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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS-5527-P]

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: Proposed rule.

SUMMARY: This proposed rule proposes to implement 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 proposed RO Model would promote quality and financial accountability for providers and suppliers of radiotherapy (RT). The RO Model would 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 proposed ETC Model would 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 would include ESRD facilities and certain clinicians caring for beneficiaries with ESRD – or Managing Clinicians – located in selected geographic areas as participants. CMS would assess the performance of participating Managing Clinicians and ESRD facilities on their rates of home dialysis and kidney and kidney-pancreas transplants during each Measurement Year (MY), and would subsequently adjust certain of their Medicare payments upward or downward during the corresponding performance payment adjustment period based on their home dialysis rate and transplant rate. CMS would also positively adjust certain Medicare payments to participating ESRD facilities and Managing Clinicians for home dialysis and home dialysis-related claims in the initial 3 years of the ETC Model.

We believe that these two proposed models would test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

DATES: Comment period: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time on [insert date **60 days from date of publication in the Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-5527-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5527-P,
P.O. Box 8013,
Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5527-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-8013.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Megan.Hyde@cms.hhs.gov, for questions related to General Provisions.

RadiationTherapy@cms.hhs.gov, for questions related to the Radiation Oncology Model.

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

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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I. Executive Summary

A. Purpose

The purpose of this proposed rule is to propose the implementation and testing of two new mandatory models under the authority of the Innovation Center, as well as to propose certain general provisions that would 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 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 a lower volume of items and services. As a result, care may be fragmented, unnecessary, or duplicative.

The goal for the proposed models is to preserve or enhance the quality of care furnished to beneficiaries while reducing program spending through enhanced financial accountability for model participants. We propose that the performance period of the proposed RO Model would begin in 2020, and end December 31, 2024. We propose to implement the proposed payment

adjustments under the proposed ETC Model over the course of 6 and a half years, beginning January 1, 2020, and ending June 30, 2026.

The proposed models would 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 proposed models because, as discussed in depth in sections III and IV of this proposed rule, we believe that participants in these models would have significant opportunity to redesign care and improve the quality of care furnished to beneficiaries receiving these services.

We believe the proposed models would 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 proposed RO and ETC Models would require the participation of providers and suppliers that might not otherwise participate in these models, and would be tested in multiple geographic areas.

The proposed models would 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. We believe that participation in the proposed models by a large number of providers and suppliers with diverse characteristics would result in a robust data set for evaluating the models' proposed payment approaches and would stimulate the rapid development of new evidence-based knowledge. Testing the proposed models in this manner would 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 seek public comment on the proposals contained in this proposed rule, and also on any alternatives considered.

B. Summary of the Major Proposed Provisions

1. General Provisions

The proposed general provisions would be applicable only to participants in the RO Model and the ETC Model. We have identified the proposed general provisions based on standardized parameters that have been repeatedly memorialized in various documents governing participation in existing model tests and propose to make them applicable to both proposed models so that we may eliminate repetition in the proposed 42 CFR part 512. The proposed general provisions address beneficiary protections, model evaluation and monitoring, audits and record retention, monitoring and compliance, remedial or administrative 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 would apply to each model. Both the RO Model and the ETC Model have unique aspects that would require additional, more tailored provisions, including with respect to

payment and quality measurement. Such model-specific provisions are described elsewhere in this proposed rule.

2. Model Overview – Proposed Radiation Oncology Model

In this proposed rule, we propose the creation and testing of a new payment model for radiation oncology, the RO Model. The intent of the proposed RO Model is to promote quality and financial accountability for episodes of care centered on RT services. The RO Model would test whether prospective episode-based payments to physician group practices (PGPs), HOPDs, and freestanding radiation therapy centers for RT episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the proposed RO Model would benefit Medicare beneficiaries by encouraging more efficient care delivery and incentivizing higher value care across episodes of care. We propose that the RO Model would have a performance period of five calendar years, beginning in 2020, and ending December 31, 2024. We propose to test the RO Model to capture all episodes that finish within the performance period, which means that the data collection, episode payments, and reconciliation would continue into calendar year 2025.

a. Summary of Major Provisions

(1) Proposed RO Model Overview

RT is a common treatment for patients undergoing cancer treatment and is typically furnished by a physician at either a HOPD or a freestanding radiation therapy center. We are proposing the RO Model to include prospective payments for certain RT services furnished during a 90-day episode for included cancer types for certain Medicare beneficiaries. The included cancer types would 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 proposed rule for more information.) This model would not account for total cost of all care provided to the beneficiary during the 90 days of an episode. Rather, the payment would cover only select RT services furnished during an episode. Episode payments would 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 providers and 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 would have at least one PGP to furnish RT services at the HOPD. A PGP would furnish the PC as a professional participant and a HOPD would furnish the TC as a technical participant. Both would be participants in the RO Model, furnishing separate components of the same episode. A 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 proposed RO Model would test the cost-saving potential of prospective episode payments for certain RT services furnished during a 90-day episode and whether shorter courses of RT (that is, fewer doses, also known as fractions) would encourage more efficient care delivery and incentivize higher value care.

(2) Model Scope

We propose criteria for the types of cancer included under the RO Model and list 17 cancer types that meet our proposed 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 Model episodes would include most RT services furnished in HOPDs and freestanding radiation therapy centers during a 90-day episode.

We propose that participation in the RO Model be mandatory for all RT providers and suppliers within selected geographic areas. We propose to use Core Based Statistical Areas (CBSAs) delineated by the Office of Management and Budget¹ as the geographic area for the randomized selection of RO participants. We would 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 propose to exclude certain providers and suppliers from participation under the model as described in section III.C.3.c. of this proposed rule.

We propose to include beneficiaries that meet certain criteria under the RO Model. For example, the proposed criteria would 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 would be included in the RO Model's episodes of care.

(3) Overlap with Other CMS Programs and Models

We expect that there could be situations where a Medicare beneficiary included in an episode under the RO Model is also assigned, aligned, or attributed to another Innovation Center model or CMS program. Overlap could also occur among providers and 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 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 would work to resolve any potential overlaps between the RO Model and other CMS models or

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

programs that could result in repetitive services, or duplicative payment of services, and duplicative counting of savings or other reductions in expenditures.

(4) Episodes and Episode Pricing Methodology

We propose to set a separate payment amount for the PC and the TC of each of the cancer types included in the RO Model. The payment amounts would be determined based on proposed national base rates, trend factors, and adjustments for each participant's case-mix, historical experience, and geographic location. The payment amount would also be adjusted for withhold for incomplete episodes, quality, and starting in performance year (PY) 3 beneficiary experience. The standard beneficiary coinsurance amounts (typically 20 percent of the Medicare-approved amount for services) and sequestration would remain in effect. RO participants would have the ability to earn back a portion of the quality and patient experience withhold 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.

(5) Quality Measures and Reporting Requirements

We propose to adopt four quality measures and collect the CAHPS® Cancer Care Radiation Therapy Survey for the RO Model. Three of the four measures that we are proposing 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 proposed measures based on clinical appropriateness for RT services spanning a 90-day episode period. These measures would be applicable to the full range of proposed included cancer types

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).

and provide us the ability to accurately measure changes or improvements in the quality of RT services. Further, we believe that these measures would 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.

We propose that RO participants would be paid for reporting clinical data in accordance with our proposed reporting requirements as discussed in section III.C.8.e, and paid for performance on aggregated quality measure data on three proposed quality measures and pay-for-reporting on one proposed quality measure (for PY1 and PY2) as discussed in section III.C.8.f. By PY3, we plan to propose to add a set of patient experience measures via rulemaking based on the CAHPS® Cancer Care Survey for Radiation Therapy for inclusion as pay-for-performance measures. We would 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 RT episodes under the RO Model).

(6) Data Sharing Process

We propose to collect quality, clinical, and administrative data for the RO Model. We intend to share certain data with participants to the extent permitted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and other applicable law. We propose to establish data privacy compliance standards for RO participants. We propose to establish requirements around the public release of patient de-identified information by RO participants. We propose to 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 propose to 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 recoupment amounts, as applicable. Thus, we expect that the data offered under the RO Model would 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 would 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 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 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 proposed rule.

(7) Beneficiary Protections

We propose to require 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 session. 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 proposed rule.

(8) Program Policy Waivers

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. We propose to 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 proposed rule, and proposed to be codified in our regulations at § 512.280.

3. Model Overview – Proposed ESRD Treatment Choices (ETC) Model

The proposed ETC Model would 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 proposed ETC Model would include two payment adjustments. The first adjustment, the Home Dialysis Payment Adjustment (HDPA), would be a positive adjustment on certain home dialysis and home dialysis-related claims during the initial three years of the model. The second adjustment, the Performance Payment Adjustment (PPA), would 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 kidney and kidney-pancreas transplants and home dialysis among attributed beneficiaries during the applicable MY. We propose to implement the payment adjustments under the ETC Model beginning January 1, 2020, and ending June 30, 2026.

a. Summary of Major Provisions

(1) Proposed 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 propose the ETC Model to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians – clinicians who 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 propose to adjust payments for home dialysis claims with claim through dates from January 1, 2020, through December 31, 2022 through the HDPA, and to assess the rates of home dialysis and kidney transplant among beneficiaries attributed to ETC Participants during the period beginning January 1, 2020, and ending June 30, 2025, with the PPA based on those rates applying to claims for dialysis and dialysis-related services with claim-through dates beginning January 1, 2021, and ending June 30, 2026.

(2) Model Scope

The proposed ETC Model would 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 would 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. Managing Clinicians and ESRD facilities located in these selected geographic areas would be required to participate in the ETC Model and would be assessed on their rates of kidney and kidney-pancreas transplant and home dialysis among their attributed beneficiaries during each MY; CMS would then adjust certain of their Medicare payments upwards or downwards during the corresponding performance payment adjustment period. Managing Clinicians and ESRD facilities located in the selected geographic areas would also receive a positive adjustment on their home dialysis claims for the first three years of the ETC Model.

(3) Home Dialysis Payment Adjustment (HDPA)

We propose that CMS would make upward adjustments to the certain payments to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and would make upward adjustments to the MCP paid to participating Managing Clinicians on home dialysis claims. The HDPA would apply to claims with claims through dates beginning on January 1, 2020, and ending on December 31, 2022.

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

We propose to assess ETC Participants' rates of home dialysis and kidney and kidney-pancreas transplants during a MY, which would include 12 months of performance data. Each MY would overlap with the previous MY, if any, and the subsequent MY, if any, for a period of

6 months. Each MY would have a corresponding PPA Period—a 6-month period, which would begin 6 months after the conclusion of the MY. CMS would adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant’s home dialysis rate and transplant rate during the corresponding MY. We propose measuring rates of home dialysis and transplants 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 propose to measure home dialysis rates for ESRD facilities and Managing Clinicians in the ETC Model by calculating the percent of dialysis treatment beneficiary years during the MY in which attributed beneficiaries received dialysis at home. We propose to measure transplant rates for ESRD facilities and Managing Clinicians based on the number of attributed beneficiaries who received a kidney or kidney-pancreas transplant during the MY out of all attributed dialysis treatment beneficiary years (and attributed beneficiary years for pre-emptive transplant beneficiaries for Managing Clinicians) during the MY. For both Managing Clinicians and ESRD facilities, we propose to calculate the rates of home dialysis and kidney and kidney-pancreas transplants among attributed ESRD Beneficiaries. For Managing Clinicians, we propose to also include attributed beneficiaries who receive preemptive transplants – transplants that occur before the beneficiary begins dialysis – in the calculation of the transplant rate. We propose that the ETC Model would 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 rates of home dialysis and transplants. The magnitude of the positive and negative PPAs for ETC Participants would increase over the course of the Model. These PPAs would begin July 1, 2021, and end June 30, 2026.

(5) Overlaps with Other Innovation Center Models and CMS Programs

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

(6) Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA, we believe we would need to waive certain Medicare program rules. In particular, we would waive certain requirements of the Act for the ESRD PPS, ESRD QIP, and Medicare Physician Fee Schedule 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. In addition, we propose that the payment adjustments made under the ETC Model, if finalized, 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 also believe it would be necessary to waive certain Medicare payment requirements of 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 would 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 propose to 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 benefit to be tailored to each beneficiary's needs.

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

(7) Monitoring and Quality Measures

Consistent with the monitoring requirements proposed in the general provisions, we propose to closely monitor the implementation and outcomes of the ETC Model throughout its duration. The purpose of this monitoring would 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 propose 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, and so would require no additional reporting by ETC Participants.

(8) Beneficiary Protections

As proposed, the ETC Model would not allow beneficiaries to opt out of the payment methodology; however, the model would not restrict a beneficiary's freedom to choose an ESRD facility or Managing Clinician, or any other provider or supplier, and ETC Participants would be subject to the general provisions protecting beneficiary freedom of choice and access to medically necessary services. We also would 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 would be subject to the general provisions regarding descriptive model materials and activities.

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 have a specific payment methodology, quality metrics, and certain other applicable policies, they also have general provisions that are very similar, including provisions on monitoring and evaluation; compliance with model requirements and applicable laws; and beneficiary protections. We believe it would promote efficiency to propose and seek comment on certain general provisions in each of these areas that would apply to both the RO Model and the ETC Model in this section II of the proposed rule. This would avoid the need to restate the same provisions separately for the two models in this proposed rule. We propose to codify these general provisions in a new subpart of the Code of Federal Regulations (42 CFR part 512, subpart A).

B. Effective Date and Scope

In § 512.100(a), we propose that the proposed general provisions in this section II of the proposed rule would apply only to the RO Model and the ETC Model, each of which we are proposing to refer to as an "Innovation Center model" for purposes of this section II of the proposed rule. These proposed general provisions would not, except as specifically noted in proposed new 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 propose that the proposed general provisions in this section II of the proposed rule would be applicable to model participants in both the RO Model (with one exception, described in this document) and the ETC Model. We are proposing 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 proposed part 512; the term “model participant” as defined in this section II of the proposed rule includes, unless otherwise specified, the terms “RO Model participant” or “ETC Participant” as those terms are defined in proposed subparts B and C of proposed part 512. We propose 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. A downstream participant may include, but would not be limited to, an individual practitioner, as defined for purposes of the RO Model. We propose 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 described in this section II of the proposed rule, as this term is used for purposes of both the RO Model and the ETC Model, we propose 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 invite public comment on the proposed general provisions discussed in this section II of the proposed rule.

C. Definitions

We propose at § 512.110 to define certain terms relevant to the general provisions proposed in this section II. of the proposed rule. We describe these proposed definitions in context throughout this section II. of the proposed 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, 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 are proposing to define the term “beneficiary” to mean an individual who is enrolled in Medicare FFS. This definition aligns with the proposed scope of the RO Model and the ETC Model, in which we propose to include only Medicare FFS beneficiaries. We also are proposing 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 this proposed part; 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. We believe it is 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.

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 proposed Innovation Center models, we are proposing to codify at § 512.120(a)(1) a requirement that model participants and their downstream participants not restrict a beneficiary’s ability to choose his or her providers or suppliers. The proposed policy would apply with respect to all Medicare FFS beneficiaries, not just model beneficiaries, because we believe it is important to ensure that the proposed Innovation Center model tests do not interfere with the general guarantees and protections for all Medicare FFS beneficiaries.

Also, we propose to codify at § 512.120(a)(2) 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. We believe this requirement is necessary to ensure Innovation Center models do not prevent beneficiaries from 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 also are proposing 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 proposed part 512 and applicable law.

We propose at § 512.110 to define the terms “provider” and “supplier,” as used in proposed part 512, in a manner consistent with how these terms are used in Medicare FFS generally. Specifically, we would 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 propose 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. 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 proposed part 512.

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, an important aspect of testing Innovation Center models is that beneficiaries continue to access and receive needed care. Therefore, we are proposing in § 512.120(b)(1) that model participants and downstream participants would be 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 propose 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 propose 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 propose 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. 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, we are proposing in § 512.120(b)(2) 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. 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 this proposal prohibiting lemon dropping is a necessary precaution to counter any incentives created by the proposed 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, we are proposing in § 512.120(b)(3) an additional provision that would 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. Further, we are seeking comments on whether prohibiting cherry-picking will prevent model participants from artificially inflating their financial or quality performance results.

3. Descriptive Model Materials and Activities

In order to protect beneficiaries from potentially being misled about Innovation Center models, we are proposing 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 proposed part 512, we propose 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. We are further proposing 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 proposed 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, 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 in no way restricts 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. Because regulating information or communication not related to the model does not advance CMS's interest in ensuring model beneficiaries are not misled about their inclusion in an Innovation Center model or their Medicare rights generally, we have proposed to define the term "descriptive model materials and activities" such that these materials are not subject to the requirements of proposed § 512.120(c)(1).

Also, we propose in § 512.120(c)(4) 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. 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. Further, to facilitate our ability to conduct this review and to monitor Innovation Center models generally, in proposed § 512.120(c)(3) we are proposing 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, we are proposing in § 512.120(c)(2) 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 are proposing 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 seek comment on whether we should propose a different disclaimer that alerts beneficiaries that we prohibit misleading information and give them contact information where a beneficiary could reach out to us if they suspect the information they have received regarding an Innovation Center model is inaccurate.

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 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, 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 proposed rule, these compliance monitoring activities are an important and necessary part of the model test.

Therefore, we are proposing to codify at § 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 we propose that the Innovation Center model evaluation will consider for the Radiation Oncology Model and ESRD Treatment Choices Model can be found in sections III.C.16. and IV.C.11. of this proposed rule, respectively. Further, we propose to conduct monitoring activities according to proposed § 512.150, described later in this proposed 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.

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, 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 are proposing in § 512.110 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, 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 propose 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." We believe it is necessary to propose this definition 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 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 (such as under 42 CFR 510.110 for the Innovation Center's Comprehensive Care for Joint Replacement Model). Building off those existing requirements, we propose 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, we are proposing in § 512.135(b) and (c) that the model participant and its downstream participants must:

- 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 proposed 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 propose that the records must be maintained for such period of time determined by CMS. We also propose that, 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. This provision will ensure that the government has access to the records.

To avoid any confusion or disputes regarding the timelines outlined in this section II.G of the proposed rule, we propose to define the term “days” to mean calendar days.

We invite 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 solicit public comments on whether we should require model participants and downstream participants to maintain records for longer than 6 years.

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 proposed § 512.150, described later in this rule, we are proposing to allow CMS to use any data obtained in accordance with proposed § 512.130 and proposed § 512.135 to evaluate and monitor the proposed Innovation Center models. We further propose 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 propose 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, we propose in § 512.140(b) 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. We would note that 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 propose to protect such information from disclosure to the full extent permitted under applicable laws, including the Freedom of Information Act. Specifically, in proposed § 512.140(b), we propose to 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.

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, 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. 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 proposed § 512.150(b), we propose to continue this standard practice of conducting compliance monitoring activities 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, including 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 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 in order 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 propose to codify in § 512.150(b)(2), that when we are conducting compliance monitoring and oversight activities, CMS or our 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. 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 propose 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 proposed § 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, we further propose in § 512.150(c)(2) 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 , we propose that, to the extent practicable, 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 participant's and downstream participants' schedules while not interfering with the operation of the Innovation Center model. Further, we propose in § 512.150(c)(3) 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. We believe this proposal is necessary to ensure an effective site visit and prevent the need for unnecessary follow-up site visits.

Also, we are proposing in § 512.150(c)(4) 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 proposed provisions. Further, we propose in § 512.150(c)(5) that nothing in proposed part 512 would limit CMS from performing other site visits as allowed or required by applicable law. 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 propose to require that model participants and each of their downstream participants must comply with all applicable laws and regulations. We note 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, we propose in § 512.150(d) 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. Also, we are considering the imposition of some of the deadlines set forth in the Medicare reopening rules at 42 CFR 405.980, et seq.; specifically we seek 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). 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 propose 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. This provision simply reflects the limits of CMS authority.

We invite public comment on these proposed provisions regarding monitoring of the proposed models and compliance by model participants.

I. Remedial Action

As stated earlier in this proposed rule, as part of the Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A, 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.

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 propose that CMS may 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, if finalized;
- 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 proposed 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 propose 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 proposed § 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 remove, 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.

We would note that because the ETC Model is a mandatory model, we would not expect to use the proposed 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 invite public comment on these proposed provisions regarding the proposed grounds for remedial actions, remedial actions generally, and whether additional types of remedial action would be appropriate.

J. Innovation Center Model Termination by CMS

We are proposing 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.

We propose at § 512.165(a) 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, 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 propose 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.

K. Limitations on Review

In proposed § 512.170, we propose 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 propose 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 propose 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 invite public comment on the proposed codification of these statutory preclusions of administrative and judicial review for models, as well as our proposed interpretations regarding their scope.

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. 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 proposed Innovation Center models and Medicare funds, we are proposing 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 proposed § 512.180(a), we propose 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 propose 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 propose that 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 propose 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. 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.

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. We believe our proposal is necessary to protect the financial integrity of the proposed 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 are considering (and solicit 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 proposed § 512.180(b), we propose 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. The purpose of this proposed 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 solicit 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 are considering requiring notice to be furnished promptly (for example, within 30 days) after a change in legal name has become effective. We invite public comment on this alternative approach.

Third, in proposed § 512.180(c), we propose 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 propose that the written notification must be furnished in a form and manner specified by CMS. For purposes of this notice obligation, we propose 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. 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 believe this proposed 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 propose that if CMS determined in accordance with proposed § 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 proposed § 512.160(b). In addition, to ensure payment of amounts owed to CMS, we propose 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 invite public comment on these proposed notification requirements. Also, we solicit 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.

III. Proposed Radiation Oncology Model

A. Introduction

We are proposing a mandatory Radiation Oncology Model (RO Model), referred to in this section III. of the proposed rule as “the Model,” that would test whether prospective episode-based payments for radiotherapy (RT) services,⁴ (also referred to as radiation therapy services) would 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, we believe that radiation oncology is well-suited for testing a prospective episode payment model. Under this proposed RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. 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. The performance period for the proposed RO Model would be five 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.

We are including the following proposals for the Model in this proposed rule: (1) the scope of the Model, including required participants and episodes under the Model test; (2) the pricing methodology under the Model and necessary Medicare program policy waivers to

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.

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.

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). We believe that a model in radiation oncology would 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. 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's 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 included various types of modalities.⁷ Such

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

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

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

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), intraoperative radiotherapy (IORT), image-guided radiation therapy (IGRT), and brachytherapy. 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 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. We intend 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. 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 a HOPD. We are not aware of any clinical rationale that explains for these differences, which persisted after controlling for diagnosis, patient case mix (to the extent possible using data available in claims), geography, and other factors. These differences also persist even though Medicare payments are lower per unit in freestanding radiation therapy centers than in HOPDs. Upon further analysis, 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 services are paid under the PFS. 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. 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 propose 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 does not have the authority to adjust payments outside of established payment methodologies under the Section 1848 governing the PFS;
- The Practice Expense (PE) component of the PFS is determined based on inputs (labor, equipment, and supplies) and input price estimates from entities paid under the PFS only, which means the PE calculation cannot consider HOPD cost data that the RO Model proposes to use as the basis for national base rates;
 - 1) ● 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

- 2) • Both the PFS and OPPS make the same payment for a service, irrespective of the diagnosis, whereas the RO Model establishes different payments by cancer type.
- 3) • Neither payment system would allow flexibility in testing new and comparable approaches to value-based payment outside of statutory quality reporting programs.

We believe a site-neutral payment policy would 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 believe 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

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

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>.

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 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 this review of claims data, we believe 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 can bill for RT services and an array of necessary planning services to make the treatment successful.¹⁸ 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.

¹²Sze, 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>.

¹³Chow, 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>.

¹⁴Chow, 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](http://www.thegreenjournal.com/article/S0167-8140(16)34483-8/abstract).

¹⁵Lutz, 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](http://www.practicalradonc.org/article/S1879-8500(16)30122-9/pdf).

¹⁶D. 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>.

¹⁷W.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>.

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

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

4. CMS Coding and Payment Challenges

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, we have 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 finalize the code as misvalued and then review the Work and PE RVU

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>.

²¹ CY 2014 PFS final rule with comment period, 78 FR 43296, 43286-43289, 43302-43311.

inputs for the code. As a result of the review, the inputs can be adjusted either upward or downward. The criteria for identifying potentially misvalued codes are set forth in section 1848(c)(2)(K)(ii) of the Act.

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 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 coding 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. Public information 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

revaluating 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 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 are discussed in detail in this rule).

Despite the aforementioned challenges related to information used to establish payment rates for RT services, 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.

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. We continue to use some CMS-specific coding, or HCPCS codes, in billing and payment for RT services under the PFS while OPPS is largely based on CPT® codes. 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

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; CY 2016 PFS correcting amendment, 81 FR 12024.

RT providers and RT suppliers, particularly when they furnish services in both freestanding radiation therapy centers and HOPDs.

Finally, 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 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, due to the differing rate-setting methodologies, PFS rates are developed in relation to other PFS office-based services, not to 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

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.

51009 of the BBA of 2018 extended these payment policies through 2019. In November 2017, 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 preparing the Report to Congress, the Innovation Center conducted an environmental scan of current evidence, as well as 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. We believe 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 this proposed rule, we propose what the Innovation Center has determined to be the best design for testing an episodic APM for RT services.

C. RO Model Proposed Regulations

In this proposed rule, we propose our policies for the RO Model, including model-specific definitions and the general framework for implementing the RO Model. We propose to define “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 propose to codify the term “performance year” at § 512.205 of our regulations.

In this proposed rule, we are including our proposed policies for each of the following:

- (1) the scope of the RO Model, including the Model participants, beneficiary population, and RT

²⁴ <https://innovation.cms.gov/resources/radiationapm-pubforum.html>

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.

We propose to codify RO Model policies at 42 CFR part 512, subpart B (proposed §§ 512.200 through 512.290). In addition, as we explain in section II of this proposed rule, if finalized, the general provisions proposed to be codified at §§ 512.100 through 512.180 would apply to the proposed RO Model.

1. Proposed Model Performance Period

We propose to test the RO Model for 5 PYs. We propose 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. Alternatively, we are considering delaying implementation to April 1, 2020 to give RO participants and CMS additional time to prepare. An April 2020 start date would only affect the length of PY1 which would be nine months. All other PYs would be 12 months. For all episodes to be completed by December 31, 2024, no new episodes may begin after October 3, 2024. We invite public comments on the proposed model performance period and potential participants’ ability to be ready to implement the RO Model by January 1, 2020. We also seek comments on delaying the start of the model performance period to April 1, 2020.

2. Proposed Definitions

We propose at § 512.205 to define certain terms for the RO Model. We describe these proposed definitions in context throughout this section III of this proposed rule. We invite public comments on these proposed definitions.

3. Proposed Participants

We propose that certain Medicare participating HOPDs, physician group practices (PGPs), and freestanding radiation therapy centers that furnish RT services (RT providers or RT suppliers) in randomly selected Core-Based Statistical Areas (CBSAs), would be required to participate in the RO Model either as “Professional participants,” “Technical participants,” or “Dual participants” (as such terms are defined in section III.C.3.b of this proposed rule). We propose to define “RO participant” at § 512.205 as a PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model pursuant to the criteria that we propose to establish at § 512.210. (See III.C.3.b Proposed RO Model Participants.) In addition, we note that the proposed definition of “model participant,” as defined in section III.C.3.b of this rule, would include a RO participant. In this section, we explain 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. Proposed Required Participation

We propose that certain RT providers and RT suppliers that furnish RT services within randomly selected CBSAs would be required to participate in the RO Model (see III.C.3.b. of this proposed rule (Proposed RO Model Participants) and III.C.3.d. of this proposed rule (Geographic Unit of Section)). 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. As such, we are interested in testing and evaluating the impact of a prospective payment approach for RT services in a variety of circumstances. 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.

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. 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 proposing a broad, representative sample of RT providers and RT suppliers in multiple geographic areas (see Section III.C.3.d. of this proposed rule for a discussion regarding the Geographic Unit of Selection). We determined that 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 would 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, 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. Further, 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. 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 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 propose that participation in the RO Model would be mandatory for all RT providers and RT suppliers furnishing RT services within the randomly selected CBSAs.

We invite public comments on our proposal for mandatory participation.

b. Proposed RO Model Participants

A RO participant, a term that we propose to define 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. A RO participant would participate in the Model as a Professional participant, Technical participant, or Dual participant.

We propose to define the term “Professional participant” as a 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 a HOPD. Professional participants would be required annually to attest to the accuracy of an individual practitioner list, as described in section III.C.9, provided by CMS, of all of the eligible clinicians who furnish care under the Professional participant’s TIN. We propose 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 a RO participant. We

further propose that an individual practitioner under the RO Model would be considered a downstream participant, as defined in section II.B. of this proposed rule.

We propose to define the term “Technical participant” to mean a 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 propose to define “Dual participant” to mean a RO participant that furnishes for 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 propose to codify the terms “Professional participant,” “Technical participant,” “Dual participant” and “individual practitioner” at § 512.205.

As previously explained, a RO participant would furnish at least one component of an episode, which we are proposing to have two components: a professional component and a technical component. We propose to define the term “professional component (PC)” to mean the included RT services that may only be furnished by a physician. We propose 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 this proposed rule for a discussion regarding our proposed included RT services.) We propose to codify the terms “professional component (PC)” and “technical component (TC)” at § 512.205.

