a Dual participant furnishes an initial treatment planning service to an RO beneficiary in a freestanding radiation therapy center or an HOPD, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service.

*RO participant* means a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model in accordance with § 512.210. An RO participant may be a Dual participant, Professional participant, or Technical participant.

*RT provider* means a Medicare-enrolled HOPD that furnishes RT services.

*RT services* are the treatment planning, technical preparation, special services (such as simulation), treatment delivery, and treatment management services associated with cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumors.

*RT supplier* means a Medicare-enrolled PGP or freestanding radiation therapy center that furnishes RT services.

*SOE* stands for "start of episode" and means the start of an RO episode.

*Stop-loss limit* means the set percentage at which loss is limited under the Model used to calculate the stop-loss reconciliation amount.

*Stop-loss reconciliation amount* means the amount owed to RO participants that have fewer than 60 episodes during 2016-2018 and that were furnishing included RT services on [insert date 60 days after the date of publication in the **Federal Register**] in the CBSAs selected for participation for the loss incurred under the Model as described in § 512.285(f).

*Technical component (TC)* means the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and administrative costs related to RT services.

*Technical participant* means an 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 TC of an RO episode.

*TIN* means Taxpayer Identification Number.

*Trend factor* means an adjustment applied to the national base rates that updates those rates to reflect current trends in the OPPS and PFS rates for RT services.

*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 reconciliation and after a 12-month claims run-out for all RO episodes initiated in the applicable PY.

**RO Model Participation**

**§ 512.210 RO participants and geographic areas.**

(a) *RO participants.* Unless otherwise specified in paragraph (b) or (c) of this section, any RO participant 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.

(b) *Participant exclusions*. A PGP, freestanding radiation therapy center, or HOPD is excluded from participation in the RO Model if it:

(1) Furnishes RT services only in Maryland;

(2) Furnishes RT services only in Vermont;

(3) Furnishes RT services only in U.S. Territories;

(4) Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or

(5) Participates in or is identified by CMS as eligible to participate in the Pennsylvania Rural Health Model.

(c) *Low Volume Opt-Out.* A PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt-out of the RO

Model for a given PY if it has fewer than 20 episodes of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. At least 30 days prior to the start of each PY, CMS notifies RO participants eligible for the low volume opt-out for the upcoming PY. The RO participant must attest to its intention of opting out of the RO Model prior to the start of the upcoming PY.

(d) *Selected CBSAs.* CMS randomly selects CBSAs to identify RT providers and RT suppliers to participate in the RO Model through a stratified sample design, allowing for participant and comparison groups to contain approximately 30 percent of all episodes in eligible geographic areas (CBSAs).

**§ 512.215 Beneficiary population.**

(a) *Beneficiary inclusion criteria*. An individual is an RO beneficiary if:

(1) The individual receives included RT services from an RO participant that billed the SOE modifier for the PC or TC of an RO episode during the Model performance period for an included cancer type; and

(2) At the time that the initial treatment planning service of an RO episode is furnished by an RO participant, the individual:

(i) Is eligible for Medicare Part A and enrolled in Medicare Part B;

(ii) Has traditional FFS Medicare 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); and

(iii) Is not in a Medicare hospice benefit period.

(b) Any individual enrolled in a clinical trial for RT services for which Medicare pays routine costs is an RO beneficiary if the individual satisfies all of the beneficiary inclusion criteria in paragraph (a) of this section.

**§ 512.217 Identification of individual practitioners.**

(a) *General*. Upon the start of each PY, CMS creates and provides to each Dual participant and Professional participant an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant.

(b) *Review of individual practitioner list.* Within 30 days of receipt of the individual practitioner list, the RO participant must review and certify the individual practitioner list, correct any inaccuracies in accordance with paragraph (d) of this section, and certify the list (as corrected, if applicable) in a form and manner specified by CMS and in accordance with paragraph (c) of this section or correct the individual practitioner list in accordance with paragraph (d) of this section.

(c) *List certification*. (1) Within 30 days of receipt of the individual practitioner list, and at such other times as specified by CMS, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the individual practitioner list to the best of his or her knowledge, information, and belief.

(2) All Medicare-enrolled individual practitioners that have reassigned their right to receive Medicare payment for provision of RT services to the TIN of the RO participant must be included on the RO participant's individual practitioner list and each individual practitioner must agree to comply with the requirements of the RO Model before the RO participant certifies the individual practitioner list.

(3) If the RO participant does not certify the individual practitioner list:

(i) Eligible clinicians in the RO Model will not be considered participants in a MIPS APM for purposes of MIPS reporting and scoring rules; and

(ii) Eligible clinicians in the RO Model will not have Qualifying APM Participant ("QP") determinations made based on their participation in the RO Model.

(d) *Changes to the individual practitioner list*. (1) *Additions*.

(i) An RO participant must notify CMS of an addition to its individual practitioner list within 30 days of when an eligible clinician reassigns his or her rights to receive payment from Medicare to the RO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) If the RO participant timely submits notice to CMS, then the addition of an individual practitioner to the RO participant's individual practitioner list is effective on the date specified in the notice furnished to CMS, but no earlier than 30 days before the date of the notice. If the RO participant fails to submit timely notice to CMS, then the addition of an individual practitioner to the individual practitioner list is effective on the date of the notice.

(2) *Removals*. (i) An RO participant must notify CMS no later than 30 days of when an individual on the RO participant's individual practitioner list ceases to be an individual practitioner. The notice must be submitted in the form and manner specified by CMS.

(ii) The removal of an individual practitioner from the RO participant's individual practitioner list is effective on the date specified in the notice furnished to CMS. If the RO participant fails to submit a timely notice of the removal, then the removal is effective on the date that the individual ceases to be an individual practitioner.

(e) *Update to Medicare enrollment information*. The RO participant must ensure that all changes to enrollment information for an RO participant and its individual practitioners,

including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with § 424.516 of this chapter.

**§ 512.220 RO participant compliance with RO Model requirements**.

(a) *RO participant-specific requirements*. (1) RO participants must satisfy the requirements of this section to qualify for the APM Incentive Payment.

(2) Each Professional participant and Dual participant must ensure its individual practitioners:

(i) Starting in PY1, discuss goals of care with each RO beneficiary before initiating treatment and communicate to the RO beneficiary whether the treatment intent is curative or palliative;

(ii) Starting in PY1, adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or, alternatively, document in the medical record the extent of and rationale for any departure from these guidelines;

(iii) Starting in PY1, assess each RO beneficiary's tumor, node, and metastasis cancer stage for the CMS-specified cancer diagnoses;

(iv) Starting in PY1, assess the RO beneficiary's performance status as a quantitative measure determined by the physician;

(v) Starting in PY1, send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of treatment to coordinate care;

(vi) Starting in PY1, discuss with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and

(vii) Starting in PY1, perform and document Peer Review (audit and feedback on treatment plans) before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment for:

(A) 50 percent of new patients in PY1,

(B) 55 percent of new patients in PY2,

(C) 60 percent of new patients in PY3,

(D) 65 percent of new patients in PY4,

(E) 70 percent of new patients in PY5.

(3) Starting in PY1, at such times and in the form and manner specified by CMS, each Technical participant and Dual participant must annually attest to whether it actively participates with a AHRQ-listed patient safety organization (PSO). Examples include maintaining a contractual or similar relationship with a PSO for the receipt and review of patient safety work product.

(b) *CEHRT.* (1) Each RO participant must use CEHRT, and ensure that its individual practitioners use CEHRT, in a manner sufficient to meet the applicable requirements of the Advanced APM criteria codified in § 414.1415(a)(1)(i) of this chapter. Before each PY, each RO participant must certify in the form and manner, and by a deadline specified by CMS, that it uses CEHRT throughout such PY in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

(2) Within 30 days of the start of PY1, the RO participant must certify its intent to use CEHRT throughout PY1 in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

**§ 512.225 Beneficiary notification.**

(a) *General.* Starting in PY1, each Professional participant and Dual participant must notify each RO beneficiary to whom it furnishes included RT services—

(1) That the RO participant is participating in the RO Model;

(2) That the RO beneficiary has the opportunity to decline claims data sharing for care coordination and quality improvement purposes. If an RO beneficiary declines claims data sharing for care coordination and quality improvement purposes, then the RO participant must inform CMS within 30 days of receiving notification from the RO beneficiary that the beneficiary is declining to have his or her claims data shared in that manner; and,

(3) Of the RO beneficiary's cost-sharing responsibilities.

