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## CMS Proposes New Payment Models for Radiation Oncology and End Stage Renal Disease (ESRD)

On July 10, the Centers for Medicare & Medicaid Services (CMS) issued a [proposed rule](#) that would implement and test two new mandatory payment models under its [Center for Medicare & Medicaid Innovation \(CMMI\)](#): the Radiation Oncology Model (**RO Model**) and the End-Stage Renal Disease (**ESRD**) Treatment Choices (**ETC Model**).

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The proposed RO Model would make prospective payments to hospital outpatient departments, freestanding radiation therapy centers and physician group practices for radiation therapy (**RT**) episodes of care.

The proposed ETC Model would make payment adjustments to ESRD facilities and some clinicians caring for beneficiaries with ESRD, to encourage greater use of home dialysis and kidney transplants.

Both models would be mandatory, operating in selected geographic areas. CMS announced the proposed mandatory ETC Model, in addition to four new optional payment models following the July 10 [Executive Order on Advancing American Kidney Health](#).<sup>1</sup>

For quick reference, the table below summarizes key features of each proposed model. A more detailed description follows the table below.

	<b>Proposed Radiation Oncology (RO) Model</b>	<b>Proposed End-Stage Renal Disease Treatment Choices (ETC) Model</b>
<b>Payment</b>	Prospective payment for RT services for 17 cancer types furnished in 90-day episode with split for professional and technical components; site-neutral payments (common payment amount regardless of where services are furnished)	(1) Increased payment for some home dialysis and related claims during initial 3 years of model  (2) Positive or negative payment adjustments for in-center and home dialysis and related claims based on facilities' and clinicians' rates of kidney and kidney-pancreas transplants, and home dialysis
<b>Timeline</b>	1/1/2020 or 4/1/2020 – 12/31/2024 (performance period)	1/1/2020 – 6/30/2026 (period in which payment adjustments are applied)
<b>Geographic Area</b>	To be announced	To be announced (will include Maryland)
<b>Participation</b>	Mandatory participation for RT providers in geographic areas selected by CMS	Mandatory participation for ESRD facilities and clinicians in geographic areas selected by CMS
<b>Quality Measures</b>	4 MIPS-approved measures and patient satisfaction and experience survey	Standardized Mortality Ratio and Standardized Hospitality Ratio

<sup>1</sup> Centers for Medicare and Medicaid Services, "[HHS To Transform Care Delivery for Patients with Chronic Kidney Disease](#)", Press Release (Jul. 10, 2019).

<b>Program Waivers</b>	Yes (for some Medicare payment adjustment requirements)	Yes (for some Medicare payment adjustment requirements and use of the Kidney Disease Education ( <b>KDE</b> ) benefit)
<b>Quality Payment Program Status</b>	Qualifies as MIPS APM and Advanced APM	Does not qualify as a MIPS APM or Advanced APM <sup>2</sup>

## Radiation Oncology Model

The proposed RO Model would focus on prospective episode-based payments for RT services furnished during a 90-day episode to Medicare beneficiaries diagnosed with one or more of 17 specified types of cancer.<sup>3</sup>

- **Payment Amount:** The RO Model would make separate payment amounts for the professional and technical components of each episode of RT.<sup>4</sup> The professional component payment would apply to RT services that may be furnished only by a physician, and a technical component payment would apply to RT services that are not furnished by a physician, including provision of equipment, supplies, and non-physician personnel related to RT services.<sup>5</sup> The professional and technical component payments for RT services included in the RO Model would be the same for services provided at a hospital outpatient department or a freestanding radiation center,<sup>6</sup> and would be determined based on proposed national base rates, trend factors and adjustments for each participant’s case-mix, historical experience and geographic location.<sup>7</sup>
- **Adjustments to the Payment:** Payment amounts would be subject to adjustment for withholds for incomplete episodes, quality and, starting in performance year 3, beneficiary experience.<sup>8</sup> For withholds due to quality and beneficiary experience, RO Model participants would have the ability to earn back a portion of the withheld amount based on the reporting of clinical data, quality measure performance and reporting, and beneficiary-reported surveys.<sup>9</sup>
- **Mandatory Participation for Providers:** CMS proposes that participation in the RO Model would be mandatory for all RT providers and suppliers within Core Based Statistical Areas (CBSAs) randomly selected by CMS<sup>10</sup> (with some proposed exclusions).<sup>11</sup> This proposed requirement has drawn concerns from key industry