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 a 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.

c. Proposed RO Model Participant Exclusions

We propose 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.

These exclusion criteria would apply during the entire model performance period. If a RO participant undergoes changes such that one or more of the proposed 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 a RO participant subject to inclusion criteria). For example, if a RO participant moves its only service location²⁵ from a randomly selected CBSA 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

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

subsequently experiences a change such that the proposed exclusion criteria no longer apply and the PGP, freestanding radiation therapy center, or HOPD is located in one of the randomly selected CBSAs, then participation in the RO Model would be required. For example, if an HOPD is no longer classified as a PPS-exempt hospital and the HOPD is located in one of the randomly selected CBSAs, then the HOPD would become an RO participant from the date that the HOPD became no longer classified as a PPS-exempt hospital.

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

We propose 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. This global budget includes RT services and as such would overlap with the RO Model payment; thus, we propose to exclude Maryland HOPDs to avoid double payment for the same services. We propose 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.

We propose 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 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 propose to exclude HOPDs that are participating in or eligible to participate in the Pennsylvania Rural Health Model. HOPDs that are participating in the model receive a global budget similar to the Maryland Total Cost of Care Model. Further, we propose to extend the exclusion to HOPDs that are eligible to participate in the Pennsylvania Rural Health Model because they may be added to that model in the future or may be included in the evaluation comparison group for that model. We would identify the CAHs and acute care hospitals that are participating 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/>.

The proposed 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. We believe it would be inappropriate to include these entities for the reasons previously described. Also, we are proposing to exclude ASCs and RT providers and RT suppliers located in the U.S. Territories, as proposed at § 512.210, due to the low volume of RT services that they provide. In addition, we are proposing to exclude CAHs and PPS-exempt cancer hospitals due to the differences in how they are paid by Medicare.

As a result, we propose that RT services furnished by these RT providers and RT suppliers would be excluded from participation in the RO Model. If in the future we determine

that providers and suppliers in these categories should be included in the RO Model, we would propose to revise our inclusion criteria through rulemaking.

We further propose to codify these policies at § 512.210 of our regulations.

We invite public comments on these proposals.

d. Proposed Geographic Unit of Selection

We propose 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 would 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 would permit us to identify RO Model participants (see section III.C.3.c. of this proposed rule RO Model Participant Exclusions for the RT providers and RT suppliers we are proposing to exclude from the RO Model) while still using CBSA as a geographic unit of selection. We further propose to codify the term "Core Based Statistical Area (CBSA)" at § 512.205 of our regulations.

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.

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>

CBSAs do not include the extreme rural regions, but there are very 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 as such, we do not propose to include non-CBSA geographies in the RO Model test.

However, 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 selected CBSA, we are proposing to use an RT provider's or RT supplier's service location five-digit ZIP Code found on the RT provider's or RT supplier's claim submissions to CMS to link them to CBSAs selected under the Model.

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 percent) of five-digit ZIP Codes have portions of their addresses located in more than one CBSA. If each ZIP Code was assigned only to the CBSA with the largest portion of delivery locations in it, about 5 percent of all delivery locations in ZIP Codes would be assigned to a different CBSA. Rather than increase provider burden by requiring submission of more detailed geographic data by RT providers and RT suppliers, we propose 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, the greater portion of business addresses would take precedence to link the five-digit ZIP Code to the CBSA.

CMS would use a five-digit ZIP Code to CBSA crosswalk found in the Housing and Urban Development (HUD) ZIP to CBSA Crosswalk file²⁷ 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 believe that linking a five-digit ZIP Code to a single CBSA would not substantially impact statistical estimates for the RO Model. In addition, we believe 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. If finalized as proposed, CMS would provide a look-up tool that includes all five-digit ZIP Codes linked to CBSAs selected in accordance with our proposed selection policy described in this proposed rule. This tool would be located on the RO Model website.

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 the Model. 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

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

example, stakeholders questioned whether a model changed the overall volume of services related to the specific model in a given area. We would 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 under the Model, we propose 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 would then randomize the CBSAs within each stratum into participant and comparison groups until the targeted number of RO episodes within each group of CBSAs needed for a robust²⁸ test of the Model is reached. 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 would produce mistakes, that is show ‘no effect’ when an effect is actually present (like an instance 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 (like an instance when a smoke detector is sounding an alarm that suggests smoke is detected when actually no smoke is present). Given that we plan to sample 40 percent of all eligible RO episodes in eligible CBSAs nationwide (as defined in section III.C.5 of this proposed rule), we believe we should be sufficiently powered (that is, the sample size and the expected size of the effect of 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. Strata will be divided into five quintiles based on the total number of episodes

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.

within a given CBSA. The stratification would limit uneven RT provider and RT supplier and episode numbers within the participant and comparison groups of CBSAs that can result from a simple random sample. If a CBSA is randomly assigned to the participant group, then the RT providers and RT suppliers who furnish RT services in that CBSA would be RO participants. If the CBSA is randomly assigned to the comparison group, then the providers and suppliers who furnish RT services in that CBSA 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.

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 determined that 40 percent of eligible episodes (as defined in section III.C.5 of this proposed 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, and 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.

Using randomly selected stratified CBSAs would ensure that the participant and comparison groups of CBSAs would each contain approximately 40 percent of all eligible episodes nationally. The comparison group of CBSAs would be used to evaluate the impact of the RO Model on spending, quality, and utilization. The CBSAs would be randomly selected

and those CBSAs and the ZIP Codes selected for participation would be published on the RO Model website once the final rule is displayed.

4. Proposed Beneficiary Population

We propose that a Medicare FFS beneficiary be included in the RO Model if the beneficiary:

- Receives included RT services in a five-digit ZIP Code linked to a selected CBSA from a RO participant during the model performance period for a cancer type that meets the criteria for inclusion in the RO Model; and
- At the time that the initial treatment planning service of the episode is furnished by a RO participant, the beneficiary:

- ++ 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 propose to exclude from the RO Model any beneficiary who, at the time that the initial treatment planning service of the episode is furnished by a RO participant:

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

Because the RO Model would evaluate RT services furnished to beneficiaries who have been diagnosed with one of the cancer types identified as satisfying our proposed criteria for inclusion in the Model, as discussed in section III.C.5.a, we believe 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. Further, 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 of RT services as described in section III.C.6.c. We propose 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 believe that these eligibility criteria for RO beneficiaries are necessary in order to properly evaluate this change with minimal intervening effects.

We propose that a beneficiary who meets all of these criteria, and who does not trigger any of the beneficiary exclusion criteria, would be called a “RO beneficiary”. We propose to codify the terms “RO beneficiary,” “RT provider,” and “RT supplier” at § 512.205.

In addition, we propose to include in the RO Model any beneficiary participating in a clinical trial for RT services for which Medicare pays routine costs, provided that such beneficiary meets all of the proposed beneficiary inclusion criteria. 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.²⁹ 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.

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

²⁹ The current Medicare policy on routine cost in clinical trials is described in Routine Costs in Clinical Trials 100-3 section 310.1.

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

If a RO beneficiary stops meeting any of the proposed eligibility criteria or triggers any of the exclusion criteria (see section III.C.4. of this proposed rule) before the TC of an episode initiates, then the episode would be an incomplete episode as described in section III.C.6.a. of this proposed 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 proposed rule.

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 this proposed rule).

We are proposing these beneficiary eligibility criteria for purposes of determining beneficiary inclusion in and exclusion from the Model.

5. Proposed RO Model Episodes

In this proposed RO Model, Medicare would pay RO participants a site-neutral, episode-based payment amount for all specified RT services furnished to a RO beneficiary during a 90-day episode. In this section, we first explain 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 explain our proposal for testing a 90-day episode and propose the conditions that must be met to trigger an episode.

a. Proposed Included Cancer Types

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

We propose 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 ($\geq 10\%$) error in established national baseline rates; or
 - The Secretary determines a cancer type not to be suitable for inclusion in the Model.

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

We identified 17 cancer types in Table 1 that meet our proposed criteria. 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, 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.

Using the list of cancer types and relevant diagnosis codes, we analyzed 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.

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 intracavitory 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.

We are proposing that the RO Model's included cancer types would include those that are commonly treated with RT and that can be accurately priced for prospective episode payments. An up-to-date list of cancer types would be kept on the RO Model website.

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

TABLE 1: IDENTIFIED CANCER TYPES AND CORRESPONDING ICD-9 AND ICD-10 CODES

Cancer Type	ICD-9 Codes	ICD-10 Codes
Anal Cancer	154.2x, 154.3x	C21.xx
Bladder Cancer	188.xx	C67.xx
Bone Metastases	198.5x	C79.5x
Brain Metastases	198.3x	C79.3x
Breast Cancer	174.xx, 175.xx, 233.0x	C50.xx, D05.xx
Cervical Cancer	180.xx	C53.xx
CNS Tumors	191.xx, 192.0x, 192.1x, 192.2x, 192.3x, 192.8x, 192.9x	C70.xx, C71.xx, C72.xx
Colorectal Cancer	153.xx, 154.0x, 154.1x, 154.8x	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	140.xx, 141.0x, 141.1x, 141.2x, 141.3x, 141.4x, 141.5x, 141.6x, 141.8x, 141.9x, 142.0x, 142.1x, 142.2x, 142.8x, 142.9x, 143.xx, 144.xx, 145.0x, 145.1x, 145.2x, 145.3x, 145.4x, 145.5x, 145.6x, 145.8x, 145.9x, 146.0x, 146.1x, 146.2x, 146.3x, 146.4x, 146.5x, 146.6x, 146.7x, 146.8x, 146.9x, 147.xx, 148.0x, 148.1x, 148.2x, 148.3x, 148.8x, 148.9x, 149.xx, 160.0x, 160.1x, 160.2x, 160.3x, 160.4x, 160.5x, 160.8x, 160.9x, 161.xx, 195.0x	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Kidney Cancer	189.0x	C64.xx
Liver Cancer	155.xx, 156.0x, 156.1x, 156.2x, 156.8x, 156.9x	C22.xx, C23.xx, C24.xx
Lung Cancer	162.0x, 162.2x, 162.3x, 162.4x, 162.5x, 162.8x, 162.9x, 165.xx	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	202.80, 202.81, 202.82, 202.83, 202.84, 202.85, 202.86, 202.87, 202.88, 203.80, 203.82, 200.0x, 200.1x, 200.2x, 200.3x, 200.4x, 200.5x, 200.6x, 200.7x, 200.8x, 201.xx, 202.0x, 202.1x, 202.2x, 202.4x, 202.7x, 273.3x	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x
Pancreatic Cancer	157.xx	C25.xx
Prostate Cancer	185.xx	C61.xx
Upper GI Cancer	150.xx, 151.xx, 152.xx	C15.xx, C16.xx, C17.xx
Uterine Cancer	179.xx, 182.xx	C54.xx, C55.xx

We would maintain the list of ICD-10 codes for included cancer types under the RO Model on the RO Model website. Any addition or removal of these proposed cancer types would be communicated via the RO Model website and written correspondence to RO participants. We would 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 invite public comments on our proposal.

b. Episode Length and Trigger

(1) Proposed Episode Length

We are proposing that the length of an episode under the RO Model be 90 days. 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. 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. 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 will have occurred and any payment would be made to the RO participant in accordance with our incomplete episode policy. We refer readers to sections III.C.5.b and III.C.6.a for an overview of our proposed episode trigger and incomplete episode policies, respectively.

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. We intend to make a summary-level, de-identified file titled the “RT Expenditures by Time” available on the RO Model’s website that supports our findings in this preliminary analysis.

Based on our 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 are proposing a 90 day episode duration.

(2) Proposed Episode Trigger

Because we only want to include episodes in which beneficiaries actually receive RT services, we propose 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 Table 2: List of RO Model Bundled HCPCS) 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 previously explained, an episode that is triggered would 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 cases 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), the Professional participant would provide the Technical participant with a signed radiation prescription and the final treatment plan, all of which is usually done electronically. This will inform the Technical participant of when the episode began.

(3) Proposed Policy for Multiple Episodes and the Clean Period

Given our 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 a RO participant to extend a treatment course beyond the 90-day episode in order to trigger a new episode, we propose that another episode may not be triggered until at least 28 days after the previous episode has ended. This is because, while a missed week of treatment is not uncommon, a break from RT services for more four weeks (or 28 days) generally signals the start of a new course of treatment³⁰. We refer to the 28-day period after an episode has ended, during which time a RO participant would bill for medically necessary RT services furnished to a RO beneficiary in accordance with Medicare FFS billing rules, as the “clean period.” We propose to codify the term “clean period” at § 512.205 of our regulations.

If clinically appropriate, a RO participant may initiate another episode for the same beneficiary after the 28-day clean period has ended. During the clean period, a RO participant would be required to bill for RT services for the beneficiary in accordance with FFS billing rules. 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 invite public comment on our proposal.

³⁰ 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.

c. Proposed Included RT Services

We propose 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. The subcomponents of RT services have been described in the following manner:³¹

Consultation: A consultation is an evaluation and management (E&M) service, which typically consists of a medical exam, obtaining a problem-focused medical history, and decision making about the patient's condition/care.

Treatment planning: Treatment planning tasks include determining a patient's disease-bearing areas, identifying the type and method of radiation treatment delivery, specifying areas to be treated, and selecting radiation therapy treatment techniques. Treatment planning often includes simulation (the process of defining relevant normal and abnormal target anatomy and obtaining the images and data needed to develop the optimal radiation treatment process).

Treatment planning may involve marking the area to be treated on the patient's skin, aligning the patient with localization lasers, and/or designing immobilization devices for precise patient positioning.

Technical preparation and special services: Technical preparation and special services include radiation dose planning, medical radiation physics, dosimetry, treatment devices, and special services. More specifically, these services also involve building treatment devices to refine treatment delivery and mathematically determining the dose and duration of radiation

³¹ American Society for Radiation Oncology (ASTRO). Basics of RO Coding. <https://www.astro.org/Basics-of-Coding.aspx>.

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.

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 are proposing 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 propose 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, 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.

We are 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.

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

Given that physicians sometimes contract with others to supply and administer brachytherapy radioactive sources (or radioisotopes), we considered omitting these services from the episode payment. After considering either including or excluding brachytherapy radioelements from the RO Model, we are proposing 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 are proposing to exclude from the Model. We invite public comments on our proposal, including comments on the proposed inclusion of brachytherapy radioactive sources in the episodes.

The RO Model payments would replace current FFS payments only for the included RT services furnished during an episode. For the included modalities, proposed in section III.C.5.d of this proposed rule, the RO Model episode would include HCPCS codes related to radiation oncology treatment. Please see section III.C.7 for our proposed 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. RT services included on this list are referred to as “RO Model Bundled HCPCS” when they are provided during a RO Model episode since payment for these services is bundled into the RO episode payment. Thus, we propose to codify at § 512.270 that these RT services would not be paid separately during an episode. We may add, remove, or revise any of the bundled HCPCS codes included in the RO Model. We would notify participants of any changes to the HCPCS codes per the CMS annual Level 2 HCPCS code file. We would maintain a list of the HCPCS codes included in the RO Model on the RO Model website.

TABLE 2: LIST OF RO MODEL BUNDLED HCPCS

HCPCS	HCPCS Description	Category
55920	Placement Pelvic Needles/Catheters, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57155	Placement Tandem and Opioids, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57156	Placement Vaginal Cylinder, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
58346	Placement Heyman Capsules, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
77014	Computed tomography guidance for placement of	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77021	Magnetic resonance guidance for needle placement	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77261	Radiation therapy planning	Treatment Planning
77262	Radiation therapy planning	Treatment Planning
77263	Radiation therapy planning	Treatment Planning
77280	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77285	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77290	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77293	Respirator motion mgmt simul	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77295	3-d radiotherapy plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77299	Radiation therapy planning	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77300	Radiation therapy dose plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77301	Radiotherapy dose plan imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77306	Teleltx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77307	Teleltx 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
77387	Guidance for radiat tx dlvr	Radiation Treatment Delivery (Guidance)
77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services

HCPCS	HCPCS Description	Category
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77424	Io rad tx delivery by x-ray	Radiation Treatment Delivery
77425	Io rad tx deliver by elctrns	Radiation Treatment Delivery
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbtrt 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 rdnci skr surf brachytx	Radiation Treatment Delivery
77768	Hdr rdnci skn surf brachytx	Radiation Treatment Delivery
77770	Hdr rdnci ntrstl/icav brchtx	Radiation Treatment Delivery
77771	Hdr rdnci ntrstl/icav brchtx	Radiation Treatment Delivery
77772	Hdr rdnci ntrstl/icav brchtx	Radiation Treatment Delivery
77778	Apply interstitial radiat compl	Radiation Treatment Delivery
77789	Apply surf ldr radionuclide	Radiation Treatment Delivery
77790	Radiation handling	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77799	Radium/radioisotope therapy	Radiation Treatment Delivery
A9527	Iodine i-125 sodium iodide	Radiation Treatment Delivery (Brachytherapy Materials)
C1715	Brachytherapy needle	Radiation Treatment Delivery (Brachytherapy Materials)
C1716	Brachytx, non-str, gold-198	Radiation Treatment Delivery (Brachytherapy Materials)
C1717	Brachytx, non-str,hdr ir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1719	Brachytx, ns, non-hdrir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1728	Catheter, brachytherapy seed administration	Radiation Treatment Delivery (Brachytherapy Materials)
C2616	Brachytx, non-str,yttrium-90	Radiation Treatment Delivery (Brachytherapy Materials)
C2634	Brachytx, non-str, ha, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2635	Brachytx, non-str, ha, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2636	Brachy linear, non-str,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2638	Brachytx, stranded, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2639	Brachytx, non-stranded,i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2640	Brachytx, stranded, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2641	Brachytx, non-stranded,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2642	Brachytx, stranded, c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2643	Brachytx, non-stranded,c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2644	Brachytx cesium-131 chloride	Radiation Treatment Delivery (Brachytherapy Materials)
C2645	Brachytx planar, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2698	Brachytx, stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
C2699	Brachytx, non-stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
G0339	Robot lin-radsurg com, first	Radiation Treatment Delivery
G0340	Robt lin-radsurg fractx 2-5	Radiation Treatment Delivery
G6001	Echo guidance radiotherapy	Radiation Treatment Delivery (Guidance)
G6002	Stereoscopic x-ray guidance	Radiation Treatment Delivery (Guidance)
G6003	Radiation treatment delivery	Radiation Treatment Delivery
G6004	Radiation treatment delivery	Radiation Treatment Delivery
G6005	Radiation treatment delivery	Radiation Treatment Delivery
G6006	Radiation treatment delivery	Radiation Treatment Delivery
G6007	Radiation treatment delivery	Radiation Treatment Delivery
G6008	Radiation treatment delivery	Radiation Treatment Delivery
G6009	Radiation treatment delivery	Radiation Treatment Delivery
G6010	Radiation treatment delivery	Radiation Treatment Delivery
G6011	Radiation treatment delivery	Radiation Treatment Delivery
G6012	Radiation treatment delivery	Radiation Treatment Delivery
G6013	Radiation treatment delivery	Radiation Treatment Delivery
G6014	Radiation treatment delivery	Radiation Treatment Delivery
G6015	Radiation tx delivery imrt	Radiation Treatment Delivery

HCPCS	HCPCS Description	Category
G6016	Delivery comp imrt	Radiation Treatment Delivery
G6017	Intrafraction track motion	Radiation Treatment Delivery (Guidance)
Q3001	Brachytherapy radioelements	Radiation Treatment Delivery (Brachytherapy Materials)
77469	Intraoperative radiation treatment management	Treatment Management

d. Proposed Included Modalities

We propose 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 are proposing to include all of these modalities because they are the most commonly used to treat the 17 included cancer types and including these modalities would allow us to determine whether the RO Model is able to impact RT holistically rather than testing a limited subset of services.

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.³² Higher payment rates for services involving certain treatment modalities may encourage use of those modalities over others.³³

Medicare payment for RT has 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.³⁴ 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

³² 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.

³³ Ibid.

³⁴ 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.

for PBT in FFS Medicare grew rapidly,³⁵ 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 aforementioned increase in PBT volume may depend on a variety of factors.

The RO Model's episode payment is 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 groups together different modalities for specific cancer types, often with variable costs, into a single payment that reflects average treatment costs. The Model would include an historical experience adjustment which would account for RO participant's historical care patterns, including a RO participant's historical use of more expensive modalities, and certain factors that are beyond a provider's control. We believe that applying the same payment for the most commonly used RT modalities would allow physicians to pick the highest-value modalities.

Given the goals of the RO Model as well as the proposed payment design, we believe it is important to treat all modalities equally.

With respect to PBT, 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

³⁵ 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.

treatment alternatives for various types of cancer.³⁶ 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.³⁷ 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 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 invite public comment our proposal to include PBT in the RO Model.

We are considering excluding PBT from the included modalities in instances where a 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 invite public comment on whether or not the RO Model should

³⁶ 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.

³⁷ http://medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf

include RO beneficiaries participating in federally-funded, multi-institution, randomized control clinical trials for PBT.

6. Proposed Pricing Methodology

a. Overview

The proposed pricing methodology describes 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. We propose 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 a RO beneficiary during an episode, which is calculated as set forth in proposed § 512.255. We further propose to codify this term, “participant-specific professional episode payment,” at § 512.205 of our regulations.

We propose 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 a RO beneficiary during an episode, which is calculated as set forth in proposed § 512.255. We further propose to codify this term, “participant-specific technical episode payment,” at § 512.205 of our regulations.

There are eight primary steps to the proposed pricing methodology. In the first step, we would 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. The calculation of these rates would be based on Medicare FFS claims paid during the CYs 2015-2017 that are included under

an episode where the initial treatment planning service occurred during the CYs 2015-2017 as described in section III.C.6.b. 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 exclude those episodes that do not meet the criteria described in section III.C.5 of this proposed rule. From those episodes, we would then calculate the amount CMS paid on average to providers for the PC and TC for each of the included cancer types in the HOPD setting, creating the Model’s national base rates. Unless a broad rebasing is done after a later PY in the Model, these national base rates would be fixed throughout the model performance period.

In the second step, we would 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 OPPS and PFS. We propose 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 propose 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, 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 would 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 would 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 providers' historical care patterns and certain factors that are beyond a provider's control, which vary systematically among providers and suppliers so as to warrant adjustment in payment. 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 would 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 would 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. The efficiency factor measures if a 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 would further adjust payment by applying a discount factor. The discount factor, the set percentage by which CMS reduces an episode payment amount, after the trend factor and adjustments have been applied, but before standard CMS adjustments including the geographic practice cost index (GPCI), sequestration, and beneficiary cost-sharing, would reserve savings for Medicare and reduce beneficiary cost-sharing. We propose to codify the term "discount factor" at § 512.205.

In the fifth step, we would 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 during the reconciliation process, which we discuss further in section III.C.11. We propose to define the term “duplicate RT service” to mean any included RT service (as identified at § 512.235) that is furnished to a single RO beneficiary by a RT provider or RT supplier or both that did not initiate the PC or TC of that RO beneficiary after the episode. We propose to codify “duplicate RT service” at § 512.205. 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 a RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an RT treatment planning service to that RO beneficiary; or (2) traditional Medicare stops being the primary payer at any point during the relevant 90-day period the RO beneficiary; or (3) a RO beneficiary stops meeting the beneficiary population criteria under § 512.215(a) or triggers the beneficiary exclusion criteria under § 512.215(b) before the technical component of an episode initiates.

We would also 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 would 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 would apply geographic adjustments to payments. In the seventh and final eighth step, we would 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 payment amounts for the provision of the PC and TC of each included cancer type in the Model. We would 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 is a pricing example for an episode of lung cancer. We provide this example to show how each pricing component (that is, national base rates, trend factors, case mix and historical experience adjustments, withhold, discount factors, geographic adjustment, beneficiary coinsurance, and sequestration) figures into these amounts. We also intend to provide 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.

b. Proposal to Construct Episodes Using Medicare FFS Claims and Calculate Episode Payment

We would 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 described in section III.C.3.d. We would exclude those episodes that do not meet the criteria described in section III.C.5 of this proposed 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 described in section III.C.5.b. We would 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 would neither Winsorize nor cap payment amounts nor adjust for outliers in this step.

So that all payment amounts are in 2017 dollars, we would 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 would 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.

Conversion of 2015 and 2016 payment amounts to 2017 dollars would be done differently, depending on which step of the pricing methodology is 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.

c. Proposed National Base Rates

We propose 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 withhold for each of the proposed included cancer types. We further propose to codify this term at § 512.205 of our regulations.

The following episodes would be excluded from calculations to determine the national base rates:

- Episodes with any services furnished by a CAH;
- Episodes without positive (>\$0) total payment amounts for professional services or technical services;

- Episodes assigned a cancer type not identified as cancer types that meet our criteria (see Table 1);
- Episodes that are not assigned a cancer type;
- Episodes with RT services furnished in Maryland, Vermont, or a U.S. Territory;
- Episodes in which a PPS-exempt cancer hospital furnishes the technical component (is the attributed technical provider);
- Episodes in which a Medicare beneficiary does not meet the eligibility criteria proposed in section III.C.4.

We are proposing 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 are proposing 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 this section exclude episodes that are in accordance with proposals set forth in section III.C.5.

(1) Proposed National Base Rate Calculation Methodology

When calculating the national base rates, we would only use episodes that meet the following criteria: (1) episodes initiated in 2015-2017; (2) episodes attributed to a HOPD; and (3) during an episode, the majority of technical services were provided in a HOPD (that is, more technical services were provided in a HOPD than in a freestanding radiation therapy center). 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 would publish the national base rates and 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.

Our proposed national base rates for the model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3.

TABLE 3 –NATIONAL BASE RATES BY CANCER TYPE (in 2017 DOLLARS)

RO Model-Specific Placeholder Codes ³⁸	Professional or Technical	Cancer Type	Base Rate
XXXXX	Professional	Anal Cancer	\$2,968
XXXXX	Technical	Anal Cancer	\$16,006
XXXXX	Professional	Bladder Cancer	\$2,637
XXXXX	Technical	Bladder Cancer	\$12,556
XXXXX	Professional	Bone Metastases	\$1,372
XXXXX	Technical	Bone Metastases	\$5,568
XXXXX	Professional	Brain Metastases	\$1,566
XXXXX	Technical	Brain Metastases	\$9,217
XXXXX	Professional	Breast Cancer	\$2,074
XXXXX	Technical	Breast Cancer	\$9,740
XXXXX	Professional	Cervical Cancer	\$3,779
XXXXX	Technical	Cervical Cancer	\$16,955
XXXXX	Professional	CNS Tumor	\$2,463
XXXXX	Technical	CNS Tumor	\$14,193
XXXXX	Professional	Colorectal Cancer	\$2,369
XXXXX	Technical	Colorectal Cancer	\$11,589
XXXXX	Professional	Head and Neck Cancer	\$2,947
XXXXX	Technical	Head and Neck Cancer	\$16,708
XXXXX	Professional	Kidney Cancer	\$1,550
XXXXX	Technical	Kidney Cancer	\$7,656
XXXXX	Professional	Liver Cancer	\$1,515
XXXXX	Technical	Liver Cancer	\$14,650
XXXXX	Professional	Lung Cancer	\$2,155
XXXXX	Technical	Lung Cancer	\$11,451
XXXXX	Professional	Lymphoma	\$1,662

³⁸ The final HCPCS codes specific to the RO Model would be published in the CY2020 Level 2 HCPCS code file.

RO Model-Specific Placeholder Codes³⁸	Professional or Technical	Cancer Type	Base Rate
<i>XXXXX</i>	Technical	Lymphoma	\$7,444
<i>XXXXX</i>	Professional	Pancreatic Cancer	\$2,380
<i>XXXXX</i>	Technical	Pancreatic Cancer	\$13,070
<i>XXXXX</i>	Professional	Prostate Cancer	\$3,228
<i>XXXXX</i>	Technical	Prostate Cancer	\$19,852
<i>XXXXX</i>	Professional	Upper GI Cancer	\$2,500
<i>XXXXX</i>	Technical	Upper GI Cancer	\$12,619
<i>XXXXX</i>	Professional	Uterine Cancer	\$2,376
<i>XXXXX</i>	Technical	Uterine Cancer	\$11,221

d. Proposal to Apply Trend Factors to National Base Rates

We would next apply a trend factor to the 34 different national base rates in Table 3. 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. We propose that 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 would 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 would be FFS rates from 2017.

To calculate the numerator, we would multiply: (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor would be

applied) was furnished for the most recent calendar year with complete data³⁹ by (b) the corresponding FFS payment rate (as paid under OPPS or PFS) for the upcoming performance year.

To calculate the denominator, we would multiply: (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor would be applying) 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 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:

$$\text{2020 Trend factor} = (\text{2017 volume} * \text{2020 corresponding FFS rates as paid under OPPS or PFS}) / (\text{2017 volume} * \text{2017 corresponding FFS rates as paid under OPPS or PFS})$$

We would then multiply: (a) the trend factor for each national base rate by (b) the corresponding national base rate for the PC and TC of each cancer type from Step 1, yielding 34 trended national base rates. The trended national base rates for 2020 would be made available on the RO Model's website once CMS issues the CY 2020 OPPS and PFS final rules that establish payment rates for the year.