(b) *Form and manner of notification.* Notification of the information specified in paragraph (a) of this section must be carried out by an RO participant by providing each RO beneficiary with a CMS-developed standardized written notice during the RO beneficiary's initial treatment planning session. The RO participants must furnish the notice to the RO beneficiary in the form and manner specified by CMS.

(c) *Applicability of general Innovation Center provisions.* The beneficiary notifications under this section are not descriptive model materials and activities under § 512.120(c). The requirement described in § 512.120(c)(2) does not apply to the standardized written notice described in paragraph (b) of this section.

**Scope of RO Episodes Being Tested**

§ **512.230 Criteria for determining cancer types.**

(a) *Included cancer types*. CMS includes in the RO Model test cancer types that satisfy all of the following criteria. The cancer type:

(1) Is commonly treated with radiation; and

(2) Has associated current ICD-10 codes that have demonstrated pricing stability.

(b) *Removing cancer types*. CMS removes cancer types in the RO Model if it determines:

(1) RT is no longer appropriate to treat a cancer type per nationally recognized, evidence-based clinical treatment guidelines;

(2) CMS discovers a ≥10 percent error in established national base rates; or

(3) The Secretary determines a cancer type not to be suitable for inclusion in the RO Model.

(c) *ICD-10 codes for included cancer types*. CMS displays on the RO Model website no later than 30 days prior to each PY the ICD-10 diagnosis codes associated with each included cancer type.

**§ 512.235 Included RT services.**

(a) 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.

(b) All other RT services furnished by an RO participant during the Model performance period are subject to Medicare FFS payment rules.

**§ 512.240 Included modalities.**

The modalities included in the RO Model are 3-dimensional conformal RT (3DCRT), intensity-modulated RT (IMRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), proton beam therapy (PBT), image-guided radiation therapy (IGRT), and brachytherapy.

**§ 512.245 Included RO episodes.**

(a) *General*. Any RO episode that begins on or after January 1, 2021, and ends on or before December 31, 2025, is included in the Model performance period.

(b) *Death or election of hospice benefit.* An RO episode is included in, and paid for under, the RO Model if the RO beneficiary dies after the TC of an RO episode has been initiated, or if the RO beneficiary elects the Medicare hospice benefit after the initial treatment planning service, provided that the TC is initiated within 28 days following the initial treatment planning service. Each RO participant will receive both installments of the episode payment under such circumstances, regardless of whether the RO beneficiary dies or elects the Medicare hospice benefit before the relevant course of RT treatment has ended.

(c) *Clean periods.* An RO episode must not be initiated for the same RO beneficiary during a clean period.

**Pricing Methodology**

**§ 512.250 Determination of national base rates**.

CMS determines a national base rate for the PC and TC for each included cancer type.

(a) National base rates are the historical average cost for an episode of care for each of the included cancer types prior to the Model performance period.

(b) National base rates are determined in the following manner:

(1) CMS excludes claims from RT suppliers and RT providers in Maryland and Vermont and all inpatient and ASC claims from the construction of episodes and;

(2) CMS excludes the following:

(i) episodes with any RT services furnished by a CAH,

(ii) episodes that are not attributed to an RT provider or RT supplier, and

(iii) episodes in which either the PC or TC is attributed to an RT provider or RT supplier with a U.S. Territory service location.

(3) CMS calculates the episode amount CMS paid on average to RT providers and RT suppliers for the PC and TC for each of the included cancer types in the HOPD setting, creating the RO Model's national base rates.

**§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts**.

(a) Thirty days before the start of each PY, CMS provides each RO participant its case mix and historical experience adjustments for both the PC and TC as calculated in paragraphs (c)(3) and (4) of this section. If an RO participant is not eligible to receive a historical experience adjustment or case mix adjustment as described under paragraph (c)(7) of this section, then CMS provides a zero value for those adjustments.

(b) Any episode used to calculate the participant-specific professional episode payment amounts and the participant-specific technical episode payment amounts for an RO participant is subject to the exclusions described in § 512.250(b)(1) and(2).

(c) CMS calculates the participant-specific professional episode payment amounts and participant-specific technical episode payment amounts for each included cancer type using the following:

(1) *Trend factors*. For every PY, CMS adjusts the national base rates for the PC and TC of each cancer type by calculating a separate trend factor for the PC and TC of each included cancer type.

(2) *Geographic adjustment.* CMS adjusts the trended national base rates prior to applying each RO participant's case mix and historical experience, and prior to applying the discounts and withholds, for local cost and wage indices based on where RT services are furnished, as described by existing geographic adjustment processes in the OPPS and PFS.

(3) *Case mix adjustment*. CMS establishes and applies a case mix adjustment to the national base rate after the trend factor and geographic adjustment have applied. The case mix adjustment reflects episode or RO episode characteristics that may be beyond the control of RO participants such as cancer type, age, sex, presence of a major procedure, death during the episode, and presence of chemotherapy.

(4) *Historical experience adjustment.* CMS establishes and applies a historical experience adjustment to the national base rate after the trend factor, geographic adjustment, and case mix adjustment have been applied. The historical experience adjustments reflect each RO participant's actual historical experience.

(5) *Blend.* CMS blends each RO participant's historical experience adjustment and the geographically-adjusted trended national base rate. The blend for RO participants with a professional historical experience adjustment or technical historical experience adjustment with a value equal to or less than zero is 90/10, meaning the calculation of the participant-specific episode payment amount is weighted according to 90 percent of the RO participant's historical experience adjustment and 10 percent of the geographically-adjusted trended national base for PY1 through PY5. The blend for RO participants with a professional historical experience

adjustment or technical historical experience adjustment of more than zero is 90/10 in PY1, 85/15 in PY2, 80/20 in PY3, 75/25 in PY4, and 70/30 in PY5.

(6) *Changes in business structure.* (i) RO participants must notify CMS in writing of a merger, acquisition, or other new clinical or business relationship, at least 90 days before the date of the change as described in § 424.516.

(ii) CMS updates case mix and historical experience adjustments according to the relevant treatment history that applies as a result of a merger, acquisition, or other new clinical or business relationship in the RO participant's case mix and historical experience adjustment calculations from the effective date of the change.

(7) *Adjustments for RO participants with fewer than 60 episodes during 2016-2018.*

(i) RO participants that have fewer than 60 episodes from 2016-2018 do not receive a historical experience adjustment during the Model performance period.

(ii) RO participants that have fewer than 60 episodes from 2016-2018 do not receive a case mix adjustment for PY1.

(iii) RO participants described in § 512.255(b)(7)(ii) that continue to have fewer than 60 episodes in the rolling 3-year period used to determine the case mix adjustment for each PY (2017-2019 for PY2, 2018-2020 for PY3, 2019-2021 for PY4, and 2020-2022 for PY5) and that have never received a case mix adjustment do not receive a case mix adjustment for that PY.

(iv) RO participants that have fewer than 60 episodes from 2016-2018 and were furnishing included RT services in the CBSAs selected for participation on [insert date 60 days after the date of publication in the **Federal Register]** are eligible to receive a stop-loss reconciliation amount, if applicable, for the loss incurred under the RO Model as described in § 512.285(f).

(8) *Discount factor.* CMS deducts a percentage discount from each episode payment after applying the trend factor, geographic adjustment, and case mix and historical experience adjustments to the national base rate. The discount factor for the PC is 3.75 percent. The discount factor for TC is 4.75 percent.

(9) *Incorrect payment withhold.* To account for duplicate RT services and incomplete episodes:

(i) CMS withholds from each RO participant 1 percent from each episode payment, after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount to the national base rate.