<sup>2</sup> Centers for Medicare and Medicaid Services, Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures, CMS-5527-P (Unpublished in Federal Register), <https://www.hhs.gov/sites/default/files/CMS-5527-P.pdf>, pgs. 300-302.

<sup>3</sup> Supra note 2 at 8.

<sup>4</sup> Id. at 9.

<sup>5</sup> Id. at 63.

<sup>6</sup> Id. at 49.

<sup>7</sup> Id. at 11.

<sup>8</sup> Id.

<sup>9</sup> Id.

<sup>10</sup> Id. at 10.

<sup>11</sup> Id. at 65. Specifically, CMS proposes to exclude from RO Model participation any physician group practice, freestanding radiation therapy center or hospital outpatient department that furnishes RT only in Maryland, Vermont or the U.S. Territories; is classified as an ambulatory surgery center, critical access hospital, or Prospective Payment System-exempt cancer hospital; or participates in or is identified as eligible to participate in the Pennsylvania Rural Health Model.

leaders given the model’s significant departure from the status quo.<sup>12</sup>

- **Forms of Participation:** An RO Model participant would be able to participate as a Professional participant, Technical participant, or Dual participant.<sup>13</sup> Two separate participants could furnish the technical and professional components of the same episode (*e.g.*, a physician group practice could furnish the professional component as a Professional participant and a hospital outpatient department could furnish the technical component as a Technical participant).<sup>14</sup> A participant like a freestanding radiation therapy center also could elect to furnish both the professional component and technical component as a Dual participant through a single entity.<sup>15</sup>
- **Covered Cancer Types:** The covered cancer types are anal cancer, bladder cancer, bone metastases, brain metastases, breast cancer, cervical cancer, CNS tumors, colorectal cancer, head and neck cancer, kidney cancer, liver cancer, lung cancer, lymphoma, pancreatic cancer, prostate cancer, upper GI cancer, and uterine cancer.<sup>16</sup>
- **Beneficiary Participation:** Medicare beneficiaries eligible for Medicare and enrolled in Medicare Part B who have a diagnosis of at least one of the covered cancer types and who receive RT services from a provider participating in the RO Model would automatically be a beneficiary of the model.<sup>17</sup> Only beneficiaries who have traditional Medicare Fee-for-Service as their primary payer are included—Medicare Advantage enrollees are excluded.<sup>18</sup> Professional and Dual participants must notify beneficiaries of their inclusion in the RO Model through a standardized written notice during their initial treatment planning session.<sup>19</sup> Beneficiaries may not opt out of the RO Model’s payment methodology, but may exercise their freedom to choose a provider that is not subject to mandatory participation in the RO Model (*i.e.*, a provider in a different CBSA).<sup>20</sup> A beneficiary may also opt out of sharing his or her data under the RO Model.<sup>21</sup>
- **Quality Measure and Reporting Requirements:** CMS proposes to adopt four quality measures focused on the effectiveness of the RO Model.<sup>22</sup> The measures relate to (1) plan of care for pain; (2) preventive care, screening, and follow-up planning for depression; (3) advanced care planning; and (4) treatment summary communications for radiation oncology.<sup>23</sup> RO Model participants would be required to report data for all applicable patients, not just beneficiaries participating in the RO Model.<sup>24</sup> CMS also proposes to administer a patient satisfaction and experience survey to RO Model beneficiaries through a CMS-approved contractor beginning April 1, 2020. These measures would be scored to calculate an Aggregate Quality Score (AQS) that would be applied against any withheld payment amounts.<sup>25</sup> CMS believes that adoption of these proposed quality measures will meet the

<sup>12</sup> See American Society for Radiation Oncology, [Statement in Response to HHS Secretary Azar’s comments on radiation oncology alternative payment model](#), Nov. 8, 2018; Gregory Twachtman, “[First take on radiation oncology APM mixed](#),” MDedge, Jul. 12, 2019.