To the extent that CMS introduces new HCPCS codes that CMS determines should be included in the Model, we propose 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.⁴⁰

³⁹ 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.

⁴⁰ 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.

We propose to use this trend factor methodology as part of the RO Model's pricing methodology.

e. Proposal to Adjust for Case Mix and Historical Experience

After applying the proposed trend factor in section III.C.6.d, we propose to adjust the 34 trended national base rates to account for each RO participant's historical experience and case mix history.

(1) Proposed Case Mix Adjustments

The cost of care can vary according to many factors that are beyond a provider's control, and the presence of certain factors, otherwise referred to here as case mix variables, may vary systematically among providers and warrant adjustment in payment. For this reason, we propose to apply a RO participant-specific case mix adjustment for the PC and the TC that would be applied to the trended national base rates.

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 propose 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 is developed from the same episodes used to determine the Model's national base rates, that is 2015-2017 episodes attributed

to all HOPDs nationally. We would first Winsorize, or cap, the episode payments in the national beneficiary profile at the 99th and 1st percentiles, with the percentiles being identified separately by cancer type. We would 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 would determine a RO participant's predicted payments, or the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. For PY1, these predicted payments would be based on episode data from 2015 to 2017. These predicted payments would be summed across all episodes attributed to the RO participant to determine a single predicted payment for the PC or the TC. This process would be carried out separately for the PC and the TC.

We would then determine a 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 a RO participant to determine a single expected payment for the PC or the TC. The difference between a RO participant's predicted payment and a RO participant's expected payment, divided

by the expected payment, would constitute either the PC or the TC case mix adjustment for that RO participant. Mathematically this would be expressed as follows:

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

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

(2) Proposed Historical Experience Adjustments and Efficiency Factor

To determine historical experience adjustments for a RO participant we would use episodes attributed to the RO participant that initiated during 2015-2017. We would 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 would use episodes as described in section III.C.6.b (that is, all episodes nationally), except we would Winsorize, or cap, episode payments attributed to the RO participant at the 99th and 1st 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 would not vary by cancer type.

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 would then be divided by (c) the summed expected payments used in the case mix adjustment calculations. We would repeat these same calculations for the historical experience adjustment for the TC. 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 proposed calculation, if a 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 a 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 would use an efficiency factor. Efficiency factor means the weight that a 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, 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.

(3) Proposal to Apply the Adjustments

To apply the case mix adjustment, the historical experience adjustment, and the efficiency factor as described in section III.C.6.e to the trended national base rates detailed in Step 2, for the PC we would multiply: (a) the corresponding historical experience adjustment by (b) the corresponding efficiency factor, and then add (c) the corresponding case mix adjustment and (d) the value of one. This formula creates a combined adjustment that can be multiplied with the national base rates. Mathematically this would be expressed as:

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

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

a total of 17 RO participant-specific episode payments for Professional participants and Technical participants.

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

(4) Proposal for HOPD or Freestanding Radiation Therapy Center with Fewer than Sixty Episodes during 2015-2017 Period

Under this proposed rule, if a HOPD or freestanding radiation therapy center (identified by a CCN or TIN) furnishes RT services during the model performance period within a selected CBSA and is required to participate in the Model because it meets eligibility requirements, but has fewer than 60 episodes attributed to it during the 2015-2017 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts would equal the trended national base rates in PY1. In PY2, if an RO participant with fewer than 60 episodes attributed to it during the 2015-2017 period continues to have fewer than sixty episodes attributed to it during the 2016-2018 period, then 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 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 would 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 would 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.,

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

We are proposing 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. If the new TIN or CCN begins to furnish RT services within a selected CBSA, then it must participate in the Model. We are proposing this policy in order to prevent HOPDs and freestanding radiation therapy centers from engaging in mergers, acquisitions, or other new clinical or business relationships so as to avoid participating in the Model.

The RO Model requires 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 proposed at § 512.180(c), except that under the RO Model, RO participants must also provide a notification regarding a new clinical relationship that may or may constitute a change in control. If there is sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN. For our

proposed policy regarding change in legal business name and change in control provisions, we refer readers to discussion in section II.L and proposed regulations at § 512.180(b) and (c).

f. Proposal to Apply a Discount Factor

After applying participant-specific adjustments under section III.C.6.e to the trended national base rates, we would next deduct a percentage discount from those amounts for each performance year. The discount factor would not vary by cancer type. The discount factor for the PC would be 4 percent. The discount factor for the TC would be 5 percent. We are proposing the 4 and 5 percent discounts based on discounts in other models tested under section 1115A and private payer models. We believe these figures for the discount factor, four and 5 percent for the PC and TC, respectively, strike an appropriate balance in creating savings for Medicare while not creating substantial financial burden on RO participants with respect to reduction in payment.

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

g. Proposal to Apply Withholds

We propose 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 outline our proposals for three withhold policies in this section of this proposed rule.

(1) Proposed Incorrect Payment Withhold

We propose 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 described in section III.C.6.a; and (2) incomplete episodes as described in section III.C.6.a of this proposed rule.

We are proposing 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 a RO participant's cash flow. We believe that a 2 percent incorrect payment withhold would set aside sufficient funds to capture a RO participant's duplicate RT services and incomplete episodes during the reconciliation process. We anticipate that duplicate RT services requiring reconciliation will be uncommon, and that few overpayments for such services would therefore be subject to our proposed 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 would use the annual reconciliation process described in section III.C.11 to determine whether a RO participant is eligible to receive back the full 2 percent withhold amount, a portion of it, or must repay funds to CMS. We propose to define the term "repayment amount" to mean the amount owed by a RO participant to CMS, as reflected on a reconciliation report. We propose to codify the term "repayment amount" at § 512.205 of our regulations. In addition, we propose to define the term "reconciliation report" to mean the annual report issued by CMS to a RO participant for each performance year, which specifies the RO participant's reconciliation

payment amount or repayment amount. We further propose to codify the term “reconciliation report” at § 512.205.

(2) Proposed Quality Withhold

We propose 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 propose to define the term “AQS” to mean the numeric score calculated for each RO participant based on its performance on, and reporting of, proposed quality measures and clinical data, as described in section III.C.8.f, which is used to determine the amount of a RO participant’s quality reconciliation payment amount. We further propose to codify this term at § 512.205 of our regulations. The annual reconciliation process described in section III.C.11 would determine how much of the 2 percent withhold a Professional participant or Dual participant would receive back.

(3) Proposed Patient Experience Withhold

We would withhold 1 percent for the TC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factor have been applied starting in PY3 (January 1, 2022 through December 31, 2022) to account for patient experience in the Model. Technical participants and Dual participants would be able to earn back up to the full amount of the patient experience withhold for a given PY based on their results from the patient-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS® Cancer

Care Survey) Cancer Care Survey for Radiation Therapy as described in section III.C.8.b. of this proposed rule.

Like the incorrect payment and quality withhold, the annual reconciliation process described in section III.C.11. of this proposed rule would determine how much of the 1 percent withhold a participant would receive back.

We propose the incorrect payment withhold, the quality withhold, and the patient experience withhold be included in the RO Model's pricing methodology.

h. Proposal to Adjust for Geography

Geographic adjustments are standard Medicare adjustments that occur in the claims system. Even though the Model would establish a common payment amount for the same RT services regardless of where they are furnished, payment would still be processed through the current claims systems, with adjustments as discussed in section III.C.7, for OPPS and PFS. 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 would adjust the trended national base rates that have been adjusted for each RO participant's case mix, historical experience and after which the discount rate and withhold 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. 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 would create a set of RO Model-specific RVUs using the national (unadjusted) payment rates for each HCPCS code of the included RT services for each cancer type included in the RO Model. 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 a 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 episodes under the Model would have different RO Model-specific RVU shares, but these shares would not vary by cancer type. Table 4 provides the proposed relative weight of each for the PCs and TCs of the RO Model-specific RVUs share.

TABLE 4 RVU SHARES

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

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 propose to apply the OPPS Pricer as is automatically applied under OPPS outside of the Model. We propose 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.

i. **Proposal to Apply Coinsurance**

We propose to calculate the coinsurance amount for a RO beneficiary after applying, as appropriate, the proposed case mix and historical experience adjustments, withhold, 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). This policy would remain the same under the RO Model. RO beneficiaries would pay 20 percent of each of the bundled PC and TC payments for their cancer type, regardless of what their total coinsurance payment amount would have been under the FFS payment system.

We believe that maintaining the 20 percent coinsurance payment will 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.

We note 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 withhold and discounts described in the previous section, 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 episode. In other words, the proposed withhold and discount factors would, on average, be expected to reduce the total amount RO beneficiaries or secondary insurers would owe RO participants. In addition, because episode payment amounts under the RO Model would include payments for RT services that would likely be provided over multiple visits, the beneficiary coinsurance payment for each of the episode's payment amounts would likewise be higher than it would otherwise be for a single RT service visit. For RO beneficiaries who do not have a secondary insurer, 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, we would continue to apply the limit on beneficiary liability for copayment for a procedure (as described in section 1833(t)(8)(C)(i) of the Act) to the trended national base rates that concern the TC after the case mix and historical experience adjustments, discount factor, applicable withhold, and geographic adjustment have been applied.

We invite 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 proposed case mix and historical experience adjustments, withhold, discount factors, and geographic adjustments have been applied.

j. Example of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1

Table 5 details the participant-specific professional episode payment paid by CMS to a single TIN for the furnishing of RT professional services to RO beneficiary for an episode of lung cancer. The participant-specific professional episode payment in this example does not include any withhold amount that the RO participant would be eligible to receive back or repayment if more money is needed beyond the withhold amount from the RO participant.

TABLE 5 EXAMPLE: PARTICIPANT-SPECIFIC PROFESSIONAL EPISODE PAYMENT FOR LUNG CANCER
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	$c = a * b$
Case Mix Adjustment (d)	0.02	For example (102-100) / 100
Historical Experience Adjuster (e)	0.14	For example (116-102) / 100
Year 1 Efficiency Factor (f)	0.90	
Adjustments combined (g)	1.15	$g = d + (e * f) + 1$
Subtotal (h)	\$2,568.42	$h = c * g$
Discount Factor (i)	0.96	
Subtotal (j)	\$2,465.68	$j = i * h$
Withhold #1 (Incorrect Payment) (k)	0.98	
Withhold #2 (Quality Performance) (l)	0.98	
Subtotal2 (m)	\$2,368.04	$m = j * k * l$
Geographic Adjustment (n)	1.02	
2019 Total Episode Payment to Participant including Coinsurance owed by RO beneficiary (o)	\$2,415.40	$o = m * n$
20% Beneficiary Coinsurance Determined (p)	\$483.08	$p = o * 0.20$
80% Participant Payment (q)	\$1,932.32	$q = o * 0.80$
Sequestration Claims Payment Adjustment to Participant Payment (r) [r = participant-specific professional episode payment]	\$1,893.67	$r = q * 0.98$
Episode Payment 1 (s)*	\$946.84	$s = r / 2$
Episode Payment 2 (t)*	\$946.84	$t = r / 2$

[^] All numbers are rounded to two decimal places.

Table 6 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 a RO beneficiary for an episode of lung cancer. The sequence and naming conventions of steps (n)-(r) in Table 6 may vary under the OPPS.

TABLE 6 EXAMPLE: PARTICIPANT-SPECIFIC TECHNICAL EPISODE PAYMENT FOR LUNG CANCER IN PY1 AND PY2

ALL NUMBERS ARE ILLUSTRATIVE ONLY[^]

	Technical Component	
	Amount	Formula
National Base Rate (a)	\$11,451.00	
Trend Factor (b)	1.04	
Subtotal (c)	\$11,909.04	$c = a * b$
Case Mix Adjustment (d)	0.02	For example (102-100) / 100
Historical Experience Adjustment (e)	0.11	For example (113-102) / 100

Year 1 Efficiency Factor (f)	0.90	
Adjustments combined (g)	1.12	$g = d + (e * f) + 1$
Subtotal (h)	\$13,326.22	$h = c * g$
Discount Factor (i)	0.95	
Subtotal (j)	\$12,659.91	$j = i * h$
Withhold #1 (Incorrect Payment) (k)	0.98	
Withhold #2 (Patient Experience) (l) - NOT APPLIED UNTIL PY3		
Subtotal2 (m)	\$12,406.71	$m = j * k$
Geographic Adjustment (n)	1.02	
2019 Total Episode Payment to Participant including coinsurance owed by RO beneficiary (o)	\$12,654.84	$o = m * n$
20% Beneficiary Coinsurance Determined (p)	\$2,530.97	p = o * 0.20
80% Participant Payment (q)	\$10,123.87	$q = o * 0.80$
Sequestration Claims Payment Adjustment to Participant Payment (r) [r = participant-specific technical episode payment]	\$9,921.40	$r = q * 0.98$
Episode Payment 1 (s)*	\$4,960.70	s = r / 2
Episode Payment 2 (t)*	\$4,960.70	t = r / 2

[^] All numbers are rounded to two decimal places.

We invite public comment on our proposed pricing methodology.

7. Proposed Professional and Technical Billing and Payment

Similar to how many procedure codes have professional and technical components as identified in the CMS National Physician Fee Schedule Relative Value File, all 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. We believe that the best design for a prospective episode payment system for RT services is 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 reduces the likelihood that the limit on beneficiary liability for copayment for a procedure provided in a HOPD (as described in section 1833(t)(8)(C)(i) of the Act) is met.

Accordingly, we propose to pay for complete episodes in two installments: one tied to when the episode begins, and another tied to when the episode ends. Under this proposed policy

a Professional participant would receive two installment payments for furnishing the PC of an episode, a Technical participant would receive two installment payments for furnishing the TC of an episode, and a Dual participant would receive two installment payments for furnishing the PC and TC of an episode.

To reduce burden on RO participants, we propose to 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 would make changes to the current Medicare payment systems using the standard Medicare Fee for Service operations policy related Change Requests (CRs).

Our proposed design for testing a prospective episode payment model (that is, the RO Model) for RT services requires making prospective episode payments for all RT services included in an episode, as proposed in section III.C.5.c, instead of using Medicare FFS payments for services provided during an episode. Local coverage determinations (LCDs), which provide information about the reasonable and necessary conditions of coverage allowed, would still apply to all RT services provided in an episode.

Professional participants and Dual participants would be required to bill a new model-specific HCPCS code and a modifier indicating the start of an episode (SOE modifier) for the PC once the treatment planning service is furnished. 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. Payment for the PC would be made through the PFS and would only be paid to physicians (as identified by their respective TINs).

Under our proposed billing policy, a Professional participant or Dual participant that furnishes the PC of the episode must bill one of the new RO Model-specific HCPCS codes and SOE modifier. This would indicate within the claims systems that an episode has started. Upon submission of a claim with a RO Model-specific HCPCS codes and 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 must bill the same RO Model-specific HCPCS code that initiated the episode with a modifier indicating the end of an episode (EOE) after the end of the 90-day episode. This would indicate that the episode has ended. Upon submission of a claim with a RO Model-specific HCPCS codes and EOE modifier 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 must bill a new model-specific HCPCS code with a SOE modifier. 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 model-specific HCPCS code with a SOE modifier. We would pay the second half of the payment for the TC of the episode after the end of the episode. The Technical participant or Dual participant must bill the same RO Model-specific HCPCS code with an EOE modifier that initiated the episode. This would indicate that the episode has ended.

Similar to the way PCs are billed, we would develop a new HCPCS codes (and any modifiers) for the TC of each of the included cancer types. 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. 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.

The TC of the episode would begin on or after the date that the PC of the episode is initiated and 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. This is because the treatment planning service and the actual RT treatment do not always occur on the same day.

RO participants would be required to submit encounter data (no-pay) claims that include all RT services identified on the RO Model Bundled HCPCS list (Table 2) as services are furnished and would otherwise be billed under the Medicare FFS systems. We will monitor trends in utilization of RT services during the Model. These claims will not be paid because the bundled payments cover RT services provided during the episode. The encounter data would be used for evaluation and model monitoring, specifically trending utilization of RT services, and other CMS research.

If a RO participant provides clinically appropriate RT services during the 28 days after an episode ends, then the RO participant must bill Medicare FFS for those RT services. A new episode may not be initiated during the 28 days after an episode ends. As we explain in section III.C.5.b.(3). of this proposed rule, we refer to this 28 day period as the “clean period.”

In the event that a RO beneficiary changes RT provider or RT supplier after the SOE claim has been paid, CMS would subtract the first episode payment paid to the RO participant from the FFS payments owed to the RO participant for services furnished to the beneficiary before the transition occurred and listed on the no-pay claims. This would occur during the

annual reconciliation process described in section III.C.11. of this proposed rule. The subsequent provider or supplier (whether or not they are a RO participant) would bill FFS for furnished RT services.

Similarly, in the event that a beneficiary dies, enters hospice, or chooses to defer treatment after the PC has been initiated and the SOE claim paid but before the TC of the episode has been initiated (also referred to as an incomplete episode), during the annual reconciliation process 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, 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 enters hospice after both PC and TC of the episode have been initiated, the RO participant(s) may bill EOE claims and be paid the second half of the episode payment amounts regardless of whether treatment was completed. This is because death and hospice are included in the case mix adjuster.

There may be instances where new providers and suppliers begin furnishing RT services in a CBSA selected to participate in the RO Model. These new providers and suppliers would be RO participants and would have to be identified as such in the claims systems. When a claim is submitted with a RO Model-specific HCPCS code for a site of service that is located within one of the randomly selected CBSAs as identified by the service location's ZIP Code, but the CCN or TIN is not yet identified as a RO participant in the claims systems, 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, they will be identified in the claims system and will 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 there is sufficient data to calculate those adjustments as described in the pricing methodology section III.C.6. of this proposed rule.

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 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.

8. Quality

The quality measures we propose in this proposed rule, along with the proposed clinical data elements in section III.C.8.e, would be scored according to the methodology proposed in section III.C.8.f to calculate the Aggregate Quality Score (AQS). The AQS would be applied to the quality withhold described in section III.C.6.g.(2). of this proposed rule to calculate the quality reconciliation payment amount due to a Professional participant or Dual participant as specified in section III.C.11. of this proposed rule. 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 this proposed rule.

a. Proposed Measure Selection

We propose to adopt the following set of quality measures for the RO Model in order to assess the quality of care provided during episodes. We would begin requiring annual quality measure data submission by Professional participants and Dual participants in March of 2021 for episodes starting and ending in PY1. Quality measures will continue requiring annual data submissions thereafter through the remainder of the model performance period as described in section III.C.8.c. of this proposed rule. These quality measures would be used to determine a RO participant's AQS, proposed in section III.C.8.f. of this proposed rule, and subsequent quality reconciliation amount, described in section III.C.11. of this proposed rule. Based on the considerations set forth in this rule, we propose the following measures for the RO Model beginning in PY1 and continuing thereafter:

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

We are proposing to adopt these quality measures for the RO Model for two reasons. First, the Model is designed to preserve or enhance quality of care, and quality measures would allow us to quantify the impact of the Model on quality of care, RT services and processes, outcomes, patient satisfaction, and organizational structures and systems. Second, as discussed in section III.C.9 of this proposed rule, we intend for the RO Model to qualify as an Advanced

⁴¹ National Quality Forum.

APM, and also meet the criteria to be a MIPS APM. As stated previously, we believe the proposed quality measures would satisfy the quality measure-related requirements for both an Advanced APM and a MIPS APM. We believe that the following proposed 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. These measures are already adopted in MIPS, and we believe the other proposed measure is evidence based, reliable, and valid. We note, however, that we have not proposed an outcome measure for the RO Model. Under 42 CFR 414.1415(b)(3), the quality measures upon which an Advanced APM bases payment to participants for covered professional services under the terms of the APM must include at least one additional measure that is an outcome measure unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period. Because we have determined there are currently no outcome measures available or applicable for the RO Model, this requirement does not apply to the RO Model. However, if a relevant outcome measure becomes available, we would consider it for inclusion in the RO Model's measure set if deemed appropriate.

We believe our proposed use of quality measures as described in our proposed AQS scoring methodology in section III.C.8.f. of this proposed rule would meet the quality measure and cost/utilization requirement for a MIPS APM under section 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 participants and Dual participants would be familiar with the measures used in the Model. Lastly, we considered cross-cutting measures that would allow comparisons of quality across episode payment models and other CMS model tests.

While 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 scoring on quality performance, we intend to adjust the measure set in future PYs by adding new measures or removing measures if we determine those adjustments to be appropriate at the time. Prior to adding or removing measures we would use notice and comment rulemaking.

Table 7 includes the four proposed RO Model quality measures and CAHPS® Cancer Care Survey, the level at which measures would be reported, and the measures' status as pay-for-reporting or pay-for-performance, as described in section III.C.8.b. of this proposed rule. The table also includes the RO Model clinical data elements collection, proposed in section III.C.8.e. of this proposed rule.

TABLE 7. RO PARTICIPANT QUALITY MEASURE, CLINICAL DATA, AND PATIENT EXPERIENCE SUBMISSION REQUIREMENTS

RO Participant Data Submission Requirements	Level of Reporting	Pay-for Reporting	Pay-for-Performance
1. Oncology: Medical and Radiation - Plan of Care for Pain- NQF #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

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

In this section, we describe more fully the proposed quality measures that we propose to use in the RO Model for purposes of designing a model that could qualify as an Advanced APM and a MIPS APM, and for measuring quality of care. We describe each measure and our reasons for its proposed selection in this proposed rule. We also describe the CAHPS® Cancer Care Survey for Radiation Therapy and our proposal to administer the survey as part of the Model.

We selected these proposed 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 that we are proposing are currently NQF-endorsed⁴² process measures approved for MIPS.⁴³ The three NQF-endorsed measures approved for MIPS (Plan of Care for Pain; Screening for Depression and Follow-Up Plan; and Advance Care Plan) will be applied as pay-for-performance, given that baseline performance data exists.⁴⁴ The fourth measure in the RO Model (Treatment Summary Communication) will 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.f.(1) of this proposed rule. All four measures are clinically appropriate for RT. We selected these measures based on clinical appropriateness to cover RT

⁴² NQF endorsement summaries:

http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx

⁴³ See the CY 2018 QPP final rule (82 FR 53568).

⁴⁴ 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.

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 are also proposing the CAHPS® Cancer Care Survey to collect information that we believe is appropriate and specific to a patient's experience during an RT episode. We believe these measures and the CAHPS® Cancer Care Survey⁴⁵ would allow the RO Model to develop an aggregate quality score (AQS) in our pay-for-performance methodology (described in section III.C.8.f.) that incorporates performance measurement with a focus on clinical care and patient experience.

(1) Proposed Oncology: Medical and Radiation - Plan of Care for Pain (NQF #0383; CMS Quality ID #144)

We propose to adopt the Oncology: Medical and Radiation - Plan of Care for Pain measure in the RO Model. The Oncology: Medical and Radiation - Plan of Care for Pain 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.”⁴⁶ 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 malignancies, one third of patients undergoing treatment, and three quarters of

⁴⁵ As discussed in section III.C.8.b(5) and III.C.8.f, the CAHPS® Cancer Care Survey would be administered beginning in April 1, 2020, and we would seek to include measures in the aggregate quality score beginning in PY3.

⁴⁶ 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.

patients with advanced disease.⁴⁷ 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.

We believe this measure is appropriate for inclusion in the RO Model because it is specific to a RT episode of care. It considers the quality of care of medical and radiation oncology and is NQF endorsed. The RO Model would adopt the measure according to the most recent version of the specifications, which is under review at NQF in Fall 2019. The current measure version is 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). 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 we believed that it was necessary to remove the measure from the RO Model, then we would propose to do so through notice and comment rulemaking.

This measure is currently undergoing triennial review for NQF endorsement, and while we expect changes to the measure specifications, we do not believe these changes would change the fundamental basis of the measure, nor do we believe they would impact the measure's appropriateness for inclusion in the RO Model. NQF endorsement is a factor in our decision to propose the Medical and Radiation - Plan of Care for Pain measure, but it is not the only factor, so if the measure were to lose its NQF endorsement, we may choose to retain it so long as we

⁴⁷ 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/>

believe it continues to support CMS and HHS policy goals. Therefore, we propose to adopt the Plan of Care for Pain measure with the associated specifications available beginning in PY1. This measure will be a pay-for-performance measure and scored in accordance with our proposed methodology in section III.C.8.f.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data to the RO Model-specific data collection system in the manner consistent with that submission portal and the measure specification. The current version of the Plan of Care for Pain measure specification states the data would 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 proposed rule.

For the RO Model, we propose to use the registry specifications for this measure.

Detailed measure specifications may be found at:

https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_144_Registry.pdf.

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

We propose to adopt the Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure in the RO Model. The Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure 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.”⁴⁸ We believe this clinical topic is appropriate for a RT episode of care even though it is not specific to RT. While this measure is drafted for consideration of general mental health, it can also be applied to RT. 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, we believe inclusion of this measure is desirable to screen and treat the potential mental health effects of RT.^{49,50,51,52,53,54} 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. 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 use in other CMS programs. If we were to remove the measure, we would use notice and comment in rulemaking. This measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our proposed methodology in section III.C.8.f.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data to the RO Model-specific data collection system

⁴⁸ 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.

⁴⁹ 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

⁵⁰ 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. doi:10.1371/journal.pone.0027181

⁵¹ 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. doi:10.1200/jop.2016.011072

⁵² Pinquart, M., & Duberstein, P. R. (2010). Depression and cancer mortality: A meta-analysis. *Psychological Medicine*, 40(11), 1797-1810. doi:10.1017/s0033291709992285

⁵³ Massie, M. J. (2004). Prevalence of Depression in Patients With Cancer. *Journal of the National Cancer Institute Monographs*, 2004(32), 57-71. doi:10.1093/jncimimonographs/lgh014

⁵⁴ 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

in the manner consistent with that submission portal and the measure specification. The current version of the Preventive Care and Screening: Screening for Depression and Follow-Up Plan measure specification states the data would 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 proposed rule.

For the RO Model, we propose to use the registry specifications for this measure.

Detailed measure specifications may be found at:

https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_134_Registry.pdf

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

We propose to adopt the Advance Care Plan measure in the RO Model. 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 is a cross-cutting measure across all specialties and a variety of settings, but we believe that it is 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 and has been collected for OCM (beginning in 2018 as OCM-24) and MIPS (beginning in CY2018 as CMS #047), making its data collection processes reasonably well established. 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 use in other CMS programs and initiatives. If we believed it was necessary to remove the measure from the Model, we would propose to do so through notice and comment rulemaking. This measure would be a pay-for-performance measure beginning in PY1 and scored in accordance with our proposed methodology in section III.C.8.f.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data the RO Model-specific data collection system in the manner consistent with that submission portal and the measure specification. The current version of the Advance Care Plan measure specification states the data would 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 proposed rule.

For the RO Model, we propose to use the registry specifications for this measure. Detailed measure specifications may be found at:

[https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_047_Registry.pdf.](https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_047_Registry.pdf)

(4) Proposed Treatment Summary Communication – Radiation Oncology

We propose to adopt the Treatment Summary Communication – Radiation Oncology measure in the RO Model. 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 communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment.”⁵⁵ We believe this measure is appropriate for inclusion in the RO Model because it is specific to a RT episode of care. This measure assesses care coordination and communication between providers during transitions of cancer care treatment and recovery. While this measure is not NQF endorsed, 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 propose to include the measure as we believe it to be valid and relevant to the RO Model’s goals. This measure will be the one pay-for reporting measure included in the calculation of the AQS until a benchmark is established that would enable it to be pay-for-performance, which is expected to be beginning in PY3.

As discussed further in section III.C.8.c, we would require Professional participants and Dual participants to report quality measure data to the RO Model-specific data collection system in the manner consistent with that submission portal and the measure specification. The current version of the Treatment Summary Communication measure specification states the data would 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

⁵⁵ 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.

chart that was communicated to the physician(s) providing continuing care and to the patient 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 proposed rule.

For the RO Model, we propose to use the registry specifications for this measure.

Detailed measure specifications may be found at: <http://www.qualityforum.org/QPS/0381>.

(5) Proposed CAHPS® Cancer Care Survey for Radiation Therapy

We propose 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. We are proposing the CAHPS® cancer care survey for inclusion in the Model as it is appropriate and specific to patient experience of care within a RT 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.

In future rulemaking, we plan to propose a set of patient experience measures based on the CAHPS® Cancer Care survey, which would be included in the AQS as pay-for-performance measures beginning in PY 3.

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 invite public comment on our proposal to administer the CAHPS® Cancer Care Survey for Radiation Therapy for purposes of testing the RO Model.

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

We propose the following data collection processes for the four proposed quality measures described in section III.C.8.b.(1) through (4). of this proposed rule beginning in PY1.

First, we propose to require Professional participants and Dual participants to report aggregated quality measure data, instead of beneficiary-level quality measure data. These data will be used to calculate the participants' quality performance as discussed in section III.C.8.f.(1). of this proposed rule and subsequent quality reconciliation payments on an annual basis.