(ii) CMS determines during the annual reconciliation process set forth at § 512.285 whether an RO participant is eligible to receive a portion or all of the withheld amount or whether any payment is owed to CMS.

(10) *Quality withhold*. In accordance with § 414.1415(b)(1) of this chapter, CMS withholds 2 percent from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. RO participants may earn back this withhold, in part or in full, based on their AQS.

(11) *Patient experience withhold*. Starting in PY3,

(i) CMS withholds 1 percent from each technical episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate.

(ii) RO participants may earn back their patient-experience withhold, in part or in full, based on their results from the CAHPS® Cancer Care Radiation Therapy survey.

(12) *Coinsurance.* RO participants may collect beneficiary coinsurance payments for services furnished under the RO Model in multiple installments under a payment plan.

(i) The availability of payment plans may not be used as a marketing tool to influence beneficiary choice of health care provider.

(ii) RO participants offering a payment plan may inform the RO beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter.

(iii) The beneficiary coinsurance payment equals 20 percent of the episode payment amount to be paid to the RO participant(s) prior to the application of sequestration for the billed RO Model-specific HCPCS code with a SOE modifier and for the billed RO Model-specific HCPCS code with an EOE modifier for the PC and TC, except as provided in paragraph (c)(12)(iv) and(v) of this section.

(iv) In the case of incomplete episodes

(A) The beneficiary coinsurance payment equals 20 percent of the FFS amounts that would have been paid in the absence of the RO Model for the services furnished by the RO participant that initiated the PC and the RO participant that initiated the TC (if applicable), except for a subset of incomplete episodes described in paragraph (c)(12)(iv)(B); or

(B) If an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided a Technical participant or the same Dual participant that provided the initial treatment planning service furnishes a  a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service, the beneficiary coinsurance payment equals 20 percent of

the first installment of the episode payment amount to be paid to the RO participant(s) prior to the application of sequestration for the billed RO Model-specific HCPCS code with an SOE modifier for the PC and TC. If an RO participant bills the RO Model-specific HCPCS code and EOE modifier with a date of service that is prior to the date that the RO beneficiary ceases to have traditional FFS Medicare, then the beneficiary coinsurance payment equals 20 percent of the full episode payment amount for the PC or TC, as applicable.

(v) In the case of duplicate RT services, the beneficiary coinsurance payment equals 20 percent of the episode payment amount to be paid to the RO participant(s) per § 512.255(c)(12)(iii) and 20 percent of the FFS amount to the RT provider and/or RT supplier furnishing one or more duplicate RT services.

(13) *Sequestration*. CMS deducts 2 percent from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate.

**Billing and Payment**

**§ 512.260 Billing.**

(a) *Reassignment of billing rights.* Each Professional participant and Dual participant must ensure that its individual practitioners reassign their billing rights to the TIN of the Professional participant or Dual participant.

(b) *Billing under the RO Model.* (1) Professional participants and Dual participants must bill an RO Model-specific HCPCS code and a SOE modifier to indicate that the treatment planning service has been furnished and that an RO episode has been initiated.

(2) Dual participants and Technical participants must bill an RO Model-specific HCPCS code and SOE modifier to indicate that a treatment delivery service was furnished.

(3) RO participants must bill the same RO Model-specific HCPCS code that initiated the RO episode and an EOE modifier to indicate that the RO episode has ended.

(4) RO participants may submit a claim with an EOE modifier only after the RT course of treatment has ended, except that such claim must not be submitted earlier than 28 days after the date of the initial treatment planning service.

(c) *Billing for RT services performed during a clean period.* RO participants must bill for any medically necessary RT services furnished to an RO beneficiary during a clean period in accordance with existing FFS billing processes in the OPPS and PFS.

(d) *Submission of no-pay claims.* RO participants must submit no-pay claims for any medically necessary included RT services furnished to an RO beneficiary during an RO episode pursuant to existing FFS billing processes in the OPPS and PFS.

**§ 512.265 Payment.**

(a) *Payment for episodes.* CMS pays an RO participant for all included RT services furnished to an RO beneficiary during a completed RO episode as follows:

(1) CMS pays a Professional participant a participant-specific professional episode payment for the professional component furnished to an RO beneficiary during an RO episode.

(2) CMS pays a Technical participant a participant-specific technical episode payment for the technical component furnished to an RO beneficiary during an RO episode.

(3) CMS pays a Dual participant a participant-specific professional episode payment and a participant-specific technical episode payment for the professional component and technical component furnished to an RO beneficiary during an RO episode.

(b) *Payment installments*. CMS makes each of the payments described in paragraph (a) of this section in two equal installments, as follows:

(1) CMS pays one-half of a participant-specific professional episode payment to a Professional participant or Dual participant or one-half of the participant-specific technical episode payment to a Technical participant or Dual participant after the RO participant bills an RO Model-specific HCPCS code with a SOE modifier.

(2) CMS pays the remaining half of a participant-specific professional episode payment to a Professional participant or Dual participant or one-half of the participant-specific technical episode payment to a Technical participant or Dual participant after the RO participant bills an RO Model-specific HCPCS code with an EOE modifier.

(c) *Duplicate RT services*. Duplicate RT services are reimbursed at the FFS amount, whether or not the RT provider or RT supplier that furnished such services is an RO participant.

**§ 512.270 Treatment of add-on payments under existing Medicare payment systems.**

(a) CMS does not make separate Medicare FFS payments to RO participants for any included RT services that are furnished to an RO beneficiary during an RO episode.

(b) An RO participant may receive Medicare FFS payment for items and services furnished to an RO beneficiary during an RO episode, provided that any such other item or service is not an included RT service.

**Data Reporting**

**§ 512.275 Quality measures, clinical data, and reporting.**

(a) *Data privacy compliance*. The RO participant must --

(1) Comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the Innovation Center model, including any patient-identifiable derivative data, as well as the terms of any attestation or agreement entered into by the RO participant with CMS as a condition of receiving that data. Such laws may include, without

limitation, the privacy and security rules promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as modified, and the Health Information Technology for Economic and Clinical Health Act (HITECH).

(2) Contractually bind all downstream recipients of CMS data to the same terms and conditions to which the RO participant was itself bound in its agreements with CMS as a condition of the downstream recipient's receipt of the data from the RO participant.

(b) *RO participant public release of patient de-identified information*. The RO participant must include the disclaimer codified at § 512.120(c)(2) on the first page of any publicly-released document, the contents of which materially and substantially references or is materially and substantially based upon the RO participant's participation in the RO Model, including but not limited to press releases, journal articles, research articles, descriptive articles, external reports, and statistical/analytical materials.

(c) *Reporting quality measures and clinical data elements.* In addition to reporting described in other provisions in this part, Professional participants and Dual participants must report selected quality measures on all patients and clinical data elements describing cancer stage, disease characteristics, treatment intent, and specific treatment plan information on beneficiaries treated for specified cancer types, in the form, manner, and at a time specified by CMS.

**Medicare Program Waivers**

**§ 512.280 RO Model Medicare program waivers.**

(a) *General.* The Secretary may waive certain requirements of title XVIII of the Act as necessary solely for purposes of testing of the RO Model. Such waivers apply only to the participants in the RO Model.

(b) *Hospital Outpatient Quality Reporting (OQR) Program.* CMS waives the application of the Hospital OQR Program 2.0 percentage point reduction under section 1833(t)(17) of the Act for only those Ambulatory Payment Classifications (APCs) that include only RO Model-specific HCPCS codes during the Model performance period.

(c) *Merit-based Incentive Payment System (MIPS).* CMS waives the requirement under section 1848(q)(6)(E) of the Act and § 414.1405(e) of this chapter to apply the MIPS payment adjustment factor, and, as applicable, the additional MIPS payment adjustment factor (collectively referred to as the MIPS payment adjustment factors) to the TC of RO Model payments to the extent that the MIPS payment adjustment factors would otherwise apply to the TC of RO Model payments.

(d) *APM Incentive Payment.* CMS waives the requirements of § 414.1450(b) of this chapter such that technical component payment amounts under the RO Model shall not be considered in calculation of the aggregate payment amount for covered professional services as defined in section 1848(k)(3)(A) of the Act for the APM Incentive Payment made under § 414.1450(b)(1) of this chapter.