<sup>13</sup> *Supra* note 2 at 9.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* at 78.

<sup>17</sup> *Id.* at 73.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 13.

<sup>20</sup> *Id.* at 74.

<sup>21</sup> *Id.* at 185.

<sup>22</sup> *Id.* at 133.

<sup>23</sup> *Id.* at 122.

<sup>24</sup> *Id.* at 134.

<sup>25</sup> *Id.* at 121.

quality measure-related requirements that would qualify the RO Model as an [Advanced Alternative Payment Model](#) (APM) and as a [Merit-Based Incentive Payment System \(MIPS\) APM](#).<sup>26</sup>

- **Data Sharing:** CMS proposes to offer RO Model participants the opportunity to request a claims data file that contains patient identifiable data on the participant’s patient population, which can be used for treatment, care management and quality improvement activities.<sup>27</sup> CMS will also permit RO Model participants to reuse the data for provider incentive design and implementation.<sup>28</sup>
- **Beneficiary Waivers:** CMS will waive some Medicare payment-related requirements for carrying out testing of the RO Model, such as the payment reduction for Hospital Outpatient Quality Reporting (OQR) and the requirement to apply the additional MIPS payment adjustment factor for services billed under the RO Model.<sup>29</sup>
- **Performance Period:** The proposed RO Model would have a performance period of five calendar years, beginning in 2020 (either January 1, 2020 or April 1, 2020), and ending on December 31, 2024.<sup>30</sup> However, the model would capture all episodes that finish within the performance period, meaning that data collection, episode payments, and reconciliation would continue into calendar year 2025.<sup>31</sup>

### **ESRD Treatment Choices (ETC) Model**

The proposed ETC Model is a mandatory payment model for ESRD facilities and clinicians caring for beneficiaries with ESRD (**Managing Clinicians**) located in selected geographic areas. Its stated goal is to test whether adjusting Medicare payments to ESRD and Managing Clinicians would increase rates of home dialysis and kidney and kidney-pancreas transplants.<sup>32</sup>

- **Payment Amounts:** The Model would include two types of payment adjustments:
  1. The **Home Dialysis Payment Adjustment (HDP)** would increase payments for some Medicare home dialysis and home dialysis-related claims during the initial three years of the Model, for participating ESRD facilities and Managing Clinicians.<sup>33</sup>
  2. The **Performance Payment Adjustment (PPA)** would increase or reduce payments (in increasing amounts over time), for both home and in-center dialysis and related claims (from the ESRD Prospective Payment System for ESRD facilities and [monthly capitation payments \(MCPs\)](#) to Managing Clinicians as an ESRD patient management fee).<sup>34</sup> The adjustment would tie to ESRD facilities’ and Managing Clinicians’ rates of kidney and kidney-pancreas transplants and home dialysis among attributed beneficiaries during the Measurement Year.<sup>35</sup> The PPA would be applied during a six-month period after

<sup>26</sup> Id. at 123.

<sup>27</sup> Id. at 12-13.

<sup>28</sup> Id. at 13.

<sup>29</sup> Id. at 14, 153-163.

<sup>30</sup> Id. at 5.

<sup>31</sup> Id. at 8.

<sup>32</sup> Id. at 14.

<sup>33</sup> Id. at 16-17.

<sup>34</sup> Centers for Medicare and Medicaid Services, “[Proposed End-Stage Renal Disease Treatment Choices \(ETC\) Mandatory Model](#),” Fact Sheet (Jul. 10, 2019).