Second, we propose to require that data be reported for all applicable patients (for example, not just Medicare beneficiaries or beneficiaries with radiation episodes under the Model) based on the numerator and denominator specifications for each measure. 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 reporting portal in the form, manner and at the time consistent with the RO Model requirements.

Similar to the approach taken for the Quality Payment Program,⁵⁶ 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.

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 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 propose 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 measure submission portal. 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 would submit quality measure data for the time period noted in the measure specification. Thus, if a measure is calculated on an annual CY basis, participants would not adjust the reporting period to reflect the model time period. We anticipate this adherence to the measure specifications used in MIPS would reduce measure reporting burden for RO

⁵⁶ 42 CFR 414.1380(b)(1)(iii).

participants. In the event that the model implementation begins on April 1, 2020, the calendar year submission would remain; this would allow RO participants to use their MIPS data submission to meet the RO Model requirements. We believe that any segmentation to reflect only the RO Model time period in PY1 would be inconsistent with the measure, and add substantial reporting burden to RO participants. RO participants would submit data based on the individual measure specifications as previously discussed, unless otherwise announced by CMS. 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 would determine that Professional participants and Dual participants successfully collected and submitted quality measure data if the data are accepted in the RO Model portal by the reporting deadline of March 31 after the PY. 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.

As discussed in section III.C.8.f, 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 that RO participants would have the opportunity to become more familiar with the CAHPS® Cancer Care survey process and ask any questions.

d. Proposed Maintenance of Technical Specifications for Quality Measures

As part of its regular maintenance process for NQF-endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 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 would confirm existing or minor specification changes with NQF on an annual basis. NQF solicits information from measure stewards for annual reviews, and it reviews measures for continued endorsement in a specific three-year cycle. We note that NQF's annual or triennial maintenance processes for endorsed measures may result in the NQF requiring updates to the measures. Additionally, the Model includes measures that are not NQF-endorsed, but we anticipate that they will similarly require non-substantive technical updates to remain current.

e. Proposed Clinical Data Collection

In addition to collecting quality measure data, we also propose under § 512.275(c) 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 discuss more fully in sections III.C.8.f(1) and section III.C.14, respectively.

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 proposed 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. We

would determine the specific data elements and reporting standards prior to the start of the Model and would communicate them on the Model website.

In addition, we would provide education, outreach, and technical assistance. 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. 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 may also use it to begin developing and testing new radiation oncology-specific quality measures during the Model.

To facilitate data collection, we plan to share the proposed clinical data elements and reporting standards with EHR vendors and the radiation oncology specialty societies prior to the start of the Model. Our goal would be 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 and reduce the additional reporting burden on providers and may increase the quality of reporting. Providers 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 a model-specific data collection system. We would create a template for RO participants to complete with the specified clinical data elements, provide a secure 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 are also proposing to establish reporting standards. We propose that all Professional participants and Dual participants must submit clinical data information biannually, in July and January, each PY for RO beneficiaries with the applicable cancer types that completed their 90-day episode within the previous six months. This would be in addition to the quality measure data as described in section III.C.8.c.

We are specifically interested in feedback on the five cancer types where we propose to collect clinical data, which data elements should be captured for the five cancer types, and potential barriers to collecting data of this type.

We invite comments on our proposal to collect clinical data.

f. Proposal to Connect Performance on Quality Measures to Payment

(1) Proposed Calculation for the Aggregate Quality Score

The AQS would be based on each Professional participant's and Dual participant's: (1) performance on the set of proposed evidenced-based quality measures in sections III.C.8.b(1), (2), and (3) of this proposed rule compared to those measures' quality performance benchmarks; (2) reporting of data for the proposed pay-for-reporting measures (those without established performance benchmarks) in section III.C.8.b.(4) of this proposed rule; and (3) reporting of clinical data elements on applicable RO beneficiaries proposed in section III.C.8.e. of this proposed 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 proposed in section III.C.8.b.⁵⁷ 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

⁵⁷ 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.

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 propose 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)

Quality measures would be scored as pay-for-performance or pay-for-reporting, depending on whether established benchmarks exists, as proposed in section III.C.8. 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. The measures proposed as pay-for-performance for PY1 are selected 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 each measure, and we would score RO participants' quality measure performance similarly using MIPS benchmarks.⁵⁸ For example, when a Professional participant's or Dual participant's measured performance reaches the performance level specified for three points, we will award the

⁵⁸ The benchmarks are published annually at this CMS site: <https://qpp.cms.gov/about/resource-library>

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 would provide credit to the Professional participant or Dual participant for reporting the required data for the measure. We intend to 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 be scored as pay-for-reporting (instead of pay-for-performance). Professional participants and Dual participants that report the 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 proposed in section III.C.8.b(4), the Treatment Summary Communication measure would 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 propose to weight all four of our proposed quality measures (those deemed pay-for-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 10 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) 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 propose specific weights for additional 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 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 on a given measure.

For example, a Professional participant or Dual participant might have sufficient cases to report numerical data on three 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 would 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, it would receive 0 out of 10 for that measure in the quality portion of the AQS, and the denominator would remain at 40 points, which would then be recalibrated to 50 points. For example, if the same Professional participant or Dual participant scored 20 points out of 40 possible points, it would be equivalent to 25 points after recalibrating the denominator to 50 points ($(20/40) * 50 = 25$).

Our assessment of whether the Professional participant 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 data elements to us as requested, which we discuss in section III.C.8.c. 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 propose to 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. 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.

To calculate the AQS, we propose to sum each Professional participant’s 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 rule. Table 8 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 8 EXAMPLE: AQS CALCULATION DETAILS**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	
	Pay-for-performance <i>Did not meet minimum case requirements</i>	0	0	
Measure 3 (c)		0		
Measure 4 (d)	Pay-for-reporting	10	10	
Subtotal (e)		23	30	$e = a+b+c+d$
			50	$f = (\text{participant score of } e * 50) / \text{maximum points of } e$
Weighted to 50% (f)		38.3		
Clinical Data Elements (g)	$\geq 95\%$ of applicable RO beneficiaries	50	50	
Total (h)		88.3	100	$h = f+g$
AQS (i)		88.3%		$i = \text{participant score of } h / \text{maximum points of } h$

Table 9 details the AQS calculation for a Professional participant or Dual participant that did not meet the reporting requirements for the clinical data elements and the pay-for-reporting measure.

TABLE 9 EXAMPLE: AQS CALCULATION DETAILS**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 <i>Did not report data as required</i>	0	10	
Subtotal (e)		10.5	40	$e = a+b+c+d$
Weighted to 50% (f)		13.1	50	$f = (\text{participant score of } e * 50) / \text{maximum points of } e$
Clinical Data Elements (g)	<95% of applicable RO beneficiaries	0	50	
Total (h)		13.1	100	$h = f+g$
AQS (i)		13.1%		$i = \text{participant score of } h / \text{maximum points of } h$

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 invite public comment on the proposed calculation for the AQS methodology.

(2) Proposal to Apply the AQS to the Quality Withhold

We propose the following method to apply the AQS to the amount of the quality withhold that could be earned back by a RO participant. 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 \$2,465.68⁵⁹, the example AQS of 88.3 would result in a quality reconciliation payment amount of \$43.64 ($\$2,465.68 * 1.77\% = \43.64).⁶⁰

We would continue to weight measures equally in PY1 through PY5 unless we determine that the Model needs to emphasize specific clinical transformation priorities or add new measures. Any updates to the scoring methodology in future PYs would 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, 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.

We invite public comments on our proposal to apply the AQS to the amount of the quality withhold proposed in section III.C.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)

⁵⁹ This number refers to the result in line (j) in Table 5.

⁶⁰ This number is prior to the geographic adjustment and sequestration being applied.

We anticipate that the RO Model would be both an Advanced APM and a MIPS APM. For purposes of the Quality Payment Program, we propose that the RO participant, specifically either a Dual participant or a Professional participant, would be the APM Entity.

We propose to establish an “individual practitioner list” under the RO Model, created by CMS and sent to Dual participants and Professional participants to review, revise, certify, and return to CMS so that CMS may make QP determinations for the APM incentive payment amount and to identify any MIPS eligible clinicians who would be scored for MIPS based on their participation in this MIPS APM. If finalized as proposed, the individual practitioner list would serve as the Participation List as defined in the regulation at section 414.1305 for the Model. We propose to codify the term “individual practitioner list” for purposes of the RO Model in § 512.205 of our regulations.

The individuals included on the individual practitioner list would include physician radiation oncologists that are eligible clinicians participating in the RO Model with either a Dual participant or a Professional participant as described in section III.C.5.a of this proposed 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, MIPS eligible clinicians who are identified on the participation list for the performance period of an APM Entity participating in a MIPS APM are scored for MIPS using the APM scoring standard as provided in our regulation at 42 CFR 414.1370. Only Professional participant physicians and Dual participant physicians included on the individual practitioner list would be considered eligible clinicians.

We propose that prior to the start of each PY, we would create and provide each Dual participant and Professional participant with an individual practitioner list. 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, CMS would create and provide the new Dual participant or Professional participant with an individual practitioner list.

In order to certify the list, an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the list. 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. 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 are not proposing that HOPDs that are Technical participants be a part of this list process because as HOPDs they are paid by OPPS, which is not subject to the Quality Payment Program. We propose that 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, the RO participant must notify CMS within 15 days of an individual practitioner becoming a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely addition will be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice of the addition, the addition is effective on the date of the notice. The notice must be submitted in a form and manner specified by CMS.

In order to remove an individual practitioner from the list, the RO participant must notify CMS within 15 days if 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 will be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice of the removal, the removal is effective on the date of the notice. The notice must be submitted in a form and manner specified by CMS. Further, we propose 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. The certified individual practitioner list would be used for purposes related to QP determinations as specified in 42 CFR part 414 subpart O. We further propose that if the Dual participant or Professional participant does 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. We propose to codify these provisions relating to the individual practitioner list at § 512.217.

In order to be an Advanced APM, the RO Model must meet the criteria specified in our regulation at 42 CFR 414.1415. 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 hospitals are the APM Entities, each hospital, 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 propose 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 propose 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 solicit public comments on this proposal.

Second, to be an Advanced APM, 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 discuss the RO Model's proposed quality measure set in section III.C.8.b. We intend to use the results of the following proposed 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.: (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 propose 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. Specifically, we believe that these measures would meet the criteria under 42 CFR 414.1415(b).

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. There currently are no such outcome measures available or applicable for the RO Model's first QP Performance Period. If a relevant outcome measure becomes available, we would consider it for inclusion in the RO Model's measure set if deemed appropriate.

Third, the APM must require participating APM Entities to bear financial risk for monetary losses of more than a nominal amount or, be a Medical Home Model expanded under the Innovation Center's authority, in accordance with section 1115A(c) of the Act. We expect that the RO Model would 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.

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." 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, we propose that the APM Entities would be at risk for all costs associated with RT services as defined in section III.C.5.c 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 aforementioned 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 is responsible under the APM exceed expected expenditures, the RO participant is 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 a 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, we anticipate that the proposed RO Model would meet the criteria to be a MIPS APM under the Quality Payment Program starting in PY1 if the implementation date is

finalized as January 1, 2020 or PY2 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). Pursuant to § 414.1370(a), MIPS eligible clinicians who are identified on a participation list for the performance period of an APM Entity participating in a MIPS APM are scored under MIPS using the APM scoring standard. We propose to use the same individual practitioner list developed as previously proposed, to identify the relevant eligible clinicians for purposes of making QP determinations and applying the APM scoring standard under the Quality Payment Program.

We note 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 described in section II.F and III.C.14. Under our proposed monitoring policy, RO participants would be monitored for compliance with the RO Model requirements. CMS may, based on the results of such monitoring, deny an eligible clinician who is participating in the RO Model QP status if the eligible clinician or the eligible clinician's APM entity (that is, the respective RO participant) is non-compliant with RO Model requirements.
- Our proposal in section III.C.10.c, which explains that technical component payments under the RO Model would not be included in the aggregate payment amount for covered professional services that is used to calculate the amount of the APM Incentive Payment.

We invite public comment on these proposals.

10. Proposed Medicare Program Waivers

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 discuss 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. Proposed Waiver of Hospital Outpatient Quality Reporting (OQR) Program Payment Adjustment

We believe that it is 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 this proposed rule, we are proposing 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 or 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 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, will continue to be paid under the OPPS and subject to the 2.0 percentage point reduction under the Hospital OQR Program when applicable. We believe this waiver is 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 episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. 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. 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. We believe 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 believe 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 are proposing 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 seek 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.

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

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 propose 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 (as identified in Table 2) because we believe 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 episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center. Applying the MIPS payment adjustment factors would undermine our goal of site-neutral payments under the RO Model.

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. We believe 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. We believe that without this waiver, model participants may be incentivized to change their behavior and steer beneficiaries towards freestanding radiation therapy centers if they expect the MIPS payment adjustment factors would be positive, and away from freestanding radiation therapy centers if they expect the MIPS payment adjustment factors would be negative.

RO participants that bill for services under the professional RO Model-specific HCPCS codes would 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. We believe subjecting a RO participant to payment consequences under 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, we believe 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.

- c. Proposed Waiver of Requirement to Include Technical Component Payments in Calculation of the APM Incentive Payment Amount

We believe that it is 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 42 CFR 414.1450(b). The regulation at 42 CFR 414.1450(b) establishes the APM Incentive Payment Amount; 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 would bill the Model-specific HCPCS codes that are relevant to their RO participant type.

We believe this waiver is 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 would 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, Dual participants may change their billing behavior by shifting the setting in which they furnish RT services from HOPDs to freestanding radiation therapy centers in order to increase the amount of participant-specific technical episode payments, producing unwarranted increases in their APM Incentive Payment amount. We believe this would prejudice the model testing of site neutral payments as well as potentially interfere 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 believe 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.

d. Proposed General Payment Waivers

We believe 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 propose to waive:

- Section 1848(a)(1) of the Act that requires payment for physicians' services to be determined under the PFS to allow the 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 would be necessary because otherwise the proposed RO Model payments would 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 proposed participant-specific technical episode payment would be set by the OPPS (we note that the waiver of OPPS payment would be limited to RT services under the RO Model); and
- Section 1833(t)(16)(D) of the Act regarding payment for stereotactic radiosurgery (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 propose 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 described in section III.C.6) is effective at reducing program expenditures while preserving or enhancing the quality of care. Specifically, as proposed, the RO Model would test whether adjusting the current fee-for-service payments for RT services to a

prospective episode-based payment model would 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.

e. Proposed Waiver of Appeals Requirements

We believe that it is 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 propose to implement this waiver so that RO participants may utilize the proposed timely error and reconsideration request process specific to the RO Model as proposed in section III.C.12 of this proposed rule to review potential RO Model reconciliation errors. We would note 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 propose to implement this waiver because the proposed pricing methodology for the RO Model is unique and as such we have developed and proposed a separate timely error notice and reconsideration request process that RO participants would use in lieu of the claims appeals process under section 1869 of the Act.

In section III.C.12 of this proposal, we propose a process for RO participants to contest the calculation of their reconciliation payment amounts, the calculation of their reconciliation recoupment amounts, and the calculation of their AQS. Reconciliation payment amount means a payment made by CMS to a 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 note, in the specific circumstance wherein a provider acts on behalf of the beneficiary in a claims appeal, section 1869 applies. We only propose to waive the right of RO participants to avail themselves of the claims appeals process under section 1869 to the extent otherwise applicable.

f. Proposed Waiver of Amendments Made by Section 603 of the Bipartisan Budget Act of 2015

We believe that it is 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 propose 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 III.C.7. In addition, we would not apply the PFS relativity adjuster to the RO Model payment and would instead pay them in the same manner as other RO Model participants because the RO Model pricing methodology's design as described in Section III.C.6.c 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. We believe this waiver is necessary to allow for consistent model evaluation and ensure site neutrality in RO Model payments, which is a key feature of the RO Model.

We invite public comments on our proposed payment waivers.

11. Proposed Reconciliation Process

We propose to conduct an annual reconciliation for each RO participant after each PY to reconcile payments due to the RO participant with payments owed to CMS due to the withhold policies discussed in section III.C.6.g. The annual reconciliation would occur in August following a PY in order to allow time for claims run-out, data collection, reporting, and calculating results.⁶¹ For example, 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 believe that an annual reconciliation

⁶¹ Claims run-out is the period of time that CMS allows for the timely submission of claims by providers and suppliers before reconciliation.

is appropriate because incomplete episodes and duplicate RT services as described in section III.C.6.a may result in additional payment owed to a RO participant or owed to CMS for RT services furnished to a RO beneficiary in those cases.

a. Proposed True-Up Process

We propose to conduct an annual true-up of reconciliation for each PY, which would mean the process to calculate additional payments or repayments for incomplete episodes and duplicate RT services that are identified after claims run-out. More specifically, 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, and reducing potential confusion for RO participants. We would follow the same process each performance year. We would true-up the PY1 reconciliation approximately one year after the initial reconciliation proposed in § 512.285.section III.C.11. As a result, we would conduct a true-up of PY1 in August 2022, a true-up of PY2 in August 2023, and so forth.

We invite public comments on our proposed true-up process.

b. Proposed Reconciliation Amount Calculation

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

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

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

- For Professional participants during the Model's performance period: If the RO participant is a Professional participant, then we would add the Professional participant's incomplete episode reconciliation 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: If the RO participant is a Technical participant then the Technical participant's reconciliation amount would be equal to the incomplete episode reconciliation amount. There would be no further additions or subtractions.
- For Technical participants in PY3, PY4, and PY5: We would add the Technical participant's incomplete episode reconciliation amount to the patient experience reconciliation amount, proposed 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 would add the Dual participant's incorrect payment reconciliation 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 would add the Dual participant's incorrect payment reconciliation 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.

We invite public comment on our proposal on calculating reconciliation amounts.

Table 10 represents an example reconciliation for a Professional participant. The numbers listed in the table are illustrative only. In this example, the incorrect payment withhold amount for this Professional participant is \$6,000 or 2 percent of \$300,000 (the total payments for this participant after the trend factor, adjustments, and discount factor have been applied). The Professional participant owes CMS \$3,000 for duplicate payments due to claims submitted on behalf of beneficiaries who received RT services by another provider or supplier during their episode. Lastly, the Professional participant owes CMS \$1,500 for cases of incomplete episodes

whereby the PC of the episode was billed and due to death or other reason, the TC was not billed by the time of reconciliation. In this example, the payments for duplicate RT services and incomplete episodes would be subtracted from the incorrect payment withhold amount to render \$1500 due to the participant from CMS for the incorrect payment reconciliation amount (a). This amount is then added to the quality reconciliation amount (b). The quality withhold amount for this participant is also \$6,000 or 2 percent of \$300,000. This participant's performance on the AQS entitles 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 payment of \$6,600 total reconciliation payment (c) is due to the participant from CMS for that performance year. We note that this example does not include the geographic adjustment or the 2 percent adjustment for sequestration.

TABLE 10: EXAMPLE RECONCILIATION CALCULATION FOR A PROFESSIONAL PARTICIPANT

Professional participant	Formula	Example 1
Incorrect Payment Reconciliation Amount (a)		
<i>Incorrect Payment Withhold Amount (a₁)</i>	<i>a₁</i>	\$6,000
<i>Duplicate RT Services Adjustment (a₂)</i>	<i>a₂</i>	(\$3,000)
<i>Incomplete Billing Adjustment (a₃)</i>	<i>a₄</i>	(\$1,500)
Total (a ₁ + a ₂ + a ₃)	$a = a_1 + a_2 + a_3$	\$1500
Quality Reconciliation Amount (b)		
<i>Quality Withhold (b₁)</i>	<i>b₁</i>	\$6,000
<i>AQS (b₂)</i>	<i>b₂</i>	0.85
Product (b ₁ * b ₂)	$b = b_1 * b_2$	\$5,100
Total Payment/Recoupment (c)	$c = a + b$	\$6,600

12. Proposed Timely Error Notice and Reconsideration Request Processes

We believe it is 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 (proposed in section III.C.11), or AQS

(proposed in section III.C.8.f(1)) as reflected on a RO reconciliation report that has not been deemed final. Therefore, we are proposing 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 propose to 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 is 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 will 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 propose a two-level process for RO participants to request reconsideration of determinations related to calculation of their reconciliation payment, recoupment amount, or AQS under the RO Model. We propose the first level to be a timely error notice process and the second level to be reconsideration review process, as subsequently discussed. The processes proposed here are

based on the processes implemented under certain current models being tested by the Innovation Center.

We propose that only RO participants may utilize either the first or second level of the reconsideration process, unless otherwise stated in other sections of this proposed subpart. We believe that only RO participants should be able to utilize the proposed process because non-participants will not receive calculation of a reconciliation payment amount, repayment amount, or AQS, and will generally have access to the section 1869 claims appeals processes to appeal the payments they receive under the Medicare program.

1. Timely Error Notice

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 propose that the first level of the proposed reconsideration process would be a timely error notice. Specifically, we are proposing that RO participants could provide written notice to CMS of a suspected error in the calculation of their reconciliation payment amount, repayment amount, or AQS for which a determination has not yet been deemed to be final under the terms of this proposed part. The RO participant shall have 30 days from the date the RO reconciliation report is issued to provide their timely error notice. This would be subject to the limitations on administrative and judicial review as previously

described. Specifically, a 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 proposed § 512.290. We propose 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 propose that CMS 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 propose to codify this timely error notice policy at § 512.290(a).

2. Reconsideration Review

We propose that the second level of the proposed reconsideration process would permit RO participants to dispute CMS's response to the RO participant's identification of errors in the timely error notice, by requesting a reconsideration review by a CMS reconsideration official. As is the case for many models currently being tested by the Innovation Center, we propose that the CMS reconsideration official would 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. We are proposing that, to be considered, 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. We propose the reconsideration review request would be submitted in a form and manner specified by CMS.

As there would not otherwise be a timely error notice response for the reconsideration official to review, we are proposing that in order to access the reconsideration review process, a

RO participant must have timely submitted a timely error notice to CMS in the form and manner specified by CMS, and this timely error notice must not have been precluded from administrative and judicial review. Specifically, where the RO participant does not timely submit a timely error notice with respect to a particular reconciliation payment amount, repayment, recoupment amount, or AQS, we propose the reconsideration review process would not be available to the RO participant with regard 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.

If the RO participant did timely submit a timely error notice and the RO participant is dissatisfied with CMS's 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 propose that the reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment amount, repayment, recoupment amount, or AQS in accordance with the terms of the RO Model.

We propose that 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. 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 is the final step of the Innovation Center administrative dispute resolution process, we propose that the determination made by the CMS reconsideration official would be final and binding. This proposed reconsideration review process is consistent with other resolution processes used throughout the agency. We propose to codify this reconsideration review process at § 512.290(b).

We invite public comment on these proposed provisions regarding the proposed timely error notice and reconsideration review processes.

13. Proposed 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 previously described, 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 proposed model, including the model participant's participation in the proposed model,

which could then also be used to inform the public and other model participants regarding the impact of the proposed model on both program spending and the quality of care.

a. Data Privacy Compliance

In proposed § 512.275(a), we propose that, as a condition of their receipt of patient-identifiable data from CMS for purposes of the RO Model, RO participants must comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the RO Model and the terms of any agreement entered into by the RO participant and CMS as a condition of the RO participant receiving such data. These laws include, without limitation, the standards for the privacy of individually identifiable health information and the security standards for the protection of electronic protected health information under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). Additionally, we are proposing that RO participants would be required to contractually bind all downstream recipients of CMS data to comply with all laws pertaining to any patient-identifiable data requested from CMS and the terms of any agreement that the RO participant enters into with CMS as a condition of receiving the data under the RO Model, as a condition of the downstream recipient's receipt of the data from the RO participant and their maintenance thereof. We believe requiring RO participants to bind their downstream recipients in writing to comply with applicable law and requirements is necessary to protect the individually identifiable health information data that may be shared with RO participants by CMS for care redesign and care coordination purposes.

b. RO Participant Public Release of Patient De-Identified Information

We are not proposing to restrict RO participants' ability to publicly release patient de-

identified information that references the RO participant's participation in the RO Model. Information that RO participants may publicly release about their participation in the RO Model may include, but is not limited to, 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 that have been de-identified in accordance with HIPAA requirements in 45 CFR 164.514(b). In order to ensure external stakeholders understand that information the RO participant releases represents their own content and opinion, and does not reflect the input or opinions of CMS, we propose 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 propose to utilize the same disclaimer for public release of information by the RO participant that we propose to codify at § 512.120(c)(2) for purposes of descriptive model materials and activities: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views 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 are proposing 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.

c. Proposed Data Submitted by RO Participants

In addition to the quality measures and clinical data described in section III.C.8, we propose 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 a HOPD. We would require RO participants to

supply and/or confirm the NPIs for the physicians who bill for RT services using the applicable TINs. 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 propose 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 propose to do this through annual web-based surveys. The data requested for use under the RO Model will be used to better understand participants' office activities, benchmarks, and track participant compliance.

d. Proposed Data Provided to RO Participants

Thirty (30) days prior to the start of each PY, we propose to provide RO participants with updated participant-specific professional episode payment and technical episode payment amounts (for example, episode price files) 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 and 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 recoupment amount, as applicable. To seek such care coordination and quality improvement data RO participants should use a Participant Data Request and Attestation (DRA) form, which will be available on the RO Model website. 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 further propose 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 shall not 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, the RO participant would be required to make "reasonable efforts to limit" the information to the "minimum necessary" as defined by 45 CFR 164.500 through 164.534 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 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. We propose that 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 invite public comment on our proposals related to data sharing for the RO Model.

f. Access to Share Beneficiary Identifiable Data

As discussed earlier in this proposed 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 would 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, would 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 would 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/circulars_default) 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>). The RO participant would be required to acknowledge that the use of unsecured telecommunications, including insufficiently secured transmissions over the Internet, to transmit directly or indirectly identifiable information from the files specified in the DRA or any such derivative data files would be strictly prohibited. Further, the RO participant would be required to agree that the data specified in the DRA would not be physically moved, transmitted, or disclosed in any way from or by the site of the Data Custodian indicated in the DRA without written approval from CMS, unless such movement, transmission, or disclosure is required by a law. At the conclusion of the RO Model and reconciliation process, the RO participant would be required to destroy all data in its possession as agreed upon under the DRA.14. Proposed Monitoring and Compliance

If finalized, the general provisions relating to monitoring and compliance proposed 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 the 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). We believe that the general provisions relating to monitoring and compliance are 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 beneficiaries from potential harms that may result from the activities of a RO participant.

Consistent with § 512.150(b), we anticipate that monitoring activities may include documentation requests sent to RO participants and individual practitioners on the individual practitioner list; audits of claims data, quality measures, medical records, and other data from RO participants and clinicians on the individual practitioner list; interviews with members of the staff and leadership of the RO participant and clinicians on the individual practitioner list; interviews with beneficiaries and their caregivers; monitoring quality outcomes; site visits; monitoring quality outcomes and clinical data, if applicable; and tracking patient complaints and appeals. We anticipate using the most recent claims data available to track utilization as described in section III.C.7, and beneficiary outcomes under the Model. More specifically, we may 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. We believe this type of monitoring is important because as RO participants transition from receiving FFS payment to receiving new (episode-based) payment, we want

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 may 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. This work may involve pairing clinical data with claims data to identify specific issues by cancer type.

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

We would monitor RO participants for compliance with RO Model requirements. We anticipate 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 randomly selected CBSA). We anticipate 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 intend to monitor patient and provider/supplier characteristics, such as variations in size, profit status, and episode utilization patterns, over time to detect changes that might suggest attempts at such manipulation.

To allow us to conduct this monitoring, RO participants would report data on program activities and beneficiaries consistent with the data collection policies proposed in section III.C.8. These data would be analyzed by CMS or 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 would 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 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.

We invite public comment on our proposal.

b. Proposed Monitoring for Model Compliance

As explained in section III.C.9, we propose to require all participants to annually attest in a form and manner specified by CMS that they would use CEHRT throughout such PY in a manner sufficient to meet the requirements as set forth in 42 CFR 414.1415(a)(1)(i). In addition, we further propose that each Technical participant and Dual participant would be required to attest annually that it actively participates in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). This attestation would be required to ensure compliance with this RO Model requirement. CMS may change these intervals throughout the Model upon advanced written notice to the RO participants. We propose to codify these RO Model requirements at § 512.220(a)(3). We note that CMS may monitor the accuracy of such attestations and that false attestations would be punishable under applicable federal law.

In addition, we would monitor for compliance with the other RO Model requirements listed in this section through site visits and medical record audits conducted in accordance with § 512.150. We propose to codify at § 512.220(a)(2) to require that all Professional participants and Dual participants document in the medical record that the participant: (i) has discussed goals of care with each RO beneficiary before initiating treatment and communicated to the RO beneficiary whether the treatment intent is curative or palliative; (ii) adheres to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or document in the medical record the rationale for the departure from these guidelines; (iii) assesses the RO beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnoses; (iv) assesses the RO beneficiary's performance status as a quantitative measure determined by the physician; (v) sends a treatment summary to each RO beneficiary's referring physician within three months of the end of treatment to coordinate care; (vi) discusses with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and (vii) performs and documents Peer Review (audit and feedback on treatment plans) for 50 percent of new patients in PY1, for 55 percent of new patients in PY2, for 60 percent of new patients in PY3, for 65 percent of new patients in PY4, and for 70 percent of new patients in PY5 preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment.