(e) *PFS Relativity Adjuster*. CMS waives the requirement to apply the PFS Relativity Adjuster to RO Model-specific APCs for RO participants that are non-excepted off-campus provider-based departments (PBDs) identified by section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), which amended section 1833(t)(1)(B)(v) and added paragraph (t)(21) to the Social Security Act.

(f) *General payment waivers.* CMS waives the following sections of the Act solely for the purposes of testing the RO Model:

(1) 1833(t)(1)(A).

(2) 1833(t)(16)(D).

(3) 1848(a)(1).

(4) 1833(t)(2)(H).

(5) 1869 claims appeals procedures.

**Reconciliation and Review Process**

**§ 512.285 Reconciliation process.**

(a) *General.* CMS conducts an initial reconciliation and a true-up reconciliation for each RO participant for each PY in accordance with this section.

(b) *Annual reconciliation calculations*. (1) To determine the reconciliation payment or the repayment amount based on RO episodes initiated in a PY, CMS performs the following steps:

(i) CMS calculates an RO participant's incorrect episode payment reconciliation amount as described in paragraph (c) of this section.

(ii) CMS calculates the RO participant's quality reconciliation amount as described in paragraph (d) of this section, if applicable.

(iii) CMS calculates the RO participant's patient experience reconciliation amount, as described in paragraph (e) of this section, if applicable.

(iv) CMS calculates the stop-loss reconciliation amount, as described in paragraph (f) of this section, if applicable.

(v) CMS adds, as applicable, the incorrect episode payment reconciliation amount, any quality reconciliation payment amount, any patient experience reconciliation amount, and any stop-loss reconciliation payment amount. The sum of these amounts results in a reconciliation payment or repayment amount.

(2) CMS calculations use claims data available at the time of reconciliation.

(c) *Incorrect episode payment reconciliation amount.* CMS calculates the incorrect episode payment reconciliation amount as follows:

(1) *Total incorrect payment withhold amount.* CMS calculates the total incorrect payment withhold amount by adding the incorrect payment withhold amount for each episode initiated in the PY.

(2) *Total duplicate RT services amount.* CMS calculates the total duplicate RT services amount by adding all FFS amounts for duplicate RT services furnished during each episode initiated in the PY. The duplicate RT services amount is capped for each episode and will not be more than the participant-specific professional episode payment amount or participant-specific technical episode payment amount received by the RO participant for an RO episode, even if the duplicate RT services amount exceeds the participant-specific professional episode payment amount or the participant-specific technical episode payment amount.

(3) *Total incomplete episode amount.* CMS calculates the total incomplete episode amount for a subset of incomplete episodes.

(i) Incomplete episodes in which an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided an RO participant furnishes a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service, are not included in the incomplete episode amount.

(ii) For all other incomplete episodes initiated in the PY, CMS determines the total incomplete episode amount by calculating the difference between the following amounts:

(A) The sum of all FFS amounts that would have been paid to the RO participant in the absence of the RO Model for any included RT services furnished during such incomplete episodes, as determined by no-pay claims. This sum is what CMS owes the RO participant for such incomplete episodes.

(B) The sum of the participant-specific episode payment amounts paid to the relevant RO participant for such incomplete episodes initiated in the PY.

(4) *Total incorrect episode payment amount*. CMS calculates the total incorrect episode payment amount as follows:

(i) If the sum described in paragraph (c)(3)(ii)(A) of this section is more than the sum described in paragraph (c)(3)(ii)(B) of this section, the difference is subtracted from the total duplicate RT services amount and the resulting amount is the total incorrect episode payment amount.

(ii) If the sum described in paragraph (c)(3)(ii)(A) of this section is less than the sum described in paragraph (c)(3)(ii)(B) of this section, the difference is added to the total duplicate RT services amount and the resulting amount is the total incorrect episode payment amount.

(5) *Incorrect episode payment reconciliation amount*. If the total incorrect episode payment amount represents money owed by the RO participant to CMS, CMS subtracts the total incorrect episode payment amount from the total incorrect payment withhold amount. In the case that the total incorrect episode payment amount represents money owed by CMS to the RO participant, CMS adds the total incorrect episode payment amount to the total incorrect payment withhold amount. The resulting amount is the RO participant's incorrect episode payment reconciliation amount.

(d) *Quality reconciliation payment amount*. For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for each PY by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY.

(e) *Patient experience reconciliation amount*. For PY3 and subsequent PYs, CMS determines the patient experience reconciliation amount for RO participants by multiplying the participant's AQS (as a percentage) by the total patient experience withhold amount for all RO episodes initiated during the PY.

(f) *Stop-loss reconciliation amount.* CMS determines the stop-loss reconciliation amount for RO participants that have fewer than 60 episodes during 2016 through 2018 and were furnishing included RT services at [insert date 60 days after the date of publication in the **Federal Register**] in the CBSAs selected for participation by--

(1) Using no-pay claims, CMS calculates the total FFS amount by summing the FFS amounts that would have been paid to the RO participant in the absence of the RO Model for all included RT services furnished during the RO episodes initiated in the PY; and

(2) CMS calculates the sum of all participant-specific professional episode payments and participant-specific technical episode payments paid to the RO participant for the RO episodes initiated in the PY.

(3) If the total FFS amount exceeds the sum of the participant-specific episode payment amounts for the PY by more than 20 percent then CMS owes the RO participant the amount that exceeds 20 percent, either increasing the amount of the RO participant's reconciliation payment or reducing the amount of the RO's participant's reconciliation repayment.

(g) *True-up reconciliation*. CMS conducts a true-up reconciliation in the same manner described in paragraph (b) of this section (except that the quality reconciliation payment amount and the patient experience reconciliation amount are not calculated) to determine any additional reconciliation payment or repayment amount that are identified using 12-months of claims run-out.

(h) *Reconciliation report.* CMS issues each RO participant a reconciliation report for each PY. Each reconciliation report contains the following:

(1) The RO participant's reconciliation payment or repayment amount, if any, for the relevant PY.

(2) Any additional reconciliation payment or repayment amount owed for a previous PY as a result of the true-up reconciliation.

(3) The net reconciliation payment or repayment amount owed.

(i) *Payment of amounts owed.* (1) CMS issues a reconciliation payment to the RO participant in the amount specified in the reconciliation report 30 days after the reconciliation report is deemed final.

(2) The RO participant must pay a repayment amount to CMS in the amount specified in the reconciliation report by a deadline specified by CMS. If the RO participant fails to timely pay the full repayment amount, CMS recoups the repayment amount from any payments otherwise owed by CMS to the RO participant, including Medicare payments for items and services unrelated to the RO Model.

(3) No coinsurance is owed by an RO beneficiary with respect to any repayment amount or reconciliation payment.

**§ 512.290 Timely error notice and reconsideration review process**.

(a) *Timely error notice.* Subject to the limitations on review in § 512.170, an RO participant that identifies and wishes to contest a suspected error in the calculation of its reconciliation payment or repayment amount or AQS must provide written notice of the suspected calculation error to CMS within 45 days of the date of the reconciliation report. Such timely error notice must be in a form and manner specified by CMS. RO participants are not permitted to contest the RO Model pricing methodology or AQS methodology.

(1) Unless a timely error notice is received by CMS within 45 days of the date of issuance of a reconciliation report, the reconciliation payment or repayment amount determination specified in that reconciliation report is deemed binding and not subject to further review.

(2) If CMS receives a timely error notice, then CMS responds in writing within 30 days either to confirm that there was an error in the calculation or to verify that the calculation is correct. CMS may extend the deadline for its response upon written notice to the RO participant.

(3) Only the RO participant may use the timely error notice process described in this paragraph and the reconsideration review process described in paragraph (b) of this section.

(b) *Reconsideration review.* (1) *Reconsideration request by an RO participant*. (i) If the RO participant is dissatisfied with CMS' response to the timely error notice, then the RO participant may request a reconsideration review as specified in paragraph (b)(2) of this section.