<sup>35</sup> Supra note 2 at 16-17.

the Measurement Year. Rates would be measured using Medicare claims data, Medicare administrative data including enrollment data, and the Scientific Registry of Transplant Recipients (SRTR) data.<sup>36</sup>

- **Mandatory Participation**: CMS would select ESRD facilities and Managing Clinicians to participate in the model according to their location in randomly selected geographic areas (Hospital Referral Regions or HRRs). CMS intends the selection to account for approximately 50% of ESRD facilities and Managing Clinicians in all 50 states and in the District of Columbia. However, ESRD facilities and Managing Clinicians in Maryland must generally be included in the model (to be consistent with the Total Cost of Care Model currently being tested in that state). Some facilities and clinicians would be excluded from certain parts of the model, if they serve low volumes of adult ESRD beneficiaries.<sup>37</sup>
- **Beneficiary Participation and Attribution**: Beneficiaries participating in the ESRD Model would include Medicare beneficiaries receiving dialysis or other services for ESRD, and beneficiaries who received kidney or kidney-pancreas treatments prior to receiving dialysis. CMS proposes that beneficiaries would be unable to opt out of the payment methodology, although some beneficiaries would be excluded from participation, including those under age 18, in hospice, diagnosed with dementia, or receiving dialysis for acute kidney injury.<sup>38</sup> ETC Participants would be required to notify beneficiaries of the ETC Participant's participation in the ETC Model by prominently displaying informational materials in the ESRD facilities and Managing Clinician offices or facilities where beneficiaries receive care.<sup>39</sup> Participating beneficiaries would be attributed on a month-by-month basis to the ESRD facility accounting for the most dialysis claims during the month for that beneficiary, and to the Managing Clinician billing the monthly capitation payment claim for the month for services to the beneficiary.<sup>40</sup>
- **Medicare Payment Waivers**: CMS proposes to waive certain Medicare program requirements for the ESRD PPS, ESRD Quality Incentive Program, and the Medicare Physician Fee Schedule to make payment adjustments to ETC Participants.<sup>41</sup> Some requirements regarding the use of the [Medicare Kidney Disease Education \(KDE\) benefit](#) (including who must furnish such KDE services, to whom they must be furnished, and certain curriculum restrictions) would also be waived.<sup>42</sup>
- **Quality Measures**: CMS proposes to use two quality measures for the ETC Model: the Standardized Mortality Ratio, and the Standardized Hospitalization Ratio.<sup>43</sup> ESRD facilities already are required to calculate these measures in connection with other CMS initiatives ([Dialysis Facility Reports](#) and the [ESRD Quality Incentive Program \(QIP\)](#)), and thus require no additional reporting for Model participants.<sup>44</sup> The proposed ETC Model quality measures would not be tied to payment adjustments under the Model. The Model would overlap with a number of other CMS dialysis-focused programs, including MIPS, the ESRD QIP, and the [Kidney Care First \(KCF\) and Comprehensive Kidney Care Contracting \(CKCC\) Models](#).<sup>45</sup>

<sup>36</sup> Id.

<sup>37</sup> Centers for Medicare & Medicaid Services, Innovation Center, [ESRD Treatment Choices \(ETC\) Model](#).

<sup>38</sup> Id. at 244-245.

<sup>39</sup> Id.

<sup>40</sup> Id; Supra note 2 at 246.

<sup>41</sup> Id. at 18.

<sup>42</sup> Id. at 289.

<sup>43</sup> Id. at 20.

<sup>44</sup> Id. at 19.

<sup>45</sup> Id. at 283.

- **Performance Period:** The payment adjustments for the selected ESRD facilities and Managing Clinicians would apply to Medicare claims from January 1, 2020 through June 30, 2026.<sup>46</sup> ss

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<sup>46</sup> Supra note 30; Id. at 5-6.