We invite public comment on this proposal.

c. Proposed Performance Feedback

We propose to provide detailed and actionable information regarding RO participant performance related to the RO Model. We intend to leverage the clinical data to be collected

through the model-specific data collection system, 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 believe these reports can drive important conversations and support quality improvement progress. The design of and frequency that these reports would be provided to participants would be determined in conjunction with the RO Model implementation and monitoring contractor.

We invite public comment on our proposal.

d. Proposed Remedial Action for Non-Compliance

We refer readers to section II.J of this proposed rule for our proposals regarding remedial and administrative action.

15. Beneficiary Protections

We propose to require Professional participants and Dual participants to notify RO beneficiaries that the RO participant is participating in this RO Model by providing written notice to each RO beneficiary during the RO beneficiary's initial treatment planning session. We intend 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 a 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 data shared 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 beneficiary notifies the RO participant.

We believe it would 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. We propose that the required RO Model beneficiary notice be exempt from the requirement at § 512.120(c)(2) and in section II.D.3 of this part, which requires that the model participant include a disclaimer statement on all descriptive model materials and activities 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.” We believe that such statement should not apply to the proposed RO Model beneficiary notice, because RO participants would be required to use standardized language developed by CMS. We propose these policies at § 512.225(c).

If beneficiaries have any questions or concern with their physicians, we encourage 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://qioprogram.org/beneficiary-and-family-centered-care-national-coordinating-center>).

We invite public comment on the proposed beneficiary protections.

16. Proposed Evaluation

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.

Our evaluation would focus primarily on understanding how successful the Model is in achieving improved quality and reduced expenditures as evidenced by changes in RT utilization

patterns (including the number of fractions and types of RT), RT costs for Medicare FFS beneficiaries in the RO Model (including Medicare-Medicaid dually eligible beneficiaries), changes in utilization and costs with other services that may be affected as a result of the RO Model (such as emergency department services, imaging, prescription drugs, and inpatient hospital care), performance on clinical care process measures (such as adhering to evidence-based guidelines), patient experience of care, and provider experience of care. 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, 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.

In addition to assessing the impact of the Model in achieving improved quality and reduced Medicare expenditures, the evaluation is likely to address questions that include (but would 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 CMMI models or CMS/non-CMS initiatives and how could they impact the evaluation findings?

CMS anticipates that the evaluation would include a difference-in-differences⁶² or similar analytic approach to estimate model effects. 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 selected CBSA geographic areas, as discussed in section III.C.3.d, would have been randomly assigned for the duration of the evaluation, allowing us to use scientifically rigorous methods for evaluating the effect of the Model.

We refer readers to section II.E of this proposed rule for our proposed policy on RO participant cooperation with the RO Model's evaluation and monitoring policies. We invite public comment on our proposed approach related to the evaluation of the RO Model.

17. Termination of the RO Model

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

⁶² 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.

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

Programs

a. Overview

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. We believe 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 expect that there would be situations where a Medicare beneficiary in a 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 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. Currently, 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 section 1115A of the Act or the Medicare Shared Savings Program (Shared Savings Program) under section 1899 of the Act. If, in the future, we determine that such adjustments are necessary, we would propose overlap policies for the RO Model through notice and comment rulemaking.

b. Accountable Care Organizations (ACOs)

We believe there would be potential overlap between the proposed 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.⁶³ We believe 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 believe 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 withholdings in the RO Model, it is difficult to determine the level of potential overlap at this time. It is also difficult to determine how many aligned ACO beneficiaries would require RT services or if those beneficiaries would seek care from a RO participant. Given that the RO Model is expected to reduce Medicare spending in aggregate, we anticipate that in most cases payments under the RO Model would be less than what Medicare would have paid outside the Model. It is possible, however, 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 expect overall payments for RT services to be lower

⁶³ The statutory limitation under § 1899(b)(4)(A) 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.

than they would be absent the Model, we want to ensure that a significant proportion of the RO Model discounts, which represent Medicare savings, would not be paid out as shared savings.

Due to these factors, we intend 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 these calculations that might be necessary due to the overlap with the RO Model would be made using the applicable ACO initiative procedures.

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 expect that there would 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).

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 proposed in section III.C.7, the RO Model would 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 only includes RT services in the episode payment. Since the RO Model makes prospective payments for only the RT services provided during an episode, a practice participating in the RO Model would receive the same prospective episode payment for RT services regardless of its participation in OCM.

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. 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 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 propose 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, again based on the number of days of overlap with the OCM episode. 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 would assume that all withhold amounts are eventually paid to the RO Participant under the RO Model, and that there are no payments to recoup. 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 intend to continue to review the potential overlap with OCM if the RO Model is finalized as proposed, including whether there are implications for OCM's prediction model for setting risk-adjusted target episode prices, which include receipt of RT services. 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.

d. Bundled Payments for Care Improvement (BPCI) Advanced

BPCI Advanced is testing a new iteration of bundled payments for 37 clinical episodes (33 inpatient and 4 outpatient).⁶⁴ BPCI Advanced 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 BPCI Advanced, a beneficiary in a RO episode could be treated by a provider or supplier that is participating in BPCI Advanced for one of the 37 clinical episodes included in BPCI Advanced. Since prospective episode payments made under the RO Model would not be affected by BPCI Advanced, BPCI Advanced would determine whether to account for RO Model overlap in its reconciliation calculations, and CMS would provide further information to BPCI Advanced participants through an amendment to their participation agreement.

19. Decision Not to Include a Hardship Exemption

We do not believe that a hardship exemption for RO participants under the Model is necessary, since in 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

⁶⁴ 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.

the proposed efficiency factor in section III.C.6.e(2) is 0.90 for all RO participants. Accordingly, we are not proposing such an exemption in this proposed rule, and will not include such an exemption in the final rule in this rulemaking.

However, to the extent any stakeholders disagree with our assessment, we welcome 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. We intend to use any input we receive on this issue to consider whether a hardship exemption might be appropriate in subsequent rulemaking for a future PY.

IV. End-Stage Renal Disease (ESRD) Treatment Choices Model

A. Introduction

The proposed End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, referred to in this section IV of the proposed rule as “the Model,” would test whether adjusting the current Medicare fee-for-service (FFS) payments for dialysis services would 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 and kidney-pancreas 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.⁶⁵ In the proposed ETC Model, CMS would 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 would include an upward adjustment on home dialysis and home dialysis-related claims with claim through dates during the initial three years of the ETC Model, that is, between January 1, 2020 and December 31, 2022. In addition, we would make an upward or downward performance adjustment on all dialysis claims and dialysis-related claims with claim through dates between July 1, 2021 and June 30, 2026,

⁶⁵ 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.

depending on the rates of home dialysis utilization and kidney and kidney-pancreas transplantation among the beneficiaries attributed to these participating ESRD facilities and Managing Clinicians. The ETC Model would 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 Proposed ESRD Treatment Choices Model

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 Medicare spending.⁶⁶ Beneficiaries with ESRD face the need for coordinating treatment for many disease complications and comorbidities, while experiencing 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.^{67, 68}

ESRD is a uniquely burdensome condition; with uncertain survival, patient experience represents a critical dimension for assessing treatment. The substantially higher expenditures

⁶⁶ Kirchoff SM. Medicare Coverage of End-Stage Renal Disease (ESRD). Congressional Research Service. August 16, 2018. p. 1

⁶⁷ 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>

⁶⁸ 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

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 proposed ETC Model would 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.

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.⁶⁹ Among HD cases, 98.0 percent used in-center HD, and 2.0 percent used home hemodialysis (HHD).⁷⁰ PD is rarely conducted within a facility. In section IV.B.2 of this proposed rule, we describe how current Medicare payment rules and a lack of beneficiary education result in a bias toward in-center HD, which is often not preferred by patients or practitioners. In proposing the ETC Model, we aim to test whether new payment incentives would lead to greater rates of home dialysis (both PD and HHD) and kidney transplantation. 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.

a. Home Dialysis

⁶⁹ 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

⁷⁰ 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

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 proposed ETC Model, 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.^{71,72}

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.⁷³ 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 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.⁷⁴

⁷¹ 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

⁷² 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

⁷³ Blagg CR. A Brief History of Home Hemodialysis. *Annals in Renal Replacement Therapy*. 1996; 3: 99-105

⁷⁴ United States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO-16-125). October 2015

Additionally, 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 of home dialysis is significantly below those of Hong Kong (74 percent), New Zealand (47 percent), Australia (28 percent), and Canada (25 percent).⁷⁵

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

⁷⁵ United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 11: International Comparisons. Figure F11.12

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 notes that dialysis providers differ in many ways and have different experiences that deserve attention and consideration with regard to potentially posing a barrier to the provision of home dialysis.⁷⁶

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 CKD beneficiaries, built-up capacity at ESRD facilities, and a lack of infrastructure to support home dialysis.⁷⁷ (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.⁷⁸ 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 chronic kidney disease (CKD) stages III to V enrolled in a North American cohort study showed that as

⁷⁶ 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

⁷⁷ 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

⁷⁸ Finkelstein FO, Story K, Firaneck 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>

many as 85 percent were medically eligible for PD.⁷⁹ 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 patients were presented with HHD as an option.⁸⁰ 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.⁸¹ Another study reported 42 percent of patients preferring PD when the option was presented to them.⁸²

Recent studies show substantial support among nephrologists and patients for dialysis treatment at home.^{83, 84, 85, 86, 87} 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.

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

⁷⁹ Mendelsohn 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>

⁸⁰ 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

⁸¹ 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

⁸² 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

⁸³ 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

⁸⁴ 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.

⁸⁵ Ghaffari et al. 2013

⁸⁶ 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

⁸⁷ Schiller B, Neitzer A, Doss S. Perceptions about renal replacement therapy among nephrology professionals. *Nephrology News & Issues*. September 2010; 36-44

hospitalizations, cost differentials between PD and HD services and supplies, and lower operating costs for dialysis providers for providing home dialysis.^{88, 89, 90, 91, 92} (Most studies on the comparative cost and effectiveness of different dialysis modalities assess PD versus HD. 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, 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.⁹³ Despite selection bias present in existing research, we expect 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, if finalized.

⁸⁸ Walker R, Marshall MR, Morton RL, McFarlane P, Howard K. The cost-effectiveness of contemporary home haemodialysis modalities compared with facility haemodialysis: A systematic review of full economic evaluations. *Nephrology*. 2014; 19: 459-470 doi: 10.1111/nep.12269

⁸⁹ 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.

⁹⁰ 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

⁹¹ Quinn R, Ravani P, Zhang X, Garg A, Blake P, Austin P, Zacharias JM, Johnson JF, Padeya S, Verrel 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

⁹² 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

⁹³ United States Renal Data System, Annual Data Report, 2018. Volume 2, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. Table 1.

In addition, current research on patients in the U.S. and Canada indicates similar, or better, patient survival outcomes for PD compared to HD.^{94, 95, 96} (As previously noted, most research on the comparative effectiveness of different dialysis modalities compares PD to HD, but 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.⁹⁷ Therefore, 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, 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

⁹⁴ 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

⁹⁵ 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

⁹⁶ Mehrotra et al. 2011

⁹⁷ 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.

there is sufficient statistical power to detect meaningful variation.^{98, 99, 100, 101, 102, 103, 104} Patient benefits of HHD and PD also can include better quality of life and greater independence.^{105, 106, 107} As described in greater detail throughout this section IV of this proposed rule, one of the aims of the proposed ETC Model is to test whether new payment incentives would lead to greater rates of home dialysis.

b. Kidney Transplants

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-pancreas transplant may come from a living or deceased donor, the pancreas can only come from a deceased donor. Candidates for kidney transplant undergo a rigorous evaluation by a transplant center prior to placement on a waitlist, and once placed on the

⁹⁸ 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>

⁹⁹ 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/gfr674>

¹⁰⁰ 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.semephrol.2011.01.004

¹⁰¹ Mehrotra et al. 2011

¹⁰² Sinnakirouchenan R, Holley JL. 2011

¹⁰³ 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

¹⁰⁴ 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

¹⁰⁵ Ghaffari et al. 2013

¹⁰⁶ Rivara and Mehrotra. 2014

¹⁰⁷ 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 Lives. Clinical Journal of American Society of Nephrology. 2006; 1(6): 1191-1196. DOI: <https://doi.org/10.2215/CJN.01220406>

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.

A systematic review of studies worldwide finds significantly lower mortality and risk of cardiovascular events associated with kidney transplantation compared with maintenance dialysis.¹⁰⁸ Additionally, this review finds that beneficiaries who receive transplants experience a better quality of life than treatment with chronic dialysis.¹⁰⁹

Per-beneficiary-per-year Medicare expenditures for beneficiaries receiving kidney or kidney-pancreas transplants are often substantially lower than for those on dialysis.¹¹⁰ 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.¹¹¹ Among transplant recipients, there are a lower rates of hospitalizations, emergency department visits, and readmissions.¹¹² 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.

¹⁰⁸ 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>

¹⁰⁹ Tonelli, M. et al. 2011

¹¹⁰ United States Renal Data System. Annual Data Report, 2018. Volume 2. Chapter 9: Healthcare expenditures for Persons with ESRD. Figure F9.8

¹¹¹ 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

¹¹² 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

Notwithstanding these outcomes, 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 transplant in 2016.¹¹³ 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 2016.¹¹⁴ 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, there are other likely contributing causes, such as differences in health care systems, the infrastructure supporting transplantation, and cultural factors.¹¹⁵

The main barrier to kidney transplant is the supply of available organs. Medicare is undertaking regulatory efforts to increase organ supply, discussed in section IV.B.3.a of this proposed rule. Further, 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.¹¹⁶ We anticipate that Managing Clinicians and ESRD facilities selected for participation in the

¹¹³ 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

¹¹⁴ United States Renal Data System. Annual Data Report, 2018. Volume 2. Chapter 11. International Comparisons. Figure 11.16

¹¹⁵ United States Renal Data System. Annual Data Report, 2018: Volume 2. Chapter 11. International Comparisons. https://www.usrds.org/2018/view/v2_11.aspx

¹¹⁶ 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

proposed ETC Model would address these areas of improvement through various strategies in order to improve their rates of transplantation. 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.¹¹⁷

After increasing during the 1990s, the volume of simultaneous pancreas and kidney transplants has either remained stable or declined slightly since the early 2000s. 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.¹¹⁸

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. Whereas a Managing

¹¹⁷ 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

¹¹⁸ Redfield RR, Scalea JR, Odorico 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

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 throughout this section IV of this proposed rule, one of the aims of the proposed ETC Model is to test whether new payment incentives would lead to greater rates of kidney transplantation.

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 propose 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 propose 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. 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 propose 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. One or both of the payment adjustments under the proposed 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.

2. The Medicare ESRD Program

In this section, 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 Social Security Act (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.

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).

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

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, and a transitional drug add-on payment adjustment (TDAPA). 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.

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 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).

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 may 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

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.¹¹⁹

(3) The Kidney Disease Education Benefit

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. 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.¹²⁰ 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. 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. Also, a provider of services located in a rural area is eligible as a "qualified person" to provide

¹¹⁹ Medicare Claims Processing Manual, Chapter 8, 140; <https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf>

¹²⁰ United States Government Accountability Office. 2015

the service. GAO cited literature emphasizing the importance of pre-dialysis 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

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).

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 2012.¹²¹ 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.

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.

¹²¹ United States Government Accountability Office, 2015

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.¹²²

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.¹²³

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 appropriate. A specific recommendation was to examine Medicare policies regarding monthly

¹²² United States Government Accountability Office, 2015

¹²³ United States Government Accountability Office, 2015

Medicare payments to physicians and revise them if necessary to encourage physicians to prescribe home dialysis for patients for whom it is appropriate.¹²⁴

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. The proposed ETC Model is consistent with several different recent actions to support the goal of modality choice for ESRD beneficiaries, which are described in this proposed rule.

a. Regulatory Efforts

On September 20, 2018, CMS 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). The proposed rule would, among other things, remove the requirements at 42 CFR 482.82 that currently require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. CMS proposed to remove these requirements in order to address unintended consequences of existing requirements, which have resulted in transplant programs 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. According to the proposed rule, transplant programs have avoided using these kidneys for fear of non-compliance with the Conditions of Participation for transplant centers in hospitals (§§

¹²⁴ United States Government Accountability Office. 2015

482.80 and 482.82) and potential Medicare termination of the program, despite evidence to the contrary that the use of these kidneys would not pose a problem for transplant recipients.

Although CMS proposed to remove 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. CMS stated that the agency will continue to monitor and assess outcomes, after initial Medicare approval. (83 FR 47706)

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. 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). 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 waitlisting 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. 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 year 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.¹²⁵ Although the evaluation results available for the CEC Model thus far are limited, 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 four voluntary kidney models: the Kidney Care First (KCF) Model, and three Comprehensive Kidney Care Contracting (CKCC) Models. These models build on the existing CEC Model, and include incentives for coordinating care for aligned beneficiaries with CKD or ESRD and for reducing the total cost of care for these beneficiaries, as well as providing financial incentives for successful transplants. We view the KCF Model and the CKCC Models as complementary to the proposed ETC Model, as both models would incentivize a greater focus on kidney transplants. We propose that ESRD facilities and Managing Clinicians may participate in both the ETC Model and either the KCF Model or one of the CKCC Models, as discussed in section IV.C.6. of this proposed rule.

¹²⁵ Marrufo G, et al. Comprehensive End-Stage Renal Disease Care (CEC) Model: Performance Year 1 Annual Evaluation Report. CMS Innovation Center. November 2017; innovation.cms.gov/Files/reports/cec-annrpt-py1.pdf.

C. Provisions of the Proposed Regulation

1. Proposal to Implement the ETC Model

In this section IV of the proposed rule, we propose our policies for the ETC Model, including model-specific definitions and the general framework for implementation of the ETC Model. The proposed payment adjustments are 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 acknowledge 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 recognize 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.

As previously described, 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. If the ETC Model were to begin April 1, 2020, all intervals within the currently proposed timelines, 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 3 months later. We seek comment on the alternative start date,

April 1, 2020, and the subsequent three month adjustment to all ETC Model dates, including the implementation of the HDPA and PPA.

We are also including 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 propose 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 proposed rule and each of the proposed regulatory provisions under the applicable subject area later. Section II of this proposed rule proposes that the general provisions proposed to be codified at §§ 512.100 through 512.180 would apply to both the proposed ETC Model and the proposed RO Model described in section III of this proposed rule.

2. Definitions

We propose at § 512.310 to define certain terms for the ETC Model. We describe these proposed definitions in context throughout this section IV of this proposed rule. We seek comment on the proposed definitions as a part of our seeking comment on the proposed policies for the ETC Model. If finalized, the definitions proposed in section II of this proposed rule also would apply to the ETC Model.

3. ETC Participants

a. Mandatory Participation

We propose to require all Managing Clinicians and all ESRD facilities located in selected geographic areas to participate in the ETC Model. We propose to define “selected geographic area(s)” as those Hospital Referral Regions (HRRs) selected by CMS, as described in section IV.C.3.b of this proposed 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 section IV.C.3.b of the proposed rule.

For purposes of the ETC Model, we propose to define “ESRD facility” as defined in 42 CFR 413.171. 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 propose 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, 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 propose 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. 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, analyses of claims data revealed that a variety of

clinician specialty types manage ESRD beneficiaries and bill the MCP, including non-physician practitioners. We 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.

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 the KCF Model, and the CKCC Models, 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, 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. 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 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, 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 greater detail elsewhere in this section IV of the proposed rule, we propose 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 propose 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 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. 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.

We invite public comments on our proposal for mandatory participation, as well as our proposal to select ETC Participants based on their location in a selected geographic area.

b. Selected Geographic Areas

We propose 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 believe that geographic areas would 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 section **IV.C.11** of this proposed rule. Specifically, by using geographic areas as the unit for randomized selection, we would 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 proposed 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 aim to include in the Model approximately 50 percent of adult ESRD beneficiaries. To achieve this goal, we propose 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, if finalized); 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, we believe a broad geographic distribution of participants would be necessary to effectively test the impact of the proposed payment adjustments.

We propose 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 propose 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 believe there would be a sufficient number of HRRs to support random selection and improve statistical power of the proposed Model’s evaluation. 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) forecasts an average increase of 1.5 percentage points per year. With a current home dialysis rate of 8.6 percent,¹²⁶ this represents an 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 basis¹²⁷, 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

¹²⁶ 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

¹²⁷ United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 6: Transplantation. https://www.usrds.org/2018/view/v2_06.aspx

HRRs in the US. 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.

We considered using Core Based Statistical Areas (CBSAs) or Metropolitan Statistical Areas (MSAs) as the geographic unit of selection. However, 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.

We also considered using counties or states as the geographic unit of selection. However, 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 model test 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. 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. In the alternative, we would consider using CBSAs as the geographic unit of selection, and assigning rural counties not included in CBSAs to the nearest CBSA, as this approach would use an existing methodology already used by CMS to denote regions (CBSAs, which are used, among other things, in determining the wage index adjustments to Medicare inpatient prospective payment system rates to account for variation in hospital wages and wage-related costs related to location), while also making sure that a random selection of providers and suppliers located in rural areas are included as participants in the ETC Model.

We propose 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://www.census.gov/geo/reference/gtc/gtc_census_divreg.html. 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 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 propose that the U.S. Territories, as that term is proposed to be defined in section II of this proposed rule, would be excluded from selection, as HRRs are not constructed to include these areas.

In addition, outside of the randomization, we propose 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. 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. We believe that adding Maryland-based ESRD facilities and Managing Clinicians as participants in the proposed ETC Model would assist the state of Maryland and hospitals located in that state to meet the Medicare TCOC targets established under the Maryland TCOC Model.

We propose that all HRRs that are not selected geographic areas would be referred to as “comparison geographic area(s).” We propose that comparison geographic areas would be used for the purposes of constructing performance benchmarks (as discussed in section IV.C.5.d of this proposed rule), and for the Model evaluation (as discussed in section IV.C.11 of this proposed rule).

We invite public comments on our proposal to use HRRs as the geographic unit of selection, with regional stratification, and to exclude U.S. Territories from the selected geographic areas. We invite comment on our alternative consideration to use CBSAs as the geographic unit of selection, and assign rural counties not included in CBSAs to the nearest

CBSA. We also invite comment on the inclusion of all HRRs for which at least 20 percent of the component zip codes are located in Maryland, separate from the randomization, as well as whether HRRs that include areas included in the Pennsylvania Rural Health Model, the Vermont All-Payer ACO Model, or future state-based models tested under section 1115A of the Act should also be selected geographic areas for purposes of the ETC Model.

c. Participant Selection for the ETC Model

We propose to define “ETC Participant” as an ESRD facility or Managing Clinician that is required to participate in the ETC Model in accordance with proposed § 512.325(a), which describes the selection of model participants based on their location within a selected geographic area, as previously described. In addition, we note that the proposed definition of “model participant,” as defined in section II of this proposed rule, would include an ETC Participant.

(1) ESRD Facilities

We propose that all Medicare-certified ESRD facilities located in a selected geographic area would be required to participate in the ETC Model. We propose 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.

We invite public comment on this proposal for identifying where ESRD facilities are located for purposes of selecting ESRD facilities for participation in the ETC Model.

(2) Managing Clinicians

We propose that all Medicare-enrolled Managing Clinicians located in a selected geographic area would be required to participate in the ETC Model. We propose to identify 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 would use the practice location through which the Managing Clinician bills the plurality of his or her MCP claims. We considered using the zip code of the mailing address listed in PECOS. However, 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.

We invite public comment on this proposal for identifying where Managing Clinicians are located for purposes of selecting Managing Clinicians for participation in the ETC Model.

4. Home Dialysis Payment Adjustment

We propose 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 2020 – CY 2022). 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 section IV.C.5 of this proposed rule, which would begin in mid-CY 2021 and increase in magnitude over the duration of the Model; as such we propose 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 propose 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 proposed § 512.345 (Payments Subject to the Clinician HDPA) and § 512.350 (Schedule of

Home Dialysis Payment Adjustments). We propose to define the “Facility HDPA” as 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 proposed § 512.340 (Payments Subject to the Facility HDPA) and § 512.350 (Schedule of Home Dialysis Payment Adjustments). We propose to define the “HDPA” as either the Facility HDPA or the Clinician HDPA. 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 propose to implement a 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 proposed rule.

a. Payments Subject to the HDPA

We propose that the HDPA would apply to all ETC Participants for those payments described in sections IV.C.4.b and IV.C.4.c of this proposed rule, according to the proposed schedule described in section IV.C.4.d of this proposed rule. We solicit comment on the proposal to apply the HDPA with respect to all ETC Participants, without exceptions.

We also propose that the HDPA would apply to claims where Medicare is the secondary payer for coverage under section 1862(b)(1)(C) of the Act. 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 propose 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. 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 seek comment on the proposal to apply the HDPA to Medicare as secondary payer claims.

b. Facility HDPA

For ESRD facilities that are ETC Participants, we propose to adjust Medicare payments under the ESRD PPS for home dialysis services by the HDPA according to the proposed schedule described in section IV.C.4.d of this proposed rule. As noted previously, under the ESRD PPS, a single per treatment payment is made to an ESRD facility for all renal dialysis services and 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. The current formula for determining the final ESRD PPS per treatment payment amount is as follows:

Final ESRD PPS Per Treatment Payment Amount

$$= (\text{Adjusted ESRD PPS Base Rate} + \text{Training Add On} + \text{TDAPA})$$

$$* \text{ESRD QIP Factor} + \text{Outlier Payment} * \text{ESRD QIP Factor}$$

Under our proposal, we would 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 propose 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. 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

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

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 seek comment on our proposed definition of the 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.

We propose 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 section IV.C.4.d of this proposed rule, where the beneficiary is age 18 or older during the entire month of the claim. 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. 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. Taken together, we believe these condition codes capture home dialysis services furnished by ESRD facilities, and therefore are the codes we propose to use to identify those payments subject to the Facility HDPA. We seek comment on this proposed provision.

As further described in section IV.C.7.a of this proposed rule, we also propose 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.

c. Clinician HDPA

For Managing Clinicians that are ETC Participants, we propose to adjust the MCP by the Clinician HDPA when billed for home dialysis services. We propose 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, 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 proposed ETC Model.

We propose in § 512.345 to adjust the amount otherwise paid under 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 through date during a CY subject to adjustment, as described in section IV.C.4.d of this proposed rule, where the beneficiary is age 18 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 propose to use to identify those payments subject to the HDPA. As noted previously, we propose 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. We seek comment on this proposed provision.

d. HDPA Schedule and Magnitude

We propose in new § 512.350 that the magnitude of the HDPA would decrease over the CYs 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. 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. 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. 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 propose 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 seek input from the public about the proposed magnitude and duration of the proposed HDPA.

5. Performance Payment Adjustment

We propose 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 section IV.C.5.d of this proposed rule. We propose 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 proposed § 512.370(d) (Modality Performance Score), which is used to determine the amount of the ETC Participant’s PPA, as described in proposed § 512.380 (PPA Amounts and Schedule). We seek comment on the composition of the MPS, particularly the inclusion of the transplant rate in the MPS.

There would be two types of PPAs: the Clinician PPA and the Facility PPA. We propose 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 proposed § 512.375(b) (Payments Subject to Adjustment) and proposed § 512.380 (PPA Amounts and Schedule). We propose 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 proposed § 512.375(a) (Payments Subject to Adjustment) and proposed § 512.380 (PPA Amounts and Schedule). We propose to define the “PPA” as either the Facility PPA or the Clinician PPA.

a. Annual Schedule of Performance Assessment and PPA

We propose to assess ETC Participant performance on the home dialysis rate and the transplant rate, described in sections IV.C.5.c.1 and IV.C.5.c.2 respectively, of this proposed rule, and to make corresponding payment adjustments according to the proposed schedule described later. We propose 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 propose 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 propose 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 propose to define "Performance Payment Adjustment Period (PPA Period)" as the 6-month period during which a PPA is applied in accordance with proposed § 512.380 (PPA Amounts and Schedule). Each MY included in the ETC Model and its corresponding PPA Period would be specified in proposed § 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. 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 MY 2, there would be a 6-month period of overlap between a MY and the previous MY. For example, MY 1 would begin January 1, 2020, and would run through December 31, 2020; and MY 2 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. For example, MY 1, which would end December 31, 2020, would correspond to PPA Period 1, which would begin July 1, 2021, and end December 31, 2021.