(ii) If CMS does not receive a request for reconsideration from the RO participant within 10 days of the issue date of CMS' response to the RO participant's timely error notice, then CMS' response to the timely error notice is deemed binding and not subject to further review.

(2) *Submission of a reconsideration request*. (i) *Information needed in the reconsideration request*. The reconsideration review request must--

(A) Provide a detailed explanation of the basis for the dispute; and

(B) Include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment or repayment amount or AQS in accordance with the terms of this subpart.

(3) *Form, manner, and deadline for submission of the reconsideration request.* The information specified in paragraph (b)(2)(i) of this section must be submitted--

(i) In a form and manner specified by CMS; and

(ii) Within 10 days of the date of the CMS response described in paragraph (a)(2) of this section.

(4) *Designation of and notification from a CMS-designated reconsideration official*.

(i) *Designation of reconsideration official*. CMS designates a reconsideration official who--

(A) Is authorized to receive such requests; and

(B) Was not involved in the responding to the RO participant's timely error notice.

(ii) *Notification to the RO participant*. The CMS-designated reconsideration official makes 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:

(A) The issue(s) in dispute;

(B) The briefing schedule; and

(C) The review procedures.

(5) *Resolution review*. The CMS reconsideration official makes all reasonable efforts to complete the on-the-record resolution review and issue a written determination no later than 60 days after the submission of the final position paper in accordance with the reconsideration official's briefing schedule.

**Subpart C – ESRD Treatment Choices Model**

**General**

**§ 512.300 Basis and scope.**

(a) *Basis*. This subpart implements the test of the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model under section 1115A(b) of the Act. Except as specifically noted in this subpart, the regulations under this subpart must not be construed to affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, or program integrity.

(b) *Scope*. This subpart sets forth the following:

(1) The duration of the ETC Model.

(2) The method for selecting ETC Participants.

(3) The schedule and methodologies for the Home Dialysis Payment Adjustment and Performance Payment Adjustment.

(4) The methodology for ETC Participant performance assessment for purposes of the Performance Payment Adjustment, including beneficiary attribution, benchmarking and scoring, and calculating the Modality Performance Score.

(5) Monitoring and evaluation, including quality measure reporting.

(6) Medicare payment waivers.

**§ 512.310 Definitions.**

For purposes of this subpart, the following definitions apply.

*Adjusted ESRD PPS per Treatment Base Rate* means the per treatment payment amount as defined in § 413.230 of this chapter, including patient-level adjustments and facility-level adjustments, and excluding any applicable training adjustment, add-on payment amount, outlier payment amount, transitional drug add-on payment adjustment (TDAPA) amount, and transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) amount.

*Benchmark Year* (BY) means the 12-month period that begins 18 months prior to the start of a given measurement year (MY) from which data are used to construct benchmarks against which to score an ETC Participant's achievement and improvement on the home dialysis rate and transplant rate for the purpose of calculating the ETC Participant's MPS.

*Clinician Home Dialysis Payment Adjustment (Clinician HDPA)* means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant, for the Managing Clinician's home dialysis claims, as described in §§ 512.345 and 512.350.

*Clinician Performance Payment Adjustment (Clinician PPA)* means the payment adjustment to the MCP for a Managing Clinician who is an ETC Participant based on the Managing Clinician's MPS, as described in §§ 512.375(b) and 512.380.

*Comparison Geographic Area(s)* means those HRRs that are not Selected Geographic Areas.

*ESRD Beneficiary* means a beneficiary who meets either of the following:

(1) Is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant.

(2) Has already received a kidney transplant and has a non-AKI dialysis or MCP claim--

(i) At least 12 months after the beneficiary's latest transplant date; or

(ii) Less than 12 months after the beneficiary's latest transplant date and has a kidney transplant failure diagnosis code documented on any Medicare claim.

*ESRD facility* means an ESRD facility as specified in § 413.171 of this chapter.

*ETC Participant* means an ESRD facility or Managing Clinician that is required to participate in the ETC Model pursuant to § 512.325(a).

*Facility Home Dialysis Payment Adjustment (Facility HDPA)* means the payment adjustment to the Adjusted ESRD PPS per Treatment Base Rate for an ESRD facility that is an ETC Participant for the ESRD facility's home dialysis claims, as described in §§ 512.340 and 512.350.

*Facility Performance Payment Adjustment (Facility PPA)* means the payment adjustment to the Adjusted ESRD PPS per treatment base rate for an ESRD facility that is an ETC Participant based on the ESRD facility's MPS, as described in §§ 512.375(a) and 512.380.

*Home Dialysis Payment Adjustment (HDPA)* means either the Facility HDPA or the Clinician HDPA.

*Home dialysis rate* means the rate of ESRD Beneficiaries attributed to the ETC Participant who dialyzed at home during the relevant MY, as described in § 512.365(b).

*Hospital referral regions (HRRs)* means the regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at https://www.dartmouthatlas.org/.

*Kidney transplant* means a kidney transplant, alone or in conjunction with any other organ.

*Living donor transplant (LDT) Beneficiary* means an ESRD Beneficiary who received a kidney transplant from a living donor.

*Living donor transplant rate* means the rate of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant who received a kidney transplant from a living donor during the MY, as described in § 512.365(c)(1)(ii) and § 512.365(c)(2)(ii).

*Managing Clinician* means a Medicare-enrolled physician or non-physician practitioner, identified by a National Provider Identifier (NPI), who furnishes and bills the MCP for managing one or more adult ESRD Beneficiaries.

*Measurement Year (MY)* means the 12-month period for which achievement and improvement on the home dialysis rate and transplant rate are assessed for the purpose of calculating the ETC Participant's MPS and corresponding PPA. Each MY included in the ETC Model and its corresponding PPA Period are specified in § 512.355(c).

*Modality Performance Score (MPS)* means the numeric performance score calculated for each ETC Participant based on the ETC Participant's home dialysis rate and transplant rate, as described in § 512.370(a), which is used to determine the amount of the ETC Participant's PPA, as described in § 512.380.

*Monthly capitation payment (MCP)* means 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 the physician or non-physician practitioner as specified in § 414.314 of this chapter.

*National Provider Identifier (NPI)* means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

*Performance Payment Adjustment (PPA)* means either the Facility PPA or the Clinician PPA.

*Performance Payment Adjustment Period (PPA Period)* means the six-month period during which a PPA is applied in accordance with § 512.380.

*Pre-emptive LDT Beneficiary* means a beneficiary who received a kidney transplant from a living donor prior to beginning dialysis.

*Selected Geographic Area(s)* are those HRRs selected by CMS pursuant to § 512.325(b) for purposes of selecting ESRD facilities and Managing Clinicians required to participate in the ETC Model as ETC Participants.

*Subsidiary ESRD facility* is an ESRD facility owned in whole or in part by another legal entity.

*Taxpayer Identification Number (TIN)* means a Federal taxpayer identification number or employer identification number as defined by the Internal Revenue Service in 26 CFR 301.6109-1.

*Transplant rate* means the sum of the transplant waitlist rate and the living donor transplant rate, as described in § 512.365(c).

*Transplant waitlist rate* means the rate of ESRD Beneficiaries attributed to the ETC Participant who were on the kidney transplant waitlist during the MY, as described in § 512.365(c)(1)(i) -(ii) and § 512.365(c)(2)(i)-(ii).

**ESRD Treatment Choices Model Scope and Participants**

**§ 512.320 Duration.**

CMS will apply the payment adjustments described in this subpart under the ETC Model to claims with claim service dates beginning on or after January 1, 2021, and ending on or before June 30, 2027.

**§ 512.325 Participant selection and geographic areas.**

(a) *Selected participants.* All Medicare-certified ESRD facilities and Medicare-enrolled Managing Clinicians located in a selected geographic area are required to participate in the ETC Model.

(b) *Selected Geographic Areas.* CMS establishes the Selected Geographic Areas by selecting all HRRs for which at least 20 percent of the component zip codes are located in Maryland, and a random sample of 30 percent of HRRs, stratified by Census-defined regions (Northeast, South, Midwest, and West). CMS excludes all U.S. Territories from the Selected Geographic Areas.

**§ 512.330 Beneficiary notification.**

(a) *General.* ETC Participants must prominently display informational materials in each of their office or facility locations where beneficiaries receive treatment to notify beneficiaries that the ETC Participant is participating in the ETC Model. CMS provides the ETC Participant with a template for these materials, indicating the required content that the ETC Participant must not change and places where the ETC Participant may insert its own original content. The CMS-

provided template for the beneficiary notification will include, without limitation, the following information:

(1) A notification that the ETC Participant is participating in the ETC Model;

(2) Instructions on how to contact the ESRD Network Organizations with any questions or concerns about the ETC Participant's participation in the Model;

(3) An affirmation of the ESRD Beneficiary's protections under Medicare, including the beneficiary's freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

(b) *Applicability of general Innovation Center model provisions.* The requirement described in § 512.120(c)(2) shall not apply to the CMS-provided materials described in paragraph (a) of this section. All other ETC Participant communications that are descriptive model materials and activities as defined under § 512.110 must meet the requirements described in § 512.120(c).

**Home Dialysis Payment Adjustment**

**§ 512.340 Payments subject to the Facility HDPA.**

CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility HDPA on claim lines with Type of Bill 072X, and with condition codes 74 or 76, when the claim is submitted by an ESRD facility that is an ETC Participant with a claim service date during a calendar year subject to adjustment as described in § 512.350 and the beneficiary is at least 18 years old before the first day of the month.

**§ 512.345 Payments subject to the Clinician HDPA.**

CMS adjusts the amount otherwise paid under Medicare Part B with respect to MCP claims on claim lines with CPT codes 90965 and 90966 by the Clinician HDPA when the claim

is submitted by a Managing Clinician who is an ETC Participant with a claim service date during a calendar year subject to adjustment as described in § 512.350 and the beneficiary is at least 18 years old before the first day of the month.

**§ 512.350 Schedule of home dialysis payment adjustments.**

CMS adjusts the payments specified in § 512.340 by the Facility HDPA and adjusts the payments specified in § 512.345 by the Clinician HDPA, according to the following schedule:

(a) Calendar year 2021: +3 percent.

(b) Calendar year 2022: +2 percent.

(c) Calendar year 2023: +1 percent.

**Performance Payment Adjustment**

**§ 512.355 Schedule of performance assessment and performance payment adjustment.**

(a) *Measurement Years.* CMS assesses ETC Participant performance on the home dialysis rate and the transplant rate during each of the MYs. The first MY begins on January 1, 2021, and the final MY ends on June 30, 2026.

(b) *Performance Payment Adjustment Period.* CMS adjusts payments for ETC Participants by the PPA during each of the PPA Periods, each of which corresponds to a MY. The first PPA Period begins on July 1, 2022, and the final PPA Period ends on June 30, 2027.

(c) *Measurement Years and Performance Payment Adjustment Periods.* MYs and PPA Periods follow the following schedule:

**Table 1 to Paragraph (c)--ETC Model Schedule of Measurement Years and PPA Periods**

| Measurement Year (MY) | Performance Payment Adjustment (PPA) Period |
|---|---|
| MY 1 – 1/1/2021 through 12/31/2021 | PPA Period 1 – 7/1/2022 through 12/31/2022 |
| MY 2 – 7/1/2021 through 6/30/2022 | PPA Period 2 – 1/1/2023 through 6/30/2023 |
| MY 3 – 1/1/2022 through 12/31/2022 | PPA Period 3 – 7/1/2023 through 12/31/2023 |
| MY 4 – 7/1/2022 through 6/30/2023 | PPA Period 4 – 1/1/2024 through 6/30/2024 |
| MY 5 – 1/1/2023 through 12/31/2023 | PPA Period 5 – 7/1/2024 through 12/31/2024 |
| MY 6 – 7/1/2023 through 6/30/2024 | PPA Period 6 – 1/1/2025 through 6/30/2025 |
| MY 7 – 1/1/2024 through 12/31/2024 | PPA Period 7 – 7/1/2025 through 12/31/2025 |
| MY 8 – 7/1/2024 through 6/30/2025 | PPA Period 8 – 1/1/2026 through 6/30/2026 |
| MY 9 – 1/1/2025 through 12/31/2025 | PPA Period 9 – 7/1/2026 through 12/31/2026 |
| MY 10 – 7/1/2025 through 6/30/2026 | PPA Period 10 – 1/1/2027 through 6/30/2027 |

**§ 512.360 Beneficiary population and attribution.**

(a) *General.* Except as provided in paragraph (b) of this section, CMS attributes ESRD Beneficiaries to an ETC Participant for each month during a MY based on the ESRD Beneficiary's receipt of services specified in paragraph (c) of this section during that month, for the purpose of assessing the ETC Participant's performance on the home dialysis rate and transplant rate during that MY. Except as provided in paragraph (b) of this section, CMS attributes Pre-emptive LDT Beneficiaries to a Managing Clinician for one or more months during a MY based on the Pre-emptive LDT Beneficiary's receipt of services specified in paragraph (c)(2) of this section during that MY, for the purpose of assessing the Managing Clinician's performance on the living donor transplant rate during that MY. CMS attributes ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries to the ETC Participant for each month during a MY retrospectively after the end of the MY. CMS attributes an ESRD Beneficiary to no more than one ESRD facility and no more than one Managing Clinician for a

given month during a given MY. CMS attributes a Pre-emptive LDT Beneficiary to no more than one Managing Clinician for a given MY.

(b) *Exclusions from attribution.* CMS does not attribute an ESRD Beneficiary or Pre-emptive LDT Beneficiary to an ETC Participant for a month if, at any point during the month, the beneficiary --

(1) Is not enrolled in Medicare Part B;

(2) Is enrolled in Medicare Advantage, a cost plan, or other Medicare managed care plan;

(3) Does not reside in the United States;

(4) Is younger than 18 years of age before the first day of the month of the claim service date;

(5) Has elected hospice;

(6) Is receiving dialysis only for any acute kidney injury (AKI);

(7) Has a diagnosis of dementia at any point during the month of the claim service date or the preceding 12 months, as identified using the most recent dementia-related criteria at the time of beneficiary attribution, using the CMS-HCC (Hierarchical Condition Category) Risk Adjustment Model ICD-10-CM Mappings; or

(8) Is residing in or receiving dialysis in a skilled nursing facility (SNF) or nursing facility.

(c) *Attribution services*. (1) *ESRD facility beneficiary attribution*. To be attributed to an ESRD facility that is an ETC Participant for a month, an ESRD Beneficiary must not be excluded based on the criteria specified in paragraph (b) of this section and must have received

renal dialysis services during the month from the ESRD facility. CMS does not attribute Pre-emptive LDT Beneficiaries to ESRD facilities.

(i) An ESRD Beneficiary is attributed to the ESRD facility at which the ESRD Beneficiary received the plurality of his or her dialysis treatments in that month, other than renal dialysis services for AKI, as identified by claims with Type of Bill 072X, with claim service dates at the claim header through date during the month.

(ii) If the ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month, CMS attributes the ESRD Beneficiary to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month. If the ESRD Beneficiary receives an equal number of dialysis treatments from two or more ESRD facilities in a given month and the ESRD beneficiary received the earliest dialysis treatment that month from more than one ESRD facility, CMS attributes the beneficiary to one of the ESRD facilities that furnished the earliest dialysis treatment that month at random.

(2) *Managing Clinician beneficiary attribution*. (i) An ESRD beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to a Managing Clinician who is an ETC Participant for a month if that Managing Clinician submitted an MCP claim for services furnished to the beneficiary, identified with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, with claim service dates at the claim line through date during the month.

(A) If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with a claim service date at the claim line during the month, the ESRD Beneficiary is attributed to the Managing Clinician associated with the earliest claim service date at the claim line through date during the month.