In Table 12, we propose the following schedule of MYs and PPA Periods:

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

	Measurement Year (MY)		Performance Payment Adjustment (PPA) Period	
Beginning CY 2020	MY 1	1/1/2020 through 12/31/2020	PPA Period 1	7/1/2021 through 12/31/2021
	MY 2	7/1/2020 through 6/30/2021	PPA Period 2	1/1/2022 through 6/30/2022
Beginning CY 2021	MY 3	1/1/2021 through 12/31/2021	PPA Period 3	7/1/2022 through 12/31/2022

	MY 4	7/1/2021 through 6/30/2022	PPA Period 4	1/1/2023 through 6/30/2023
Beginning CY 2022	MY 5	1/1/2022 through 12/31/2022	PPA Period 5	7/1/2023 through 12/31/2023
	MY 6	7/1/2022 through 6/30/2023	PPA Period 6	1/1/2024 through 6/30/2024
Beginning CY 2023	MY 7	1/1/2023 through 12/31/2023	PPA Period 7	7/1/2024 through 12/31/2024
	MY 8	7/1/2023 through 6/30/2024	PPA Period 8	1/1/2025 through 6/30/2025
Beginning CY 2024	MY 9	1/1/2024 through 12/31/2024	PPA Period 9	7/1/2025 through 12/31/2025
	MY 10	7/1/2024 through 6/30/2025	PPA Period 10	1/1/2026 through 6/30/2026

We invite public comment on the proposed schedule of MYs and corresponding PPA Periods.

b. Beneficiary Population and Attribution

We propose 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 propose 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. 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 propose to attribute pre-emptive transplant beneficiaries to Managing Clinicians for purposes of calculating the transplant rate, specifically. We propose to define a “pre-emptive transplant beneficiary” as a Medicare beneficiary who received a kidney or kidney-pancreas transplant prior to beginning dialysis. 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. 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. 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 are proposing to limit the definition of pre-emptive transplant beneficiary to include Medicare beneficiaries only.

We propose to attribute ESRD Beneficiaries, and pre-emptive transplant beneficiaries where applicable, to ETC Participants for each month of each MY, and we further propose that such attribution would be made after the end of each MY. We considered attributing beneficiaries to participating ESRD facilities and Managing Clinicians for the entire MY; however, 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 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. A pre-emptive transplant beneficiary may be attributed to only one Managing Clinician during a MY, regardless of the number of months for which the beneficiary is attributed to the Managing Clinician.

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. In this case, we 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 believe that prospective attribution would not work well for the particular design of this Model. In particular, 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. 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 invite public comment on the proposal to attribute beneficiaries on a monthly basis after the end of the relevant MY.

We propose to provide ETC Participants lists of their attributed beneficiaries after attribution has occurred, after the end of the MY. 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, 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.

(1) Beneficiary Exclusions

We propose to exclude certain categories of beneficiaries from attribution to ETC Participants, consistent with other CMS models and programs. Specifically, we are proposing 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 dialysis for acute kidney injury (AKI) only, 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.

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 could not ascertain a consensus in the literature that supported any specific age cut-off. We also considered excluding beneficiaries with housing insecurity from attribution for the purposes of calculating the home dialysis rate, but could not find an objective way to measure housing instability.

We invite public comment on the proposed exclusions from beneficiary attribution under the ETC Model, including criteria according to which dementia should be assessed, as well as any others, for example, physical or functional limitations, on the basis of which beneficiaries should be excluded from attribution. We also seek comments as to whether we should exclude beneficiaries over a specific age threshold, and whether there is an objective measure we could use for housing insecurity.

(2) Attribution Services

(a) Attribution to ESRD Facilities

We propose 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 propose 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. 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 propose that the ESRD Beneficiary would be attributed to the ESRD facility at which the beneficiary received the earliest dialysis treatment that month.

We propose 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 alternative, we considered 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. We do, 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. We note that this proposed policy is consistent with the CEC Model.

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. Additionally, we 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 proposed Model.

We propose 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.

We seek comment on the proposed methodology for attributing ESRD Beneficiaries to ESRD facilities and the alternatives considered, as well as our proposal not to attribute pre-emptive transplant beneficiaries to ESRD facilities.

(b) Attribution to Managing Clinicians

We propose 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.¹²⁸ Therefore, 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 propose 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). 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 would also attribute pre-emptive transplant beneficiaries to Managing Clinicians. Because pre-emptive transplant

¹²⁸ Medicare Claims Processing Manual, Chapter 8; <https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104.c08.pdf>

beneficiaries have not started dialysis at the time of their transplant, we would not be able to attribute them to Managing Clinicians based on MCP claims, as we would for ESRD Beneficiaries. Rather, we propose that pre-emptive transplant beneficiaries would be attributed to a Managing Clinician based on the Managing Clinician with whom the beneficiary had the most claims 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. 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.

We seek comment on the proposed methodology for attributing ESRD Beneficiaries and pre-emptive transplant beneficiaries to Managing Clinicians and the alternatives considered.

c. Performance Measurement

We propose 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. 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, CMS also proposes 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. 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, we believe basing the rates on claims data, supplemented with Medicare administrative data about beneficiary enrollment and transplant registry data about transplant occurrences, would 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 solicit 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.

(1) Home Dialysis Rate

We propose 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 propose to construct the home dialysis rate for ETC Participants that are ESRD facilities as described in section IV.C.5.c.1.a of this proposed rule and for ETC Participants who are Managing Clinicians as described in section IV.C.5.c.1.b of this proposed rule.

We solicit comment on our proposed methodology for assessing home dialysis rates for ESRD facilities and Managing Clinicians that are ETC Participants, as well as alternative methodologies for assessing home dialysis rates. We describe later our proposed plan for risk adjusting and reliability adjusting these rates.

(a) Home Dialysis Rate for ESRD Facilities

Under our proposal, 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 propose 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. 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. 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.

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, these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center hemodialysis, making it impossible for CMS to identify the relevant claims. We seek comment on the identification and inclusion of these particular beneficiaries in the numerator of the home dialysis rate calculation for ESRD facilities.

(b) Home Dialysis Rate for Managing Clinicians

We propose 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 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.

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.

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, these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center hemodialysis, making it impossible for CMS to identify the relevant claims. We seek comment on the identification and inclusion of these particular beneficiaries in the numerator of the home dialysis rate calculation for Managing Clinicians.

(2) Transplant Rate

We propose 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 propose to construct the transplant rate for ETC Participants that are ESRD facilities as described in section IV.C.5.c.(2)(a) of this proposed rule, and for ETC Participants who are Managing Clinicians as described in section IV.C.5.c.(2)(b) of this proposed rule.

For purposes of constructing the transplant rate, we propose two transplant rate-specific beneficiary exclusions. Specifically, we propose 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 skilled nursing facility (SNF) at any point during the month. We propose these additional exclusions to recognize that, while these beneficiaries can be candidates for home dialysis, they are generally not considered candidates for transplantation. These exclusions would be similar to the exclusions used in the Percentage of Prevalent Patients Waitlisted (PPPW) measure that has been adopted by ESRD QIP. We seek 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 are proposing 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.

We considered using rates of transplant waitlisting rather than the actual transplant rate. However, for the ETC Model, we propose to test the effectiveness of the Model's incentives on outcomes, rather than on processes. 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 acknowledge 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 believe that ESRD facilities and Managing Clinicians are well positioned to assist beneficiaries through the transplant process, and we want to incentivize this focus. Transplant waitlist measures also 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 solicit 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 solicit comment on an alternative transplant waitlist measure that would also capture living donation.

We propose using one year of data, from an MY, to construct the transplant rate to align with the construction of the home dialysis rate. However, 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, 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 section IV.C.5.c.(4) of this proposed 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 solicit feedback on our proposal to construct the transplant rate using only one year of data, from the MY.

Also, we solicit comment on our proposed methodology for assessing transplant rates and alternative methodologies considered for assessing transplant rates. We discuss later in this rule our proposed plan for risk adjusting and reliability adjusting these rates.

(a) Transplant Rate for ESRD Facilities

For ESRD facilities, we propose 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. 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 propose 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, zooplasic, open approach) 0TY10Z0 (transplantation of left kidney, allogeneic, open approach), 0TY10Z1 (transplantation of left kidney, syngeneic, open approach), and 0TY10Z2 (transplantation of left kidney, zooplasic, 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 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 propose 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.

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, 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. 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. We solicit comment on the inclusion of transplants in the numerator after the year of the transplant.

(b) Transplant Rate for Managing Clinicians

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 propose 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. 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 seek comment on the proposed inclusion of pre-emptive transplants in both the numerator and the denominator for the Managing Clinician transplant rate calculation.

We propose 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 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.

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. We recognize 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, we believe 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 propose 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 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, 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 propose 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 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.

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, we believe 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 proposed 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. We solicit comment on the inclusion of transplants in the numerator after the year of the transplant.

(3) Risk Adjustment

In order to account for underlying variation in the population of beneficiaries attributed to participating ESRD facilities and Managing Clinicians, we propose that CMS would risk adjust both the home dialysis rate and the transplant rate.

For the home dialysis rate, we propose 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. 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 are proposing 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. The CMS-HCC risk adjustment models were developed for the Medicare Advantage program and uses 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.¹²⁹ There are various CMS-HCC Models used in the Medicare Advantage program, all of which are developed using cost and diagnoses from claims data from the Medicare FFS

¹²⁹ CMS. Report to Congress: Risk adjustment in Medicare Advantage. December 2018; cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf

program, including models specific to calculating risk scores for enrollees with ESRD. Under the CMS-HCC Models, the risk factors – meaning the demographic factors and conditions (as represented by HCCs) - have a coefficient that represents the amount of risk projected to be associated with and is unique to the condition or demographic status. A relative factor is created for each demographic and condition variable by dividing the coefficient by the average annual cost of a FFS beneficiary predicted by the model in a denominator year. For payment, CMS calculates a risk score for each enrollee by adding the relative factors of an enrollee's demographics and health status (that is, HCCs). CMS then multiplies the resulting risk score (after some adjustments are applied) by the monthly capitation amount to pay the Medicare Advantage plan risk adjustment. CMS has developed a separate CMS-HCC ESRD Model for beneficiaries who are on dialysis, who have received kidney transplants, or who are in post-graft status.

We propose 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. 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.¹³⁰ This happens the year before the payment year begins, meaning that the CMS-HCC ESRD Dialysis Model

¹³⁰ 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](https://www.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>.

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.

For MY 1 (January 1, 2020 through December 31, 2020), which corresponds to PPA Period 1 (July 1, 2021 through December 31, 2021), we are proposing in section IV.C.5.g of this proposed rule that CMS would notify ETC Participants of their PPA no later than June 1, 2021. The calculation of the PPA and component risk-adjusted home dialysis rate would occur in May 2021. As the final risk scores for payment year 2020 would not be calculated for purposes of the Medicare Advantage program until 2021, we are proposing that CMS would use the final risk scores calculated by CMS for 2019, which will happen in 2020 using the CMS-HCC ESRD Dialysis Model adopted for risk adjustment of payments for payment year 2019 to risk adjust the home dialysis rates for MY 1/PPA Period 1. CMS adopted and announced the specific CMS-HCC ESRD Dialysis Model used for payments for 2019 in the CY 2019 Rate Announcement issued in April 2018.¹³¹ We are further proposing that CMS would use the final risk scores calculated by CMS in 2021, using the CMS-HCC ESRD Dialysis Model adopted for risk adjustment of payments for 2020, to risk adjust the home dialysis rates for MY 2 (July 1, 2020 through June 30, 2021)/PPA Period 2 (January 1, 2022 through June 30, 2022). CMS adopted and announced the specific CMS-HCC ESRD Dialysis Model used for payments for 2020 in the CY 2020 Rate Announcement issued on April 1, 2019¹³².

¹³¹ For the CY2019 Advance Notice and Rate Announcement, specifying the CMS-HCC ESRD Dialysis Model used for payment in 2019, see: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>.

¹³² (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>

We believe that using risk scores developed using the CMS-HCC ESRD Dialysis Model to risk adjust the ETC Model home dialysis rate is 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 each ETC Participant relative to the national benchmark. Moreover, use of the final risk scores as we are proposing means that the ETC Model would follow the same methodology and use 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 (2)(ii), so those risk factors would be used in risk adjustment for the ETC Model; 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. However, for the ETC Model, there would not be a frailty adjustment (for example, outlined in § 422.308(c)(4)) that is used in the Medicare Advantage program for certain special needs plans.

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 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. However, we believe that the HCC system for risk adjustment 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 propose that the risk-adjustment methodologies for the home dialysis rate and transplant rate would be applied independently. We considered using the same risk adjustment strategy for both rates, however, we recognize 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. Further, even in the Medicare Advantage program, a different CMS-HCC Model is used for beneficiaries who have received a transplant. We believe that the benefit of separate risk adjustment methodologies outweighs the additional complexity.

For the proposed ETC Model transplant rate, 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. 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 propose 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, 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 proposed ETC Model would exclude beneficiaries under 18 from the attribution methodology used for purposes of calculating the transplant rates, we propose 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>).

We 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.

We 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 their suitability for receiving a transplant.

We solicit comment on the proposed risk adjustment methodologies and the alternatives considered.

(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 propose to employ a reliability adjustment. Under this approach, we propose 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 propose 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 section IV.C.5.d of this proposed 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. 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. 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. However, we believe this approach balances the need for individualized performance assessment and incentives with the importance of reliably assessing the performance of each ETC Participant.

For Managing Clinicians, we propose that the performance on these measures would first be 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 propose 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 propose 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 propose 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 propose 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 propose that the individual unit would be the ESRD facility. We propose to define a subsidiary ESRD facility as an ESRD facility owned in whole or in part by another legal entity. We propose this definition in recognition of the structure of the dialysis market, as described in this rule. We propose 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 seek 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.

We acknowledge 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. We believe 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. 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, we concluded 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. We seek public comment on our proposal to address this facet of the provision of home dialysis in the larger dialysis market through the reliability adjustment as well as the alternatives considered.

d. Benchmarking and Scoring

We propose calculating two types of benchmarks for rates of home dialysis and transplants against which to assess ETC Participant performance in MY 1 and MY 2 (both of which begin in CY 2020). 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 propose 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 propose to refer to this period of time as the “benchmark year.” We propose using data from ESRD facilities and Managing Clinicians located in comparison geographic areas to construct these benchmarks. As an alternative, we 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. We propose 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 intend to establish the benchmarking methodology for future MYs through subsequent rulemaking.

Our intent in future MYs is to increase achievement benchmarks among ETC Participants above the rates observed in comparison geographic areas. By MY 9 and MY 10, in order to receive the maximum achievement score, we are 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 seek 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 propose 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 propose that an ETC Participant cannot 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. This policy would be consistent with other CMS programs and initiatives employing similar improvement scoring methodologies, including the CEC Model.

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, 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 seek 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 MY 1 and MY 2 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% improvement relative to benchmark year rate
50 th + Percentile of benchmark rates for comparison geographic areas during the benchmark year	1	Greater than 5% 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% 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 propose the following formula for determining the MPS:

MPS

$$\begin{aligned}
 &= 2 \times (\text{The higher of the home dialysis rate achievement or improvement score}) \\
 &+ (\text{The higher of the transplant rate achievement or improvement score})
 \end{aligned}$$

We propose 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. 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 recognize 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 are proposing that the home dialysis rate component take a greater weight than the transplant rate component of the MPS. We request comment on the proposed MPS calculation.

e. Performance Payment Adjustments

We propose that CMS would make upwards and downwards adjustments to payments for claims for dialysis and dialysis-related services, described in IV.C.5.e of this proposed rule, submitted by each ETC Participant with a claim through date during the applicable PPA period based on the ETC Participant's PPA. We propose 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 proposed PPAs are designed to be comparable to the MIPS payment adjustment factors for MIPS eligible clinicians, as described in sections IV.C.5.e.(1) and IV.C.5.e.(2) of this proposed rule. Specifically, the proposed PPAs are 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). The PPAs proposed for the ETC Model are also designed to increase over time and to be asymmetrical—

with larger negative adjustments than positive adjustments—in order to create stronger financial incentives.

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 are proposing 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. We believe that the proposed exclusion of ESRD facilities that fall below the low-volume threshold described in section IV.C.5.f.(1) of this proposed 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.

(1) Facility PPA

For ESRD facilities that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we propose 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). 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 propose to apply the Facility PPA to claims where Medicare is the secondary payer. We see comment on this proposal.

The formula for determining the final ESRD PPS per treatment payment amount with the Facility PPA would be as follows:

Final ESRD PPS Per Treatment Payment Amount with PPA

$$\begin{aligned}
 &= ((\text{Adjusted ESRD PPS per Treatment Base Rate} * \text{Facility PPA}) \\
 &+ \text{Training Add On} + \text{TDAPA}) * \text{ESRD QIP Factor} + \text{Outlier Payment} \\
 &\quad * \text{ESRD QIP Factor}
 \end{aligned}$$

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:

Final ESRD PPS Per Treatment Payment Amount with PPA and HDPA

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

Table 14 depicts the proposed amounts and schedule for the Facility PPA over the ETC Model's PPA periods, which we propose to codify in proposed § 512.380.

TABLE 14: PROPOSED FACILITY 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
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%

As also described in section IV.C.7.a of this proposed rule, we further propose 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.

(2) Clinician PPA

For Managing Clinicians that are ETC Participants, as described in proposed § 512.325(a) (Selected Participants), we propose 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). 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 propose to apply the Clinician PPA to claims where Medicare is the secondary payer. We seek comment on this proposal.

Table 15 depicts the proposed amounts and schedule for the Clinician PPA over the ETC Model's PPA periods, which we propose to codify in proposed § 512.380.

**TABLE 15: PROPOSED CLINICIAN PERFORMANCE PAYMENT
ADJUSTMENT AMOUNTS AND SCHEDULE**

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

We propose 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.

We seek comment on our PPA proposals, including the proposed magnitude of and schedule for these proposed payment adjustments for both ESRD facilities and Managing Clinicians participating in the ETC Model.

f. Low-Volume Threshold Exclusions for the PPA

(1) ESRD Facilities

We propose 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 at IV.C.5.b, 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 are proposing 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. We 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 invite public comment on this 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.

(2) Managing Clinicians

We propose 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. 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 propose 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 considered using 11 beneficiary-years as the low-volume

exclusion for Managing Clinicians, to mirror the proposed exclusion for ESRD facilities. However, we recognize 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 propose 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 alternative, we 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 invite 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.

g. Notification

Per the PPA schedule, we propose 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 three 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 propose to notify ETC Participants of their attributed beneficiaries, MPSs and corresponding PPAs. We propose notification of ETC Participants no later than one month before the start of the PPA Period in which the PPA would go into effect.

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 propose to conduct notifications in a form and manner determined by CMS.

h. Targeted Review

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 believe to have occurred in the calculation of the MPS. Therefore, we are proposing 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 note 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 Medicare Administrative Contractor. 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 propose 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 there to have occurred an error 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. 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 proposed § 512.170.

To request a targeted review, 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 propose 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 propose that we will 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 propose 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, it would be required to 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 conducted 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. Decisions based on the targeted review process would be final, and there would be no further review or appeal.

We considered compressing the duration of the targeted review process such that it could be completed before the PPA period in which the MPS in question sets the PPA. However, 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.

We invite public comment on these proposed provisions regarding the proposed targeted review process.

6. Overlap with Other Innovation Center Models and CMS Programs

The ETC Model would overlap with several other CMS programs and models, and we seek 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 propose 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 are proposing that the Facility HDPA and the Facility PPA would adjust the Adjusted ESRD PPS per Treatment Base Rate, as previously discussed at section IV.C.4.b of this proposed 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 propose 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 is designed to ensure that the MIPS payment adjustment factors will still have a significant weight for Managing Clinicians.

- Kidney Care First Model (KCF) and the Comprehensive Kidney Care Contracting (CKCC) Model – The KCF and CKCC Modela are optional Innovation Center models for nephrologists, dialysis facilities, transplant providers, and other providers and suppliers that are focused on beneficiaries with CKD and beneficiaries with ESRD. The KCF and CKCC Models will run from January 1, 2020, through December 31, 2025, and will have five years of financial accountability overlap with the ETC Model beginning January 1, 2021. We propose that the types of entities eligible to participate in these models -KCF practices and Kidney Contracting Entities (KCEs) – would be permitted to participate in either the KCF or one of the CKCC Models within regions where the ETC Model would be in effect. Not allowing these entities to participate as KCF practices or KCEs within the ETC Model’s selected geographic areas would limit participation in the KCF and CKCC Models, and could prevent a sufficient number of KCF practices or KCEs from participating in the KCF and KCCC Models, such that these models would not have sufficient participation to be evaluated. CMS believes it is important to test both models in order to evaluate payment incentives inside and outside the coordinated care context. The ETC Model would allow for a broader scope of test due to its mandatory nature across half

the country, while the KCF and CKCC Model will test the effects on outcomes of higher levels of risk for a self-selected group of participants. Payment adjustments under the ETC Model would be counted as expenditures for purposes of the KCF and CKCC Models. Both models would include explicit incentives for participants when beneficiaries receive kidney transplants; and 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 under the KCF and CKCC Models. 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.¹³³ As a result, CMS believes it would be appropriate to test incentives in both the ETC Model and the KCF and CKCC Models simultaneously to assess their effects on the transplant rate.

- Comprehensive ESRD Care (CEC) Model – The CEC Model is a voluntary Innovation Center model for ESRD dialysis facilities, nephrologists, and other providers and suppliers that focuses on beneficiaries with ESRD. The CEC Model will end on December 31, 2020, and therefore, would overlap for one year with the proposed ETC Model. We propose that ETC Participants could be selected from regions where there are participants in the CEC Model. Given the national distribution of CEC ESCOs, 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 geographic areas, creating a net neutral effect. We do not believe that the proposed ETC Model would significantly affect the CEC

¹³³ 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.

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. 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 by requiring termination of several ESCOs, 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 Medicare APMs – 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 propose that any increase or decrease in program expenditures that are 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 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)). We believe that this existing policy sufficiently addresses overlaps that would arise between the Medicare Shared Savings Program and the proposed ETC Model. CMS would review any 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 seek public input on our proposed overlap policies.

We invite public comments on our proposals to account for overlaps with other CMS programs and models.

7. Medicare Program Waivers

We believe it is 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 propose 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.

a. Medicare Payment Waivers

In order to make the proposed payment adjustments under the ETC Model, namely the HDPA and PPA discussed in sections IV.C.4 and IV.C.5 of this proposed rule, respectively, 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 would 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 would 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 propose 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 propose that beneficiary cost sharing be unaffected 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 run counter to the intent of the Model.

Therefore we would 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 seek comment on our proposed waivers of Medicare payment requirements related to the HDPA and PPA and beneficiary cost sharing.

b. Waiver of Select KDE Benefit Requirements

We believe 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. CMS believes 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 propose 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(c)(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 benefit¹³⁴. We propose 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 need not 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). We considered also waiving the

¹³⁴ United States Government Accountability Office. 2015

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 do not believe it is necessary for testing the Model. Moreover, ESRD facilities are already required to educate beneficiaries about their treatment modality options in the ESRD facility 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). We understand this prevents many beneficiaries in Stage V of CKD from receiving the benefits of KDE before starting dialysis or pursuing a transplant. We hypothesize 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 CKD¹³⁵. We propose 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 are proposing a waiver that would extend the KDE benefit to beneficiaries with CKD Stage V and

¹³⁵ United States Government Accountability Office. 2015

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 propose 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 propose 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 propose 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.

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.

We seek comment on our proposals to waive select requirements of the KDE benefit for purposes of testing the ETC Model and alternatives considered.

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, no fraud and abuse waivers are being issued for this Model. Thus, notwithstanding any other provision of this proposed regulation, all ETC Participants must comply with all applicable laws and regulations.

9. Beneficiary Protections

As we discuss in section IV.C.4.b, we propose 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 section II.B.2.a.(8) of this proposed 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 propose to prohibit ETC Participants from offering or paying any remuneration to influence a beneficiary's choice of renal replacement modality, unless such remuneration complies with all applicable law. We believe 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, 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. 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 previously in sections IV.C.4.c and IV.C.5.e.(2) of this proposed rule, we are proposing 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 section IV.C.7.a. of this proposed rule, we intend to use our waiver authority under section 1115A(d)(1) of the Act to issue certain payment waivers, in accordance with, which beneficiaries would be held harmless from any model-specific payment adjustments made to Medicare payments under this Model.

In proposed § 512.330(a), we would require ETC Participants 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. We are proposing this notification to further non-speculative government interests including transparency and beneficiary freedom of choice. So as not to be unduly burdensome, 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 patients, the collection of data to administer the national Medicare ESRD program, and the provision of technical assistance to ESRD providers and patients in areas

related to ESRD). 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 section II.D.3 of this proposed rule.

We invite public comment on the proposed beneficiary protections for the ETC Model.

10. Monitoring

a. Monitoring Activities

If finalized, the general provisions relating to monitoring proposed in section II.I of this rule would apply to ETC Participants, including but not limited to cooperating with the model monitoring activities per the proposed § 512.150, granting the government the right to audit per the proposed § 512.135(a), and retaining and providing access to records per § 512.135(c) and § 512.135(b), respectively. CMS would conduct the model monitoring activities in accordance with the proposed § 512.150. We believe that we must closely monitor the implementation and outcomes of the ETC Model throughout its duration. 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 propose 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 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.

We recognize 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. Therefore, to avoid inappropriate use of home dialysis, as described in section IV.C.5.c.(3) of this proposed rule, we propose to use risk adjustment to account for factors related to good candidacy for home dialysis. As described in section IV.C.5.b.(1) of this proposed rule, we also propose to exclude from beneficiary attribution certain categories of beneficiaries not well suited to home dialysis, including beneficiaries with a diagnosis of dementia. We are proposing 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, CMS would monitor for inappropriate encouragement or recommendations for home dialysis through the proposed monitoring activities. Instances of inappropriate home dialysis may show up in increased 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 propose to review a sample of medical records for indicators that a beneficiary was not suited for home dialysis. Through patient surveys and interviews, CMS would look for instances of coercion on beneficiary choice of modality against beneficiary wishes. If such instances of coercion were found, we would take one or more remedial action(s) as described at proposed § 512.160 against the ETC Participant and refer the case to CMS for further investigation and/or remedial action.

Additionally, 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 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 would be examining 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 the proposed § 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.

We welcome 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 would 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.

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 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 are seeking comment on how the proposed 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.

We invite public comment on our proposed monitoring plan for the ETC Model.

b. Quality Measures

In addition to the monitoring activities discussed previously, we propose 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.

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.¹³⁶ 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. Though 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. While we recognize that the ESRD

¹³⁶ 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>

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 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 are not proposing to use this measure for purposes of the ETC Model.

We considered including quality measures for Managing Clinicians that are reported by Managing Clinicians for MIPS or other CMS 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. 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 propose that the SHR and SMR measures would not be tied to payment under the ETC Model. However, 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 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. 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 invite public comment on the proposed quality measures and whether their proposed use would enable CMS to sufficiently monitor for adverse events for ESRD beneficiaries, in combination with the monitoring activities previously described. We also invite other suggestions as to measures that would support monitoring beneficiary health and safety under the model, while minimizing provider burden.

We also invite public comment on the proposal not to tie quality measurement to the payment adjustments in the ETC Model.

Additionally, as described in section IV.C.6 of this proposed rule, we propose 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. 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 do not propose to waive any of these requirements for purposes of testing the ETC Model.

11. Evaluation

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 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 section II.E of this rule, all ETC Participants will be required to cooperate with the evaluation.

Research questions addressed in the evaluation would include, but would 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 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 propose 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. 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.

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.

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 propose to use for purposes of calculating the MPS.

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 KCF Model, and the CKCC Models. 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, KCF, or CKCC Models.

We invite public comment on our proposed approach related to the evaluation of the proposed ETC Model.

12. Learning System

In conjunction with the proposed ETC Model, CMS intends to 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, organ procurement organizations (OPOs), and large donor hospitals. 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 believe that the 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.

13. Remedial Action

The remedial actions outlined in the general provisions in proposed § 512.160, if finalized, 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 proposed § 512.160(a) (Grounds for Remedial Action), CMS may take one or more of the remedial actions listed under proposed § 512.160(b).

14. Termination of the ETC Model

If finalized, the general provisions relating to termination of the Model by CMS proposed in section II.J of this proposed 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 proposed § 512.170, termination of the Model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

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 proposed rule need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated information collection requirements in section VII.C.4 of the Regulatory Impact Analysis.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

We have examined the impact of this proposed rule as required by Executive Order 12866 and other laws and Executive Orders, requiring economic analysis of the effects of proposed 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 hence 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 proposed rule.

A. Statement of Need

1. Need for Proposed Radiation Oncology (RO) Model

Radiotherapy (RT) services represent a promising area of health care for payment and service delivery reform. First, RT services can be 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 MPFS and increased coding complexity and administrative burden. As part of the RO Model's design, CMS would also 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 would 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 proposed rule, RO participants would be required to collect and submit data on quality measures, clinical data, and patient experience throughout the course of the RO Model, beginning January 1, 2020, with the final data submission ending in 2025.

2. Need for Proposed 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 quality of care and quality of life 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 improvement in quality of care for beneficiaries and reduced expenditures under the ETC Model inasmuch as the Model would create incentives for beneficiaries, along with their families and caregivers, to choose the optimal kidney replacement modality.

In section IV.B of this proposed 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 would 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 proposed rule, ETC Participants would receive adjusted payments and would 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 Proposed RO Model and ETC Model

As detailed in Table 16A, we estimate a net impact of \$260 million 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, we estimate a net impact of \$250 million 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, we estimate 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 expect that the ETC Model would cost an additional \$15 million, resulting from increases in education and training costs. Therefore, the net impact to Medicare spending is estimated to be \$169 million in savings as a result of the ETC Model.