(B) If more than one Managing Clinician submits a claim for the MCP furnished to a single ESRD Beneficiary with the same earliest claim service date at the claim line through date for the month, the ESRD Beneficiary is randomly attributed to one of these Managing Clinicians.

(ii) A Pre-emptive LDT Beneficiary who is not excluded based on the criteria in paragraph (b) of this section is attributed to the Managing Clinician with whom the beneficiary has had the most claims between the start of the MY and the month in which the beneficiary received the transplant for all months between the start of the MY and the month of the transplant.

(A) If no Managing Clinician has had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of claims for that beneficiary during the MY, the Pre-emptive LDT Beneficiary is attributed to the Managing Clinician associated with the latest claim service date at the claim line through date during the MY up to and including the month of the transplant.

(B) If no Managing Clinician had the plurality of claims for a given Pre-emptive LDT Beneficiary such that multiple Managing Clinicians each had the same number of services for that beneficiary during the MY, and more than one of those Managing Clinicians had the latest claim service date at the claim line through date during the MY up to and including the month of the transplant, the Pre-emptive LDT Beneficiary is randomly attributed to one of these Managing Clinicians.

**§ 512.365 Performance assessment**.

(a) *General*. For each MY, CMS separately assesses the home dialysis rate and the transplant rate for each ETC Participant based on the population of ESRD Beneficiaries and, if applicable, Pre-emptive LDT Beneficiaries attributed to the ETC Participant under § 512.360.

Information used to calculate the home dialysis rate and the transplant rate includes Medicare claims data, Medicare administrative data, and data from the Scientific Registry of Transplant Recipients.

(b) *Home dialysis rate.* CMS calculates the home dialysis rate for ESRD facilities and Managing Clinicians as follows.

(1) *Home dialysis rate for ESRD facilities*. (i) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is composed of 12 beneficiary months. Months during which attributed ESRD Beneficiaries received maintenance dialysis are identified by claims with Type of Bill 072X.

(ii) The numerator is the total number of home dialysis treatment beneficiary years plus one half the total number of self dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with Type of Bill 072X and condition codes 74 or 76.

(B) Self dialysis treatment beneficiary years included in the numerator are composed of those months during which attributed ESRD Beneficiaries received self dialysis in center, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed

ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(iii) Information used to calculate the ESRD facility home dialysis rate includes Medicare claims data and Medicare administrative data.

(iv) The ESRD facility home dialysis rate is aggregated, as described in paragraph (e)(1) of this section.

(2) *Home dialysis rate for Managing Clinicians*. (i) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966.

(ii) The numerator is the total number of home dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY plus one half the total number of self dialysis treatment beneficiary years.

(A) Home dialysis treatment beneficiary years included in the numerator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home, such that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received maintenance dialysis at home are identified by claims with CPT codes 90965 or 90966.

(B) Self-dialysis treatment beneficiary years included in the numerator are composed of those months during which an attributed ESRD Beneficiary received self dialysis in center, such

that one beneficiary year is comprised of 12 beneficiary months. Months in which an attributed ESRD Beneficiary received self dialysis are identified by claims with Type of Bill 072X and condition code 72.

(iii) Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data.

(iv) The Managing Clinician home dialysis rate is aggregated, as described in paragraph (e)(2) of this section.

(c) *Transplant rate*. CMS calculates the transplant rate for ETC Participants as follows.

(1) *Transplant rate for ESRD facilities*. The transplant rate for ESRD facilities is the sum of the transplant waitlist rate for ESRD facilities, as described in paragraph (c)(1)(i) of this section, and the living donor transplant rate for ESRD facilities, as described in paragraph (c)(1)(ii) of this section.

(i) *Transplant waitlist rate for ESRD facilities.* (A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(B) The numerator is the total number of attributed beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist. Months during which an attributed

ESRD Beneficiary was on the kidney transplant waitlist are identified using data from the SRTR database.

(ii) *Living donor transplant rate for ESRD facilities.* (A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with Type of Bill 072X, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(B) The numerator is the total number of attributed beneficiary years for LDT Beneficiaries during the MY. Beneficiary years for LDT Beneficiaries included in the numerator are composed of those months between the beginning of the MY up to and including the month of the transplant for LDT Beneficiaries attributed to an ESRD facility during the month of the transplant. LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(iii) The ESRD facility transplant waitlist rate is risk adjusted, as described in paragraph (d) of this section. The ESRD facility transplant rate is aggregated, as described in paragraph (e)(1) of this section.

(2) *Transplant rate for Managing Clinicians*. The transplant rate for Managing Clinicians is the sum of the transplant waitlist rate for Managing Clinicians, as described in paragraph (c)(2)(i) of this section, and the living donor transplant rate for Managing Clinicians, as described in paragraph (c)(2)(ii) of this section.

(i) *Transplant waitlist rate for Managing Clinicians*. (A) The denominator is the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(B) The numerator is the total number of attributed beneficiary years for which attributed ESRD Beneficiaries were on the kidney transplant waitlist. Months during which an attributed ESRD Beneficiary was on the kidney transplant waitlist are identified using data from the SRTR database.

(ii) *Living donor transplant rate for Managing Clinicians.* (A) The denominator is the sum of the total dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY and the total Pre-emptive LDT beneficiary years for attributed beneficiaries during the MY.

(*1*) Dialysis treatment beneficiary years included in the denominator are composed of those months during which an attributed ESRD Beneficiary received maintenance dialysis at home or in an ESRD facility, such that one beneficiary year is comprised of 12 beneficiary months. Months during which an attributed ESRD Beneficiary received maintenance dialysis are identified by claims with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965, or 90966, excluding claims for beneficiaries who were 75 years of age or older at any point during the month.

(*2*) Pre-emptive LDT beneficiary years included in the denominator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the living donor transplant. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(B) The numerator is the sum of the total number of attributed beneficiary years for LDT Beneficiaries during the MY and the total number of attributed beneficiary years for Pre-emptive LDT Beneficiaries during the MY.

(*1*) Beneficiary years for LDT Beneficiaries included in the numerator are composed of those months during which an LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(*2*) Beneficiary years for Pre-emptive LDT Beneficiaries included in the numerator are composed of those months during which a Pre-emptive LDT Beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. Pre-emptive LDT Beneficiaries are identified using information about living donor transplants from the SRTR Database and Medicare claims data.

(iii) The Managing Clinician transplant waitlist rate is risk adjusted, as described in paragraph (d) of this section. The Managing Clinician transplant rate is aggregated, as described in paragraph (e)(2) of this section.

(d) *Risk adjustment.* (1) CMS risk adjusts the transplant waitlist rate based on beneficiary age with separate risk coefficients for the following age categories of beneficiaries, with age computed on the last day of each month of the MY:

(i) 18 to 55.

(ii) 56 to 70.

(iii) 71 to 74.

(2) CMS risk adjusts the transplant waitlist rate to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution.

(e) *Aggregation.* (1) *Aggregation for ESRD facilities*. An ESRD facility's home dialysis rate and transplant rate are aggregated to the ESRD facility's aggregation group. The aggregation group for a Subsidiary ESRD facility includes all ESRD facilities owned in whole or in part by the same legal entity located in the HRR in which the ESRD facility is located. An ESRD facility that is not a Subsidiary ESRD facility is not included in an aggregation group.

(2) *Aggregation for Managing Clinicians*. A Managing Clinician's home dialysis rate and transplant rate are aggregated to the Managing Clinician's aggregation group. The aggregation group for a Managing Clinician who is--

(i) In a group practice is the practice group level, as identified by practice TIN; or

(ii) A solo practitioner is the individual clinician level, as identified by NPI.

**§ 512.370 Benchmarking and scoring.**

(a) *General*. (1) CMS assesses the home dialysis rate and transplant rate for each ETC Participant against the applicable benchmarks to calculate an --

(i) Achievement score, as described in paragraph (b) of this section; and

(ii) Improvement score, as described in paragraph (c) of this section.

(2)(i) CMS calculates the ETC Participant's MPS as the weighted sum of the higher of the achievement score or the improvement score for the ETC Participant's home dialysis rate and transplant rate, as described in paragraph (d) of this section.