We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

B. Overall Impact

We have examined the impacts of this 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, this proposed rule triggers these criteria.

C. Anticipated Effects

1. Scale of the Model

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 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 enough 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, we determined the sample size necessary for a minimum estimated savings impact of three percent. While a savings higher than three 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 three percent level, then we would increase the risk of missing an opportunity to detect the actual savings produced by the Model or of concluding there are savings when there are not savings.

The RO Model as proposed would include 40 percent of radiation oncology episodes in

eligible geographic areas, as defined in this proposed rule. In a simulation, we randomly selected CBSAs and found that there would be 616 physician group practices (PGPs) (325 being freestanding radiation therapy centers) and 541 hospital outpatient departments furnishing RT services in those simulated selected CBSAs. Among the simulated selected PGPs, 173 furnish RT services in both freestanding radiation therapy centers and HOPDs. 285 PGPs furnish RT services only in HOPDs, and 158 PGPs furnish RT services only in freestanding radiation therapy services. These providers and suppliers furnished 39.7 percent of radiation oncology episodes nationally, based on data from 2015 to 2017. If finalized as proposed with the Model starting in January 2020, the RO Model would have a 5-year performance period and include an estimated 364,000 episodes, 322,000 beneficiaries, and \$5.4 billion in total episode spending of allowed charges (inclusive of beneficiary cost-sharing). See Table 16A for an annual breakdown. If finalized as proposed, with an April 1, 2020 start date, the RO Model would have a 5-year performance period and include an estimated 346,000 episodes, 307,000 beneficiaries, and \$5.1 billion in total episode spending of allowed charges (inclusive of beneficiary cost-sharing). See Table 16B for an annual breakdown.

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

The ETC Model as proposed would include approximately 50 percent of ESRD Beneficiaries, through the ESRD facilities and Managing Clinicians selected for participation in the Model. The Innovation Center would randomly select 50 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, would be required to participate in the Model. There are currently 7,097 ESRD facilities and 7,283 Managing Clinicians enrolled in

Medicare, distributed across 306 HRRs and providing care for 432,436 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 would apply the payment adjustments described in section IV. of this proposed rule to claims with claim through dates between January 1, 2020 through June 30, 2026, and over that time period, would include an estimated 3,548 ESRD facilities, 3,642 Managing Clinicians, 216,218 beneficiaries, and \$169 million in net Medicare savings. See Table 17 for an annual breakdown.

c. Aggregate Effects on the Market

There may be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of these models, if finalized. 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 it is unclear 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 welcome comments on this assumption and evidence on how this rulemaking, if finalized, would impact non-Medicare payers and patients.

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 proposed RO Model would 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, 2020 and December 31, 2024.

The proposed RO Model would test differences in payment from traditional FFS Medicare by paying model participants two equal lump-sum payments, once at the start of the episode and again at the end, for episodes of care. Episodes would be defined as all Medicare items and services described in proposed § 512.235 that are furnished to a beneficiary described in proposed § 512.215 during the period of time that begins with episode initiation defined in proposed § 512.245 and ends 89 days after the start date of the episode. Once an episode is initiated, RO participants would 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 episode.

For each participating entity, the participant-specific professional payment and participant-specific technical episode payment amounts would be determined as described in detail in section III.C.6. of this proposed rule.

The RO Model would not be a total cost of care model. RO participants would 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 proposed criteria for inclusion in the RO Model and associated FFS procedure codes are included in section III.C.5. of this proposed rule.

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the proposed RO Model relative to baseline expenditures. The simulation relied upon statistical assumptions derived from retrospectively constructed RT episodes between 2015 and 2017. 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 2018 Medicare Trustees Report and applied to simulated episode payments. In addition, current relative value units under the PFS and relative payment weights under the OPPS are assumed to be fixed at the simulated levels found in the 2015 through 2017 ARC episode data.

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 2024 under the Medicare Access and CHIP Reauthorization Act of 2015. OPPS conversion factors are assumed to be updated at the Hospital Market Basket less Multifactor Productivity in our simulation. We forecast that net OPPS updates would outpace the PFS by 3.0 percent on average annually between 2019 and 2024.

(3) Medicare Estimate

Table 16 summarizes the estimated impact of the proposed RO Model. We estimate that on net the Medicare program would save \$260 million (\$250 million with an April 1 start date) over the 5 performance years (2020 through 2024) with final data submission of clinical data elements and quality measures in 2025 to account for episodes ending in 2024. 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.

We project that 82 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 2019 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 CY2017 provider billing patterns.

As proposed, the APM incentive payment would apply only to the professional episode payment amounts and not the technical episode payment amounts. We also assume HOPD line item cap as described in section 1833(t)(8)(C)(i) of the Act will continue to be applied as is done under current law.

Complete information regarding the data sources and underlying methodology for withhold reconciliation were not available at the time of this forecast. In the case of the incomplete payment withhold, we assume 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 withholdings, on net, have a negligible financial impact to CMS. In Table 16, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. No APM incentive payments would be paid based on participation in the RO Model in 2020 and 2021, due to the two-year lag between the QP performance and payment periods.

TABLE 16A. PROPOSED ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS \$) FOR PROPOSED RADIATION ONCOLOGY MODEL (Starting January 1, 2020)

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

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

TABLE 16B. PROPOSED ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS \$) FOR PROPOSED RADIATION ONCOLOGY MODEL (Starting April 1, 2020)

	Year of Proposed Model					
	2020	2021	2022	2023	2024	5-Year Total*
Net Impact To Medicare Program Spending	-30	-50	-50	-60	-60	-250
Changes to Incurred FFS Spending	-20	-40	-40	-40	-50	-190
Changes to MA Capitation Payments	-20	-30	-30	-30	-40	-140
Part B Premium Revenue Offset	10	10	20	20	20	80
Total APM Incentive Payments	0.0	0.0	4.0	4.0	4.0	12.0
Episode Allowed Charges	760	1,050	1,080	1,110	1,140	5,130
Episode Medicare Payment	590	820	840	870	890	4,000
Total Number of Episodes	52,000	71,000	73,000	74,000	76,000	346,000
Total Number of Beneficiaries	51,000	69,000	71,000	72,000	74,000	307,000

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

A key assumption underlying the above 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 model, then we estimate Medicare would only reduce net outlays by \$50 million (\$40 million with an April 1 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 start date) for the projection period. Please note that although V&I growth from 2014 through 2017 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ.

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 proposed ETC Model would be a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in section IV. of this proposed rule, for ESRD facilities and to the MCP for Managing Clinicians from January 1, 2020 to June 30, 2026.

Under the proposed ETC Model, there would be two payment adjustments designed to increase rates of home dialysis and kidney and kidney-pancreas transplants through financial incentives. The HDPA would be an upward payment adjustment on certain home dialysis and

home dialysis-related claims, as described in proposed § 512.340 and § 512.350 for ESRD facilities and § 512.345 and § 512.350 for Managing Clinicians, during the initial 3 years of the ETC Model.

The PPA would be an upward or downward payment adjustment on certain dialysis and dialysis-related claims submitted by ETC participants, as described in proposed § 512.375(a) and § 512.380 for ESRD facilities and § 512.375(b) and § 512.380 for Managing Clinicians, that would apply to claims with claim through dates beginning on July 1, 2021 and increase in magnitude over the duration of the Model. CMS would assess each ETC Participant's home dialysis rate, as described in proposed § 512.365(b), and transplant rate, as described in proposed § 512.365(c), for each Measurement Year. The ETC Participant's home dialysis rate and transplant rate would be risk adjusted and reliability adjusted, as described in proposed § 512.365(d) and proposed § 512.365(e), respectively. The ETC Participant would 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 proposed § 512.370(d). In MY 1 and MY 2, the achievement scores would be calculated in relation to a set of benchmarks based on the historical rates of home dialysis and kidney transplants among ESRD facilities and Managing Clinicians located in comparison geographic areas. We intend to increase these benchmarks over time through subsequent notice and comment rulemaking, as discussed in section IV.C.5.d. of this proposed rule. The improvement score would 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 would determine the magnitude of its PPA during the corresponding 6-month PPA Period, which would

begin 6 months after the end of the MY. An ETC Participant's MPS would be updated on a rolling basis every 6 months.

The ETC Model would not be a total cost of care model. ETC participants would still bill FFS Medicare, and items and services not subject to the ETC Model's payment adjustments would continue to be paid as they would be 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 and transplant claims reported during 2016 and 2017, the most recent years with complete data available. Both datasets and the proposed 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, or with 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.

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 proposed exclusion in proposed § 512.385(a), ESRD facilities with less than 132 total attributed beneficiary months during a given MY were excluded.

The Managing Clinicians' data were aggregated to the group TIN, individual TIN, or NPI (in order of availability) level for beneficiaries on home dialysis and were constructed using outpatient claims with CPT® codes 90965 and 90966. Beneficiaries receiving in-center dialysis were defined by outpatient claims with CPT® codes 90957, 90958, 90959, 90960, 90961, and 90962. A low-volume exclusion was applied 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 transplant data for ESRD facilities and Managing Clinicians were obtained from Medicare inpatient claims with MS-DRGs 008 and 652; and claims with ICD-10 procedure codes 0TY00Z0, 0TY00Z1, 0TY00Z2, 0TY10Z0, 0TY10Z1, and 0TY10Z2.¹³⁷ The beneficiary attribution eligibility criteria in proposed § 512.360(b) and low-volume exclusions in proposed § 512.385 were applied to the transplant data in the ESRD facilities and Managing Clinicians datasets. In addition, the transplant data were further restricted by excluding beneficiaries during any months in which they were 75 years of age or older or for any months in which they were in a skilled nursing facility.

The home dialysis score and transplant score for the PPA were calculated using the following methodology for the ESRD facilities and Managing Clinicians. A reliability adjustment was applied to the home dialysis (transplant) rate to account for the small numbers of beneficiaries attributed to individual ETC Participants and to improve comparisons between ETC

¹³⁷ SRTR data was not used in this analysis, as it was not available at the time the analysis was conducted. While this omission adds some small amount of uncertainty to the analysis, we do not believe that this lack of data compromises the validity of the analysis, as the number of kidney and kidney-pancreas transplants not identifiable through claims data is very small.

Participants and those ESRD facilities and Managing Clinicians not selected for participation in the Model for purposes of achievement benchmarking and scoring, described in section IV.C.5.d of this proposed rule. Four credibility tiers of total member months (that is, 400, 600, 800, and 1,000) were constructed with corresponding HRR weights of 80, 60, 40, and 20 percent. ETC Participant behavior for each year was simulated by adjusting the ETC Participant's baseline home dialysis (or transplant) rate for a simulated statistical fluctuation and then summing with the assumed increase in home dialysis (or transplant) rate multiplied by a randomly generated improvement scalar. The achievement and improvement scores were assigned by comparing the participant's simulated home dialysis (or transplant) rate for the MY to the percentile distribution of home dialysis (or transplant) rates in the prior year. Last, the MPS was calculated using the maximum of each achievement or improvement score. The home dialysis score constituted two -thirds of the MPS, and the transplant score one-third of the MPS.

The HDPA calculation required a simplified methodology, with home dialysis and home dialysis-related payments adjusted by 3, 2, and 1 percent during 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 (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 – Assume Rolling Benchmark

Table 17 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 would save a net total of 185 million dollars from the PPA and HDPA between January 1, 2020 and June 30, 2026, less 15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be 169 million dollars in savings. In Table 17, 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 CMS is proposing that the payment adjustments under the ETC Model would 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 ESRD facility PPA; a reduction in Medicare spending of 220 million dollars over the period from January 1, 2020 through June 30, 2026. In comparison, the net effect of the Managing Clinician PPA was only 8 million dollars in Medicare savings. This estimate was based on an empirical study of historical home dialysis utilization and transplant rates for FFS beneficiaries that CMS virtually assigned to dialysis facilities and to nephrology practices 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 proposed payment policy

assuming providers respond by marginally increasing their share of patients utilizing home dialysis. Random variables were used to vary the effectiveness that individual providers 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 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), respectively. KDE 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 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 would 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.

Individual ESRD facilities 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 would result in home dialysis ultimately representing approximately 19 percent of overall maintenance dialysis in selected geographic areas by 2026. 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 the section VII.C.2.b.(4). of the proposed rule. However, as part of the sensitivity analysis for the savings calculations for the model, we lay out different savings scenarios if the incentives ETC Model were to cause an increase in living donation and if the learning system described in section IV.C.12 of this proposed 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 17. PROPOSED ESTIMATES OF MEDICARE PROGRAM SAVINGS
(ROUNDED \$M) FOR PROPOSED ESRD TREATMENT CHOICES MODEL**

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

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

(a) Sensitivity Analysis: Medicare Estimate – Assume Fixed Benchmark

An alternative model specification was analyzed where benchmarks remain *fixed* at baseline year 0 over time (results available upon request). Both the fixed and rolling benchmark assumptions projected about 19 million dollars in increased overall HDPA Medicare payments to ESRD facilities and Managing Clinicians in 2020. We project about 1 million dollars in additional HD training add-on payments. This would represent about 20 million dollars in increased Medicare expenditures in 2020 overall. Both specifications of the benchmark also projected the net impact of approximately 1 million dollars in increased Medicare expenditures in 2021.

The two scenarios diverge after 2021, with large differences observed in overall net PPA

and HDPA savings/losses. Table 17 illustrates that when benchmarks are rolled forward, using the methodology described in section VII.C.2.b.(3), the overall *savings* in PPA net and HDPA increase each year during the 2022-2026 period. In contrast, when benchmark targets are fixed, in 2022 the overall PPA net and HDPA savings increase to 16 million dollars, followed by overall *losses* in years 2022-2026 of 0, 35, 89, and 62 million dollars, respectively. The fixed benchmark would allow the ESRD facilities and Managing Clinicians to have more favorable achievement and improvement scores over time compared to the rolling benchmark method. In summary, the total of overall net PPA and HDPA from January 1, 2020 through June 30, 2026, with the fixed benchmark, was 189 million dollars in losses, compared to a total of 185 million dollars in savings with the rolling benchmark method. The net impact on Medicare spending for the PPA and HDPA using the fixed benchmark method is 203 million dollars in *losses*.

(b) Sensitivity Analysis: Medicare Savings Estimate – Results for the 10th and 90th Percentiles

Returning to the methodology used for the Medicare estimate with a rolling benchmark, we compare the results (available upon request) for the top 10th and 90th percentiles of the 500 individual simulations to the average of all simulation results reported in Table 17. Since the impact on Medicare spending for the proposed ETC Model using the rolling benchmark method is estimated to be in savings rather than losses, the top 10th and 90th percentiles represent the most optimistic and conservative projections, respectively. The overall net PPA and HDPA for the top 10th and 90th percentiles using the rolling benchmark method are 264 and 112 million dollars in savings (compared to 185 million dollars in savings in Table 17).

(4) Effects on Kidney Transplantation

Kidney transplantation is considered the optimal treatment for most ESRD beneficiaries. However, while the proposed PPA includes a one-third weight on the ESRD facilities' or

Managing Clinician's kidney transplant rate, we decided to be conservative and did not include an assumption that the overall number of kidney transplants will increase. The number of ESRD patients on the kidney transplant wait list 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 donated kidneys. The United States Renal Data System¹³⁸ 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 would likely increase the share of ESRD Beneficiaries who join the transplant wait list but is unlikely to impact the donation 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 standard payment. Because the PPA would not impact payment to transplant centers the ETC Model would 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 live kidney donations for

¹³⁸ United States Renal Data System. 2018. "ADR Reference Table E6 Renal Transplants by Donor Type."

which significant Medicare program savings could be realized. For example, 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).^{139,140} The ETC Model as proposed does not include a proposal 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.¹⁴¹ 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 the approximate 6,000 total living kidney donations¹⁴² 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

¹³⁹ 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.

¹⁴⁰ 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.

¹⁴¹ Public Law 108-216 (section 377 of the Public Health Service (PHS) Act, 42 U.S.C. § 274f).

¹⁴² OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. <https://www.srtr.org/reports-tools/srtroptn-annual-data-report/>

transplantations by donor type compared to dialysis.¹⁴³ 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 would help reduce the number of beneficiaries under the age of 65 who would 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 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 would 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

¹⁴³ Axelrod DA, Schnitzler MA, Xiao H, et al. 2018. “An Economic Assessment of Contemporary Kidney Transplant Practice.” *American Journal of Transplantation* 18: 1168-1176.

Medicare spending is nominal relative to baseline spending and we adjust downward by 33 percent (that is, the beneficiary would 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 500 new transplants mainly from relatives of recipients, would produce approximately \$68 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.¹⁴⁴ Similar to the estimate above on the average impact to 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 would 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 would 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

¹⁴⁴ OPTN & SRTR 2017 Annual Report. Section KI Kidney Transplants. <https://www.srtr.org/reports-tools/srtroptn-annual-data-report/>

with high-KDPI would 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 would 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 would 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 would reduce long run program spending by \$143 million. Costs for this effort include a learning and diffusion investment of \$25 million over the model testing period and a potential increase in PPA adjustments to clinician and facility payments of approximately \$30 million. The projected increase in transplantation is estimated to produce a net savings of \$88 million – a net return on investment of approximately 1.6.

(5) 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.¹⁴⁵ Kidney disease education may: not be provided at all, be done only once, not be appropriate for patient's literacy level or not provided in patient's

¹⁴⁵ 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.

native language, not be done until after patient starts in-center hemodialysis, and/or not be provided to caregivers.

The proposed ETC Model would 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 growth rate to increase from 2.2 in 2020 to 3.2 in 2026. 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 (2020) was set to 2 percent, 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 during 2021 to 2026. 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 growth 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 would 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. This results in a projected doubling of the costs attributed to

the KDE benefit to approximately one million dollars in 2026.

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 dollars.

3. Effects on Medicare Beneficiaries

a. Radiation Oncology Model

We anticipate that the RO Model would benefit or have a negligible impact on the cost to beneficiaries receiving RT services. 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 would remain the same under the RO Model. More specifically, beneficiaries would be responsible for 20 percent of each of the PC and TC episode payments made under the RO Model. Since we are proposing 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 would decrease. Thus, beneficiary cost-sharing, on average, would 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 would continue under the RO Model.

In addition, we note that, because episode payment amounts under the RO Model would include payments for RT services that would likely be provided over multiple visits, individual

beneficiary coinsurance payments would likewise be higher than they would otherwise be for an individual RT service visit. We would encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments.

b. ESRD Treatment Choices Model

We anticipate that the ETC Model would 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 would remain the same under the ETC Model. However, the Model would apply the Clinician PPA and the Clinician HDPA to the amount otherwise paid by Part B to ensure beneficiaries are held harmless from any effect on cost sharing. Additionally, Medicare FFS beneficiaries are generally responsible for 20 percent of the allowed charge for Part B ESRD PPS services furnished by an ESRD facility. This policy would remain the same under the ETC Model. However, CMS proposes to waive certain requirements of title XVIII of the Act as necessary to test the Facility PPA and Facility HDPA proposed under the Model and proposes that beneficiaries would be held harmless from any effect of these payment adjustments on cost sharing.

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 plans¹⁴⁶; as well as better overall, physical, and psychological

¹⁴⁶ 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.

health^{147,148} in comparison to other dialysis options.

4. Effects on RO and ETC Participants

RO participants will be given instructions on how to bill for patients, using RO Model-specific HCPCS codes. We expect it would take medical coding staff approximately 0.72 hours $[(~36 \text{ pages} * 300 \text{ words}/\text{per page})/250 \text{ words per minute})/60 \text{ minutes}]^{149} = 0.72$ to read and learn the payment methodology and billing sections of the rule. In addition, we would add one hour to review the relevant MLN Matters publication, 1 hour to read the RO Model billing guide, and one hour to attend the billing guidance webinar, for a total of 3.72 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.¹⁵⁰ The total cost of learning the billing system for the RO Model thus is \$144.34 per participant, or approximately \$167,000 in total (1,157 expected participants x \$144.34/participant = \$167,000 total).

The ETC Model would not alter the way ETC Participants bill Medicare. Therefore, we believe that there would be no additional burden for ETC Participants related to billing practices.

We believe the burden for audits and record retention do not diverge from existing provider requirements in the Health Insurance Portability and Accountability Act (HIPAA) of

¹⁴⁷ 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

¹⁴⁸ 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.

¹⁴⁹ https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf

¹⁵⁰ 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>

1996 (HIPAA) administrative simplification rules (45 CFR 164.316(b)(2)), which require a covered entity, such as a physician billing Medicare, to retain required documentation for six years from the date of its creation or the date when it last was in effect, whichever is later. While the HIPAA Privacy Rule does not include medical record retention requirements, it does require that covered entities apply appropriate administrative, technical, and physical safeguards to protect the privacy of medical records and other protected health information (PHI) for whatever period such information is maintained by a covered entity, including through disposal. The Privacy Rule is available at 45 CFR 164.530(c). In addition, CMS requires records of providers submitting cost reports to be retained in their original or legally reproduced form for a period of at least 5 years after the closure of the cost report. This requirement is available at 42 CFR 482.24(b)(1). Given these existing requirements, we do not believe that the audit or record retention requirement in the RO Model or the ETC Model will create an additional burden or impact on participants.

Similarly, monitoring and compliance requirements for the RO Model and the ETC Model would not diverge from general monitoring requirements for Medicare Part B providers. We believe that the requirements in this section do not add additional burden or impose regulatory impact on participants.

The model evaluation for both the RO Model and the ETC Model would likely 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 would 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 would also apply to RO Model 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 \$388.00 per entity per year. Since we estimate approximately 1,157 RO Model participants, then total burden estimate for collecting and reporting quality measures and clinical data would be approximately \$449,000. 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 proposed rule that is provided for Small Businesses would also apply to RO Model participants and ETC participants that are not considered small entities. The burden estimate for reading and interpreting this proposed rule may be equal to or less than that for small businesses. We estimated that cost of reading the rule for RO participants would be approximately \$466.89 per entity with a total cost of approximately \$1,354,000 (2,900 eligible entities x \$466.89/participant). In sum, we estimate that reading the RO Model rule, learning the RO billing system, and submitting quality measures and clinical data to the RO Model would cost approximately \$1,000 per RO participant, and collectively cost approximately \$1,156,000 across the 1,157 RO participants, and an additional \$814,000 for those RO providers who read the rule, but are not ultimately selected as RO participants, for a total cost \$1,970,000. Similarly, we base

our estimate for the cost of reading the proposed rule for ETC participants on the same cost per participant as used for the RO Model, that is, \$466.89 per entity. We assume that all ESRD facilities and managing clinicians will read the rule, even though only a subset of each category would 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, the Secretary has considered small entities and has determined and certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

a. Radiation Oncology Model

This proposed 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 \$11 million to \$38.5 million in any 1 year, depending on the type of provider; the \$38.5 million per year threshold is for hospitals, whereas the \$11 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

determine whether a proposed rule is likely to have “significant” impacts on small entities.¹⁵¹

Throughout the rule we describe how the proposed changes to a prospective episode payment may affect PGPs and HOPDs.

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.¹⁵² PGPs and HOPDs also serve patients with other coverage, for example, through Medicare or commercial insurance. We believe 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 expect that the anticipated average impact of revenue based solely on Medicare FFS payments to be less than 1 percent. Therefore, we have determined that this proposed rule would not have a greater than 5 percent impact on total revenues on a substantial number of small entities. We estimate the administrative costs of adjusting to and complying with the quality measure and clinical data element reporting requirements proposed in the RO Model for small entities to be approximately \$388.00 per entity per year. To estimate the costs per small entity, we assume that a Medical

¹⁵¹ 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).

¹⁵² This figure comes from the 2018 Medicare Trustees Report, Table IV.V1, p151 from the footnote that has the A and B share.

Records & Health Information Technician with an Hourly salary (from BLS) plus 100 percent fringe benefits would cost \$38.80/hour¹⁵³ and would report the information on quality measures and clinical data elements. We would expect submission of the 4 quality data measures to take approximately 8 hours and would require submission once a year, ($\$38.80 \times 8.0 \text{ hours} \times 1 \text{ submission} = \310.40). We would expect the submission of clinical data elements to take up to an hour, but occur twice a year, that is. ($\$38.80 \times 1 \text{ hour} \times 2 \text{ submission} = \77.60). The burden costs per small entity associated with measure and data reporting proposals should be small because three of the four measures proposed 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 PGP and HOPDs.

We further estimate the administrative cost of reading and interpreting this proposed rule per small entity at approximately \$446.89. We expect that a medical health service manager reading 250 per minutes could review the rule in approximately 4.66 hours [(approximately 233 pages*300 words/per page)/250 words per minute)¹⁵⁴/60 minutes)]. We estimate 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.¹⁵⁵ Assuming an average reading speed for pages relevant to the RO Model, we estimate that it would take approximately 4.66 hours for the staff to review half of this proposed rule. For each provider that reviews the rule, the estimated cost

¹⁵³ <https://www.bls.gov/ooh/Healthcare/Medical-records-and-health-information-technicians.htm>

¹⁵⁴ https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf

¹⁵⁵ 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>

based on the expected time and salary of the person reviewing the rule ($\$446.89 = (\$95.90 * 4.66$ hrs).

We welcome public comments on our estimates and analysis of the impact of the proposed rule on those small entities.

b. ESRD Treatment Choices Model

The proposed rule includes as model participants: (1) Managing Clinicians; and (2) ESRD facilities. We assume for the purposes of the regulatory impact analysis that the great majority of Managing Clinicians would be small entities and that the greater majority of ESRD facilities would not be small entities. Throughout the rule we describe how the proposed adjustments to certain payments for 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-standards>). The great majority of ESRD facilities are not small entities as they are owned in whole or in part of 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 proposed PPA in the ETC Model, which includes both positive and negative adjustments on payments for dialysis services, would exclude ESRD facilities with fewer than 132 attributed beneficiary-months during the relevant year and the Managing Clinicians with the lowest volume of claims for the MCP using a

percentile based exclusion threshold.

For the remaining small entities that are above the exclusion threshold and randomly selected for participation, the design of the ETC Model would incorporate a risk adjustment and a reliability adjustment to allow for the calculation of home dialysis rates and transplant rates for both small entities and larger entities that may be owned in whole or in part by another company.

The risk adjustment would account for the underlying variation in the patient population of individual ESRD facilities and Managing Clinicians. The risk adjustment for the home dialysis rate would be based on 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, as described in section IV.C.5.b.(3) of the proposed rule. The transplant rate is proposed to be risk adjusted by age, as described in section IV.C.5.b.(3) of the proposed rule.

The reliability adjustment would create a weighted average between the individual ETC Participant's home dialysis rate and transplant rate and the aggregate home dialysis rate and transplant rate of the ETC Participants aggregation group, 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. The reliability adjustment allows for comparable performance rates for ESRD facilities and Managing Clinicians across the size spectrum.

Taken together, the proposed low volume threshold exclusions, risk adjustments, and reliability adjustments previously described, with the fact that the ETC Model would affect Medicare payment only for select services furnished to Medicare FFS beneficiaries, we have determined that this proposed rule would not have a greater than 5 percent impact on a substantial number of small entities.

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 603 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 proposed RO Model and ETC Model would not have a significant impact on the operations of a substantial number of small rural hospitals.

6. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that is approximately \$154 million. This proposed 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 proposed rule, if finalized as proposed, 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 proposed rule, we have identified our proposed policies and alternatives that we have considered, and provided information as to the likely effects of these alternatives and the rationale for each of the proposed policies. We solicit and welcome 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 proposed rule contains a proposed model specific to radiation oncology. It provides descriptions of the requirements that we propose to waive, identifies the proposed payment methodology to be tested, and presents rationales for our decisions and, where relevant, alternatives that were considered. We carefully considered the alternatives to this proposed 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 proposed rule also contains a proposed model specific to ESRD. It provides descriptions of the requirements that we propose to waive, identifies the performance metrics and payment adjustments to be tested, and presents rationales for our decisions, and where relevant, alternatives that were considered. We carefully considered the alternatives to this proposed 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 half 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 welcome comments on our proposals and the alternatives we have identified.

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 18 and 19, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis.

TABLE 18: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR THE RADIATION ONCOLOGY MODEL

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized (\$million/year)	-\$48 million (-\$46 million with an April 1 start date)	2018	7%	2020 – 2024
	-\$50 million (-\$48 million with an April 1 start date)	2018	3%	2020 – 2024
From Whom to Whom	From the federal government to healthcare providers			

TABLE 19: ACCOUNTING STATEMENT ESTIMATED IMPACTS FOR END STAGE RENAL DISEASE (ESRD) TREATMENT CHOICES MODEL

Category	Assuming no change in the rate of patients receiving services	Source citation (RIA, preamble, etc.)
BENEFITS		
Annualized monetized transfers: Discount rate 7%	\$20 million	Table 17
Annualized monetized transfers: Discount rate 3%	\$22 million	Table 17
From whom to whom?	From the Federal Government to ESRD facilities and Managing Clinicians	

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 proposed rule, we estimate that the financial impact of the Radiation Oncology Model and ESRD Treatment Choices Model proposed here would be net federal savings of \$429 million (\$419 million with an April 1 start date) over a 5 year performance period (2020 through 2024).

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects**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, 1315(a), and 1395hh, the Centers for Medicare & Medicaid Services proposed to amend 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 participant selection 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 Episodes Being Tested

512.230 Criteria for determining cancer types.

512.235 Included RT services.

512.240 Included modalities.

512.245 Scope of 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

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.

Quality Monitoring

512.395 Quality measures.

Medicare Program Waivers

512.397 ETC Model Medicare program waivers.

Authority: 42 U.S.C. 1302, 1315(a), 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 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.

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 pursuant to 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” 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. Notwithstanding the foregoing, 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 would take 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 six 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 pursuant to 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 use any data obtained under § 512.130, § 512.135, and § 512.150 to evaluate and monitor the Innovation Center model and may 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 to be disseminated may include 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.

(b) Notwithstanding any other provision of this part, all data that has been confirmed by CMS to be proprietary trade secret information and technology of the model participant or its downstream participants will not be released by CMS or its designee(s) 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 will be 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. Such monitoring activities may include, without limitation--

(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 § 512.150(c);

(vi) Monitoring quality outcomes and clinical data, if applicable; and

(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) To the extent practicable, CMS or its designee will provide the model participant or downstream participant with no less than 15 days advance notice of any site visit. To the extent practicable, CMS will attempt to accommodate a request for particular dates in scheduling site visits. However, the model participant or downstream participant may not request a date that is more than 60 days after the date of the initial site visit notice from CMS.

(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) Notwithstanding the foregoing, 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) *Right to correct.* If CMS discovers that it has made or received an incorrect model-specific payment under the terms of the Innovation Center model, CMS may make payment to, or demand payment from, the model participant.

(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 statutes, rules, or regulations administered by the Federal Government.

§ 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 will provide 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 assessment by CMS of the quality of care furnished by the model participant.
- (3) The attribution of model beneficiaries to the model participant by CMS, 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 60 days before 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.* 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. 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). 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 participants.
- (2) Episodes being tested under the RO Model.
- (3) Methodology for pricing and quality performance.
- (4) Payments and billing under the RO Model.
- (5) The Model as an Advanced APM and MIPS APM under the Quality Payment

Program

- (6) Program waivers issued for RO participant use.
- (7) Data reporting requirements.
- (8) Payment reconciliation and appeals 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, proposed quality measures and clinical data. The AQS is used to determine the amount of a RO participant's quality reconciliation payment amount.

Clean period means the 28-day period after an episode has ended, during which time a 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 a participant-specific professional episode payment or a participant-specific technical episode payment 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. The discount factor does not vary by cancer type. The discount factor for the professional component is 4 percent; the discount factor for the technical component is 5 percent.

Dual participant means a RO participant that furnishes for both the professional component and technical component of RT services of an episode through a freestanding radiation therapy center, identified by a single TIN.

Duplicate RT service means any included RT service that is furnished to a single RO beneficiary by a RT provider or RT supplier that did not initiate the PC or TC of that RO beneficiary during the episode.

Episode means the 90-day period that, as set forth in § 512.245, begins on the date of service that an individual practitioner under a professional participant or a dual participant furnishes an initial RT treatment planning service to a 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.

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 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 a RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an 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) A RO beneficiary stops meeting the beneficiary population criteria under § 512.215(a) or triggers the beneficiary exclusion criteria under § 512.215(b) before the technical component of an episode initiates.

Individual practitioner means a Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and have reassigned their billing rights to the TIN of a 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.

Model performance period means, the date the RO Model begins through December 31, 2024, the last date during which episodes under the Model must be completed. No new episodes may begin after October 3, 2024 in order for all episodes to be completed by December 31, 2024.

National base rate means the total payment amount for the relevant component of an episode, before application of the trend factor, discount factor, adjustments, and applicable withhold, for each of the proposed included cancer types.

NPI means National Provider Identifier.

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 a RO beneficiary during an 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 a RO beneficiary during an 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.

Professional component (PC) means the included RT services that may only be furnished by a physician.

Professional participant means a RO participant that is a Medicare-enrolled PGP identified by a single TIN that furnishes only the PC of an episode.

Radiotherapy (RT) services are the treatment planning, technical preparation, special services (such as simulation), treatment delivery, and treatment management services associated with cancer treatment that use high doses of radiation to kill cancer cells and shrink tumors.

Reconciliation payment means a payment made by CMS to a RO participant, as determined in accordance with § 512.285.

Repayment amount means the amount owed by a RO participant to CMS, as determined in accordance with § 512.260.

RO beneficiary means a Medicare FFS beneficiary who meets all of the beneficiary inclusion criteria at § 512.215(a) and who does not trigger any of the beneficiary exclusion criteria at § 512.215(b).

Reconciliation report means the annual report issued by CMS to a RO participant for each performance year, which specifies the RO participant's reconciliation payment amount or repayment amount.

RO participant means a Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that participates in the RO Model pursuant to § 512.210. A RO participant may be a Dual participant, Professional participant, or Technical participant.

RT provider means a Medicare-enrolled HOPD that furnishes RT services in a 5-digit ZIP Code linked to a selected CBSA.

RT supplier means a Medicare-enrolled PGP or freestanding radiation therapy center that furnishes RT services in a 5-digit ZIP Code linked to a selected CBSA.

Selected CBSA means a CBSA that has been randomly-selected by CMS under § 512.210(c).

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 a 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 for the TC of an episode.

TIN stands for 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 means the process to calculate additional payments or repayments for incomplete episodes and duplicate RT services that are identified after claims run-out.

RO Model Participation

§ 512.210 RO participants and geographic areas.

(a) *RO participants.* (1) Unless otherwise specified in paragraph (b) of this section, any Medicare-enrolled PGP, freestanding radiation therapy center, or HOPD that furnishes included RT services in a 5-digit ZIP Code linked to a selected CBSA to a RO beneficiary for an episode

that begins on or after January 1, 2020, and ends on or before December 31, 2024, must participate in the RO Model.

(b) *Participant exclusions.* A PGP, freestanding radiation therapy center, or HOPD will be 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 the Pennsylvania Rural Health Model.

(c) *Selected CBSAs.* CMS randomly selects CBSAs to identify RT providers and RT suppliers to participate in the Model through a stratified sample design, allowing for participant and comparison groups to contain approximately 40 percent of all episodes in eligible geographic areas (CBSAs).

§ 512.215 Beneficiary population.

(a) *Beneficiary inclusion criteria.* (1) Except as provided in paragraph (b) of this section, a beneficiary is included in the RO Model if the beneficiary:

- (i) Receives included RT services in a 5-digit ZIP Code linked to a selected CBSA from a RO participant during the model performance period for a cancer type that meets the criteria for inclusion in the RO Model; and
- (ii) At the time that the initial treatment planning service of an episode is furnished by an RO participant, the beneficiary--

(A) Is eligible for Medicare Part A and enrolled in Medicare Part B; and

(B) Has traditional FFS Medicare as his or her primary payer.

(2) Any RO beneficiary enrolled in a clinical trial for RT services for which Medicare pays routine costs will be included in the RO Model provided that the beneficiary satisfies all of the beneficiary inclusion criteria in paragraph (a)(1) of this section.

(b) *Beneficiary exclusion criteria.* A beneficiary is excluded from the RO Model if, at the initial treatment planning service the beneficiary is--

- (1) Enrolled in any Medicare managed care organization, including but not limited to Medicare Advantage plans;
- (2) Enrolled in a PACE plan;
- (3) Is in a Medicare hospice benefit period; or
- (4) Covered under United Mine Workers.

(c) *Changes during an episode.* (1) If a RO beneficiary stops meeting any of the proposed eligibility criteria before the TC of the episode has been initiated, then the episode is classified as an incomplete episode. Payments to RO participants will be retrospectively adjusted to account for incomplete episodes during the annual reconciliation process.

(2) 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 is considered an incomplete episode and, the RO participant may receive only the first installment of the episode payment. In the event that a RO beneficiary dies or enters hospice during an episode, then the RO participant may receive both installments of the episode payment regardless of whether the RO beneficiary's course of RT has ended.

§ 512.217 Identification of individual practitioners.

(a) *General.* Prior to the start of each performance year, CMS will create and provide 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 such individual practitioner list, the RO participant must review and certify the individual practitioner list 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 such 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.

(d) *Changes to the individual practitioner list.* (1) *Additions.* (i) A RO participant must notify CMS of an addition to its individual practitioner list within 15 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, 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 15 days before the date of the notice. If the RO participant fails to submit timely notice to CMS, the addition of an individual practitioner to the individual practitioner list is effective on the date of the notice.

(2) *Removals.* (i) A RO participant must notify CMS no later than 15 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, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit a timely notice of the removal, the removal is effective on the date of the notice.

(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 are required to meet the Model requirements to qualify for the APM Incentive Payment, as applicable.

(2) Each Professional participant and Dual participant must ensure its individual practitioners--

(i) 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) 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) Assess each RO beneficiary's tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnoses;
- (iv) Assess the RO beneficiary's performance status as a quantitative measure determined by the physician;
- (v) Send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of treatment to coordinate care;
- (vi) Discuss with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and
- (vii) Perform and document Peer Review (audit and feedback on treatment plans) for 50 percent of new patients in PY1, for 55 percent of new patients in PY2, for 60 percent of new patients in PY3, for 65 percent of new patients in PY4, and for 70 percent of new patients in PY5 preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment.

(3) 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 in a radiation oncology-specific AHRQ-listed patient safety organization (PSO) (per their PSO Provider Service Agreement).

(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 performance year, each RO participant must certify in the form and manner and by a deadline specified by CMS that it will use CEHRT throughout such performance year 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.* Professional participants and Dual participants must notify each RO beneficiary to whom it furnishes included RT services that—

- (1) The RO participant is participating in the RO Model;
- (2) The RO beneficiary has the opportunity to decline claims data sharing for care coordination and quality improvement purposes. If a RO beneficiary declines claims data sharing for care coordination and quality improvement purposes 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; and
- (3) Information regarding RO beneficiary 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 a 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) shall not apply to the standardized written notice described in paragraph (b) of this section.

Scope of 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
- (3) Has associated current ICD-10 codes that have demonstrated pricing stability.

(b) *Removing cancer types.* CMS will remove 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 baseline rates; or
- (3) The Secretary determines a cancer type not to be suitable for inclusion in the Model.

(c) *ICD-10 codes for included cancer types.* CMS displays on the RO Model website no later than 30 days prior to each performance year 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 will be 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), image-guided RT (IGRT), stereotactic radiosurgery (SRS), stereotactic body RT (SBRT), intraoperative radiotherapy (IORT), proton beam therapy (PBT), and brachytherapy.

§ 512.245 Scope of episodes.

(a) *General.* Any episode that begins on or after January 1, 2020, and ends on or before December 31, 2024, will be part of the RO Model test and subject to the rules under this part.

(b) *Death or election of hospice benefit.* An episode may be included in, and paid for under, the RO Model even if the RO beneficiary dies or enters hospice during the episode. In accordance with § 512.215(c), the RO participant may receive both installments of the episode payment under such circumstances, regardless of whether the RO beneficiary enters hospice before the relevant course of RT treatment has ended.

(c) *Clean periods.* An 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.

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. We exclude those episodes that do not meet the criteria described in § 512.245. From those episodes, we then calculate the amount CMS paid on average to providers for the PC and TC for each of the included cancer types in the HOPD setting, creating the Model's national base rates.

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

Before the start of each performance year CMS calculates the amounts for participant-specific professional episode payment amounts and participant-specific technical episode payment amounts for each included cancer type using the following:

(a) *Trend factors.* 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.

(b) *Case mix adjustment.* CMS establishes and applies case mix adjustments to the trended national base rates for the PC and TC of each included cancer type. These adjustments reflect 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.

(c) *Historical experience adjustment.* CMS establishes and applies historical experience adjustments to the national base rates after the trend factor and case mix adjustment have been applied. The historical experience adjustments reflect each RO participant's actual historical experience.

(d) *Efficiency factor.* The professional historical experience adjustment and technical historical experience adjustment for each RO participant are weighted by an efficiency factor. The RO participants with a professional historical experience adjustment or technical historical experience adjustment with a value equal to or less zero have a different CMS policy factor than those RO participants with a professional or technical historical experience adjustment of more than zero.

(e) *Changes in business structure.* RO participants must notify CMS in writing of a merger, acquisition, or other new clinical or business relationship, at least 90 days before the effective date of the change. CMS updates case mix and historical experience adjustments pursuant 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.

(f) *HOPD or freestanding radiation therapy center with fewer than 60 episodes during 2015-2017.* If a HOPD, or freestanding radiation therapy center (identified by a CCN or TIN) meets eligibility requirements and begins to provide RT services within a selected CBSA, but has fewer than 60 episodes from 2015 to 2017 to calculate case mix and historical experience adjustments, then its participant-specific professional episode payment amount and participant-specific technical episode payment amount are 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 through

2017 period continues to have fewer than 60 episodes attributed to it during the 2016 through 2018 period, then 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 through 2018 period, then 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 to PY5, we will reevaluate those same RO participants as we did in PY2 to determine the number of episodes in the rolling 3-year period used in the case mix adjustment for that performance year. RO participants that continue to have fewer than 60 attributed episodes in the rolling 3-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.

(g) *Discount factor.* CMS deducts a percentage discount from the trended national base rates after the case mix and historical experience adjustments have been applied. The discount factor for the PC is 4 percent. The discount factor for TC is 5 percent.

(h) *Incorrect payment withhold.* CMS withholds from each RO participant 2 percent from each episode payment, after the trend factor, adjustments, and discount factor have been applied, in order to account for duplicate RT services and incomplete episodes. CMS determines during the annual reconciliation process set forth at § 512.285 whether a RO participant is eligible to receive a portion or all of the withheld amount or whether any payment is owed to CMS.

(i) *Quality withhold.* CMS withholds 2 percent for the PC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factors are applied to comply with the Advanced APM criteria codified in § 414.1415(b)(1) of this chapter which requires an Advanced APM to include quality measure results as a factor when determining payment to participants under the terms of the APM. RO participants may earn back this withhold, in part or in full, based on their AQS.

(j) *Patient experience withhold.* CMS withholds one percent of the technical episode payment amounts starting in 2022 (PY3) to account for patient experience in the RO Model, which is based on the patient-reported Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) Cancer Care Radiation Therapy survey. RO participants may earn back this withhold, in part or in full, based on their results from the CAHPS® Cancer Care Radiation Therapy survey.

(k) *Geographic adjustment.* CMS further adjusts the trended national base rates that have been adjusted for each RO participant's case mix, historical experience, and after which the discount rate and withhold 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.

(l) *Coinurance.* RO participants may collect beneficiary coinsurance payments in multiple installments via a payment plan.

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 shall bill a RO Model-specific HCPCS code and a start-of-episode modifier to indicate that the treatment planning service has been furnished and that an episode has been initiated.

(2) Dual participants and Technical participants shall bill a RO model-specific HCPCS code and start-of-episode modifier to indicate that a treatment delivery service was furnished.

(3) RO participant shall bill the same RO Model-specific HCPCS code that initiated the episode and an end-of-episode modifier to indicate that the episode has ended.

(c) *Billing for RT services performed during a clean period.* A RO participant shall bill for any medically necessary RT services furnished to a RO beneficiary during a clean period pursuant to existing FFS billing processes in the OPPS and PFS.

§ 512.265 Payment.

(a) *Payment for episodes.* CMS pays a RO participant for all included RT services furnished to a RO beneficiary during an episode as follows—

(1) CMS pays a Professional participant a participant-specific professional episode payment for the professional component furnished to a RO beneficiary during an episode.

(2) CMS pays a Technical participant a participant-specific technical episode payment for the technical component furnished to a RO beneficiary during an 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 a RO beneficiary during an 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 and/or one-half of the participant-specific technical episode payment after the RO participant bills a RO Model-specific HCPCS code with a start-of-episode modifier.

(2) CMS pays the remaining half of a participant-specific professional episode and/or one-half of the participant-specific technical episode payment after the RO participant bills a RO Model-specific HCPCS code with an end-of-episode modifier.

§ 512.270 Treatment of add-on payments under existing Medicare payment systems.

CMS does not make separate Medicare FFS payments to RO participants for any included RT services that are furnished to a RO beneficiary during an episode. A RO participant may receive Medicare FFS payment for items and services furnished to a RO beneficiary during an 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 comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the Innovation Center model, as well as the terms of any agreement entered into by the RO participant with CMS as a condition of receiving that data. These laws include without limitation the standards for the privacy of individually identifiable health information and the security standards for the

protection of electronic protected health information under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). The RO participant must bind all downstream recipients of such data in a signed writing to comply with all applicable laws pertaining to patient-identifiable data provided by CMS, as well as the terms of any agreement entered into by the RO participant with CMS as a condition of receiving that data, as a condition of a downstream recipient's receipt of the data from the RO participant and the maintenance thereof.

(b) *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 content 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) Professional participants and Dual participants must report selected quality measures on all patients and clinical data elements, such as cancer stage, disease involvement, 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 shall 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 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) under section 1848(q)(6)(E) of the Act and § 414.1405(e) of this chapter 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.

(d) *APM Incentive Payment.* CMS waives the requirements of § 414.1450(b) 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).

(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-exempted 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) 1869 claims appeals procedures.

Reconciliation

§ 512.285 Reconciliation process.

(a) *General.* CMS uses the reconciliation process described in paragraph (b) of this section after the end of each performance year to identify any reconciliation payment amount owed to a RO participant or any repayment amount owed by a RO participant to CMS.

(b) *Annual reconciliation.* CMS conducts an annual reconciliation for each RO participant in August following each performance year.

(1) *Reconciliation report.* CMS issues each RO participant a reconciliation report for each performance year. Each reconciliation report contains the following:

- (i) The determination as to whether the RO participant is eligible for a reconciliation payment or must make a repayment to CMS.
- (ii) The RO participant's reconciliation payment amount or repayment amount for the relevant performance year, as calculated by CMS.

(2) *Reconciliation payments.* If a RO reconciliation report indicates that a RO participant has earned a reconciliation payment, then CMS must issue such payment to the RO participant in the amount specified in the reconciliation report as soon as administratively possible after the reconciliation report is deemed final. The RO participant is not permitted to collect any beneficiary cost-sharing with respect to any reconciliation payment received.

(3) *Repayment amounts.* If a final reconciliation report indicates that CMS is owed a repayment amount, then the RO participant must make a payment to CMS in the repayment amount 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.

§ 512.290 Timely error notice and reconsideration review process.

(a) *Timely error notice.* Subject to the limitations on review in § 512.170, if the RO participant identifies a suspected error in the calculation of their reconciliation payment or repayment amount or AQS for which a determination has not yet been deemed to be final under the terms of the RO reconciliation report, the RO participant may provide written notice of the suspected calculation error to CMS, in a form and manner and by a date and time specified by CMS.

(1) Unless the RO participant provides such notice, the reconciliation payment or repayment amount determination made under § 512.285(b)(1) is deemed final 30 days after it is issued.

(2) If CMS receives a timely notice of a suspected calculation error, then CMS will respond 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.

(4) The 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 paragraph (b) of this section.

(b) *Reconsideration review.* (1) If the RO participant is dissatisfied with CMS's response to the timely error notice, then the RO participant may request a reconsideration review of CMS's response within 10 days of the issue date of CMS' response in a form and manner specified by CMS.

(2) The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment or repayment amount or AQS in accordance with the terms of this subpart.

(3) 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 final.

(4) CMS designates a reconsideration official, who is a designee of CMS, who is authorized to receive such requests and who was not involved in the responding to the RO participant's timely error notice. The CMS 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:

- (i) The issues in dispute;
- (ii) The briefing schedule; and
- (iii) The review procedures.

(5) 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, and transitional drug add-on payment adjustment (TDAPA) amount.

Benchmark year means the 12-month period that begins 18 months prior to the start of a given measurement year (MY) from which data is 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 receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney or kidney-pancreas transplant.

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/>.

Managing clinician means a Medicare-enrolled physician or non-physician practitioner 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(d), 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 pursuant to § 512.380.

Pre-emptive transplant beneficiary means a beneficiary who received a kidney or kidney-pancreas transplant 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 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 § 512.365(c).

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 through dates beginning January 1, 2020, and ending June 30, 2026.

§ 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 a random sample of 50 percent of HRRs, stratified by Census-defined regions (Northeast, South, Midwest, and West), as well as all HRRs for which at least 20 percent of the component zip codes are located in Maryland. 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.

(b) *Applicability of general Innovation Center model provisions.* The requirement described in § 512.120(c) 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, 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 calendar year (CY) subject to adjustment as described in § 512.350 and the beneficiary is 18 years of age or older during the entire month of the claim.

§ 512.345 Payments subject to the clinician HDPA.

CMS adjusts the amount otherwise paid under 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 through date during a CY subject to adjustment as described in § 512.350 and the beneficiary is 18 years of age or older during the entire month of the claim.

§ 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) CY 2020: +3 percent
- (b) CY 2021: +2 percent

(c) CY 2022: +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, 2020, and the final MY ends on June 30, 2025.

(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, 2021, and the final PPA Period ends on June 30, 2026.

(c) *Measurement Years and Performance Payment Adjustment Periods.* MYs and PPA Periods follow the following schedule:

TABLE 1 to § 512.355 (c)--ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

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

§ 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 transplant beneficiaries to a Managing Clinician for one or more months during a MY based on the pre-emptive transplant beneficiary's receipt of services specified in paragraph (c)(2) of this section during that month, for the purpose of assessing the Managing Clinician's performance on the transplant rate during that MY. CMS attributes ESRD Beneficiaries and pre-emptive transplant beneficiaries to the ETC Participant for each month during a MY 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 transplant beneficiary to no more than one Managing Clinician for a given MY.

(b) *Exclusions from attribution.* CMS does not attribute an ESRD Beneficiary or a pre-emptive transplant beneficiary to an ETC Participant for a month if, at any point during the month, the ESRD Beneficiary or the pre-emptive transplant 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;
- (5) Has elected hospice;
- (6) Is receiving dialysis for acute kidney injury (AKI) only; or
- (7) Has a diagnosis of dementia.

(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 have received renal dialysis services, other than renal dialysis services for AKI, during the month from the ESRD facility. 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, as identified by claims with Type of Bill 072X, with claim through dates during the month. 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. CMS does not attribute pre-emptive transplant beneficiaries to ESRD facilities.

(2) *Managing clinician beneficiary attribution.* An ESRD Beneficiary 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 through dates during the month. A pre-emptive transplant beneficiary is attributed to the Managing Clinician with whom the beneficiary 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.

§ 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 transplant 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) *ESRD facilities.* 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. The numerator is the total number of home dialysis treatment beneficiary years for attributed beneficiaries during the MY. 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, 75, 76, or 80. Information used to calculate the ESRD facility home dialysis rate includes Medicare claims data and Medicare administrative data. The ESRD facility home dialysis rate is risk adjusted, as described in paragraph (d)(1) of this section, and reliability adjusted, as described in paragraph (e)(1) of this section.

(2) *Managing clinicians.* 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. The numerator is the total number of home dialysis treatment beneficiary years for attributed ESRD Beneficiaries during the MY. 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. Information used to calculate the Managing Clinician home dialysis rate includes Medicare claims data and Medicare administrative data. The Managing Clinician home dialysis rate is risk adjusted, as described in paragraph (d)(1) of this section, and reliability adjusted, as described in paragraph (e)(2) of this section.

(c) *Transplant rate.* CMS calculates the transplant rate for ETC Participants as follows.

(1) *ESRD facilities.* 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 or were in a skilled nursing facility at any point during the month. The numerator is the total number of attributed ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant at any time during the MY. Kidney transplants and kidney-pancreas transplants are identified

using claims with MS-DRG 008 or 652; claims with ICD-10 procedure codes 0TY00Z0, 0TY00Z1, 0TY00Z2, 0TY10Z0, 0TY10Z1, or 0TY10Z2; and information about transplants from the SRTR Database and Medicare administrative data to identify any transplants among attributed beneficiaries that are not identified through claims. The ESRD facility transplant rate is risk adjusted, as described in paragraph (d)(2) of this section, and reliability adjusted, as described in paragraph (e)(1) of this section.

(2) *Managing clinicians.* The denominator is 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 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 or were in a skilled nursing facility during the month. Beneficiary years for pre-emptive transplant beneficiaries included in the denominator are composed of those months during which a pre-emptive transplant beneficiary is attributed to a Managing Clinician, from the beginning of the MY up to and including the month of the transplant. The numerator is the total 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. ESRD Beneficiaries who received a kidney transplant or a kidney-pancreas transplant are identified using claims with MS-DRG 008 or 652; claims with

ICD-10 procedure codes 0TY00Z0, 0TY00Z1, 0TY00Z2, 0TY10Z0, 0TY10Z1, or 0TY10Z2; and information about transplants from the SRTR Database to identify any transplants among attributed beneficiaries that are not identified through claims. The Managing Clinician transplant rate is risk adjusted, as described in paragraph (d)(2) of this section, and reliability adjusted, as described in paragraph (e)(2) of this section.

(d) *Risk adjustment.* CMS risk adjusts the home dialysis rate using the methodology described in paragraph (d)(1) of this section and risk adjusts the transplant rate using the methodology described in paragraph (d)(2) of this section.

(1) The home dialysis rate for Managing Clinicians and ESRD facilities is risk adjusted using the most recent final risk score for the beneficiary available at the time of the calculation of the home dialysis rate, calculated using the CMS-HCC (Hierarchical Condition Category) ESRD Dialysis Model used for risk adjusting payment in the Medicare Advantage program.

(2) The transplant rate is risk adjusted by 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. The transplant rate is adjusted to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution.

(e) *Reliability adjustment.* (1) *ESRD facilities.* An ESRD facility's home dialysis rate and transplant rate are each reliability adjusted such that the ESRD facility's adjusted rate is the weighted average of the ESRD facility's rate and the rate of all ESRD facilities in the ESRD facility's aggregation group, weighted based on the reliability of the ESRD facility's rate. 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. The aggregation group for an ESRD facility that is not a subsidiary ESRD facility includes all ESRD facilities located in the HRR in which the ESRD facility is located, with the exception of subsidiary ESRD facilities.

(2) *Managing clinicians.* A Managing clinician's home dialysis rate and transplant rate are each reliability adjusted such that the Managing clinician's adjusted rate is the weighted average of the Managing clinician's rate and the rate of all Managing clinicians in the Managing clinician's aggregation group, based on the reliability of the Managing clinician's rate. Home dialysis rates and transplant rates are first grouped at the practice group level, as identified by practice TIN, for Managing clinicians who are in a group practice, and at the individual NPI level for Managing clinician who are solo practitioners. Performance is then aggregated to the aggregation group level. The aggregation group for Managing clinicians in a group practice is all Managing clinicians within the HRR in which the group practice is located. The aggregation group for Managing clinicians who are solo practitioners is all Managing clinicians within the HRR in which the Managing clinician is located.

§ 512.370 Benchmarking and scoring.

(a) *General.* CMS assesses the home dialysis rate and transplant rate for each ETC Participant against the applicable benchmarks to calculate an achievement score, as described in paragraph (b) of this section. CMS assesses the home dialysis rate and transplant rate for each ETC Participant against the applicable benchmarks to calculate an improvement score, as described in paragraph (c) of this section. 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.

The ETC Participant's MPS determines the ETC Participant's PPA, as described in § 512.380.

(b) *Achievement scoring.* CMS assesses ETC Participant performance on the home dialysis rate and transplant rate against benchmarks constructed based on the home dialysis rate and transplant rate among 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) *90th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 2 points

(2) *75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 1.5 points

(3) *50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year:* 1 point

(4) *30th+ 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 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:

Modality Performance Score

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

§ 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 18 years of age or older during the entire month of the claim, on claims with claim through dates during the applicable PPA Period as described in § 512.355(c).

(b) *Clinician PPA.* CMS adjusts the amount otherwise paid under 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 18 years of age or older during the entire month of the claim, on claims with claim through 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.

TABLE 1 to § 512.380 –FACILITY PPA AMOUNTS AND SCHEDELE

	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	+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%

TABLE 2 to § 512.380 – CLINICIAN PPA AMOUNTS AND SCHEDELE

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

§ 512.385 PPA exclusions.

- (a) *ESRD facilities.* CMS excludes an ESRD facility that has fewer than 11 attributed beneficiary-years during a MY from the applicability of the Facility PPA for the corresponding PPA Period.
- (b) *Managing Clinicians.* CMS excludes a Managing Clinician who falls below the low-volume threshold described in this paragraph during a MY from the applicability of the Clinician PPA for the corresponding PPA Period. The low-volume threshold is set at the bottom 5 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.

§ 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 60 days 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

payment that arises from the application of an incorrect PPA during the next PPA period that begins after the notification of the ETC Participant.

(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 the two quality measures below 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) *Kidney Disease Education (KDE) benefit waivers.* CMS waives the following requirements of title XVIII of the Act solely for purposes of testing the ETC Model:

(1) CMS waives the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(c)(i) of this chapter to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the Managing clinician who is an ETC Participant;

(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 receiving a diagnosis of ESRD 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 one month of the final KDE session by qualified staff.

Dated: July 2, 2019.

Seema Verma,
Administrator,
Centers for Medicare and Medicaid Services.

Dated: July 9, 2019.

Alex M. Azar II,
Secretary,
Department of Health and Human Services.