(ii) The ETC Participant's MPS determines the ETC Participant's PPA, as described in § 512.380.

(b) *Achievement scoring.* CMS assesses ETC Participant performance at the aggregation group level on the home dialysis rate and transplant rate against benchmarks constructed based on the home dialysis rate and transplant rate among aggregation groups of ESRD facilities and Managing Clinicians located in Comparison Geographic Areas during the Benchmark Year. CMS uses the following scoring methodology to assess an ETC Participant's achievement score.

(1) *$90^{th}$+ Percentile of benchmark rates for comparison geographic areas during the benchmark year*: 2 points

(2) *$75^{th}$+ Percentile of benchmark rates for comparison geographic areas during the benchmark year*: 1.5 points

(3) *$50^{th}$+ Percentile of benchmark rates for comparison geographic areas during the benchmark year*: 1 point

(4) *$30^{th}$+ Percentile of benchmark rates for comparison geographic areas during the benchmark year*: 0.5 points

(5) *<30th Percentile of benchmark rates for comparison geographic areas during the benchmark year*: 0 points

(c) *Improvement scoring*. CMS assesses ETC Participant improvement on the home dialysis rate and transplant rate against benchmarks constructed based on the ETC Participant's aggregation group's historical performance on the home dialysis rate and transplant rate during the Benchmark Year. CMS uses the following scoring methodology to assess an ETC Participant's improvement score.

(1) *Greater than 10 percent improvement relative to the Benchmark Year rate*: 1.5 points

(2) *Greater than 5 percent improvement relative to the Benchmark Year rate*: 1 point

(3) *Greater than 0 percent improvement relative to the Benchmark Year rate:* 0.5 points

(4) *Less than or equal to the Benchmark Year rate*: 0 points

(d) *Modality Performance Score.* CMS calculates the ETC Participant's MPS as the higher of ETC Participant's achievement score or improvement score for the home dialysis rate, together with the higher of the ETC Participant's achievement score or improvement score for the transplant rate, weighted such that the ETC Participant's score for the home dialysis rate constitutes 2/3 of the MPS and the ETC Participant's score for the transplant rate constitutes 1/3 of the MPS. CMS uses the following formula to calculate the ETC Participant's MPS:

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

**§ 512.375 Payments subject to adjustment.**

(a) *Facility PPA.* CMS adjusts the Adjusted ESRD PPS per Treatment Base Rate by the Facility PPA on claim lines with Type of Bill 072X, when the claim is submitted by an ETC Participant that is an ESRD facility and the beneficiary is at least 18 years old before the first day

of the month, on claims with claim service dates during the applicable PPA Period as described in § 512.355(c).

(b) *Clinician PPA.* CMS adjusts the amount otherwise paid under Medicare Part B with respect to MCP claims on claim lines with CPT codes 90957, 90958, 90959, 90960, 90961, 90962, 90965 and 90966 by the Clinician PPA when the claim is submitted by an ETC Participant who is a Managing Clinician and the beneficiary is at least 18 years old before the first day of the month, on claims with claim service dates during the applicable PPA Period as described in § 512.355(c).

**§ 512.380 PPA Amounts and schedules.**

CMS adjusts the payments described in § 512.375 based on the ETC Participant's MPS calculated as described in § 512.370(d) according to the following amounts and schedules in Table 1 and Table 2 to § 512.380.

**Table 1 to § 512.380 – Facility PPA Amounts and Schedule**

| | MPS | Performance Payment Adjustment Period | | | | |
|---|---|---|---|---|---|---|
| | | 1 and 2 | 3 and 4 | 5 and 6 | 7 and 8 | 9 and 10 |
| Facility Performance Payment Adjustment | ≤ 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% |

**Table 2 to § 512.380 – Clinician PPA Amounts and Schedule**

| | MPS | Performance Payment Adjustment Period | | | | |
|---|---|---|---|---|---|---|
| | | 1 and 2 | 3 and 4 | 5 and 6 | 7 and 8 | 9 and 10 |
| Clinician Performance Payment Adjustment | ≤ 6 | +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% |
| | ≤ .5 | -5.0% | -6.0% | -7.0% | -8.0% | -9.0% |

**§ 512.385 PPA exclusions.**

(a) *ESRD facilities*. CMS excludes an aggregation group (as described in § 512.365(e)(1) of Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Facility PPA for the corresponding PPA Period. CMS excludes ESRD facilities that are not Subsidiary ESRD facilities with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Facility PPA for the corresponding PPA Period.

(b) *Managing Clinicians*. CMS excludes an aggregation group (as described in § 512.365(e)(2)) of Managing Clinicians with fewer than 11 attributed ESRD beneficiary years during an MY from the applicability of the Clinician PPA for the corresponding PPA Period.

**§ 512.390 Notification and targeted review.**

(a) *Notification.* CMS will notify each ETC Participant, in a form and manner determined by CMS, of the ETC Participant's attributed beneficiaries, MPS, and PPA for a PPA Period no later than one month before the start of the applicable PPA Period.

(b) *Targeted review process.* An ETC Participant may request a targeted review of the calculation of the MPS. Requests for targeted review are limited to the calculation of the MPS, and may not be submitted in regards to: the methodology used to determine the MPS; or the establishment of the home dialysis rate methodology, transplant rate methodology, achievement and improvement benchmarks and benchmarking methodology, or PPA amounts. The process for targeted reviews is as follows:

(1) An ETC Participant has 90 days (or a later date specified by CMS) to submit a request for a targeted review, which begins on the day CMS makes available the MPS.

(2) CMS will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted.

(3) The ETC Participant may include additional information in support of the request for targeted review at the time the request is submitted. If CMS requests additional information from the ETC Participant, it must be provided and received within 30 days of the request. Non-responsiveness to the request for additional information may result in the closure of the targeted review request.

(4) If, upon completion of a targeted review, CMS finds that there was an error in the calculation of the ETC Participant's MPS such that an incorrect PPA has been applied during the PPA period, CMS shall notify the ETC Participant and must resolve any resulting discrepancy in

payment that arises from the application of an incorrect PPA in a time and manner determined by CMS.

(5) Decisions based on targeted review are final, and there is no further review or appeal.

**Quality Monitoring**

**§ 512.395 Quality measures.**

CMS collects data on these two quality measures for ESRD facilities that are ETC Participants to monitor for changes in quality outcomes. CMS conducts data collection and measure calculation using claims data and other Medicare administrative data, including enrollment data:

(a) Standardized Mortality Ratio (SMR); NQF #0369

(b) Standardized Hospitalization Ratio (SHR); NQF #1463

**Medicare Program Waivers**

**§ 512.397 ETC Model Medicare program waivers**.

The following provisions are waived solely for purposes of testing the ETC Model.

(a)(1) *Medicare payment waivers*. CMS waives the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act only to the extent necessary to make the payment adjustments under the ETC Model described in this subpart.

(2) *Beneficiary cost sharing.* The payment adjustments under the ETC Model described in this subpart do not affect the beneficiary cost-sharing amounts for Part B services furnished by ETC Participants under the ETC Model.

(b) CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(a) and (c)(2)(i) of this chapter that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing Clinician who is an ETC Participant. The KDE benefit must be furnished and billed by a Physician, clinical nurse specialist, licensed social worker, nurse practitioner, physician assistant, registered dietician/nutrition professional, or a clinic/group practice.

(2) CMS waives the requirement that the KDE is covered only for Stage IV chronic kidney disease (CKD) patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of starting dialysis to receive the KDE benefit.

(3) CMS waives the requirement that the content of the KDE sessions include the management of co-morbidities, including delaying the need for dialysis, under § 410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or ESRD, unless such content is relevant for the beneficiary.

(4) CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about chronic kidney disease and its treatment be performed by a qualified clinician as part of one of the KDE sessions under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed within 1 month of the final KDE session by qualified staff.

Dated: September 4, 2020.

**Seema Verma,**

Administrator,

Centers for Medicare & Medicaid Services.

Dated: September 9, 2020.

**Alex M. Azar II,**

Secretary,

Department of Health and Human Services.

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