: 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS-5527-P2]

RIN 0938-AT89

Radiation Oncology (RO) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, (HHS).

ACTION: Proposed rule.

SUMMARY: We are proposing to delay the current start date of the RO Model to a date to be determined through future rulemaking, and to modify the definition of the model performance period to provide that the start and end dates of the model performance period for the RO Model will be established in future rulemaking.

DATES: To be assured consideration, comments must be received at one of the addresses specified in the ADDRESSES section, by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code CMS-5527-P2.

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 **https://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-P2,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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-P2,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

FOR FURTHER INFORMATION CONTACT: Rebecca Cole at Contact RadiationTherapy@cms.hhs.gov or 1-844-711-2664, Option 5.

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: https://www.regulations.gov. Follow the search instructions on that Web site to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm any individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly

identical to other comments.

I. Background

We are committed to promoting higher quality of cancer care and improving outcomes for Medicare beneficiaries while reducing costs. As part of that effort, the Biden-Harris Administration has taken a number of steps to improve the care of Medicare cancer patients, most notably with the President's cancer agenda and the Cancer Moonshot. Additionally, the CMS Innovation Center's Oncology Care Model (OCM) focuses on patients with cancer who receive chemotherapy. In late 2019, the CMS Innovation Center released an informal Request for Information on a potential future oncology value-based model after OCM ends, and we look forward to providing additional information as soon as possible.

In December 2015, Congress passed the Patient Access and Medicare Protection Act (Pub. L. 114-115) and section 3(b) of this legislation required the Secretary of the Department of Health and Human Services to submit to Congress a report, no later than 18 months after enactment, on "the development of an episodic alternative payment model" for payment under the Medicare program for radiation therapy (RT) services. We released the 2017 Report To Congress: "Episodic Alternative Payment Model for Radiation Therapy Services," which laid out the potential for reforming the way Medicare pays for radiation oncology. Based on that work, using our authority under section 1115A of the Social Security Act, we published a proposed rule, titled "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures" (84 FR 34478), which included a proposal for implementing a mandatory model for radiation oncology services (the RO Model) (84 FR 34490 through 34535). The RO Model was designed to test whether making site-neutral, prospective, episode-based payments to hospital outpatient departments, physician group practices, and freestanding radiation therapy centers for RT episodes of care would preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing or maintaining Medicare program spending.

We published a final rule titled “Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures” that appeared in the September 29, 2020 **Federal Register** (85 FR 61114) (hereinafter referred to as the “Specialty Care Models final rule”). In that final rule, we codified policies at 42 CFR part 512 subparts A and B that included a finalized RO Model with a model performance period that was to begin January 1, 2021 and end December 31, 2025 (85 FR 61367). We finalized that each performance year (PY) would be the 12-month period beginning on January 1 and ending on December 31 of each calendar year (CY) during the model performance period, and no new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

Due to the public health emergency for the Coronavirus disease 2019 (COVID-19) pandemic, we revised the RO Model's model performance period at 42 CFR 512.205 to begin on July 1, 2021, and to end December 31, 2025 giving RO participants an additional 6 months to prepare for the RO Model. We implemented the revised model period via interim final regulations included in the final rule with comment period and interim final rule with comment period that appeared in the December 29, 2020 **Federal Register** titled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)" (85 FR 85866) (hereinafter referred to as “CY 2021 OPPS/ASC IFC”).

Section 133 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116-260) (hereinafter referred to as “CAA, 2021”), enacted on December 27, 2020, included a provision

that prohibited implementation of the RO Model before January 1, 2022. This Congressional action superseded the start date of the model performance period of July 1, 2021 established in the CY 2021 OPPS/ASC IFC. To align the RO Model regulations with the requirements of the CAA, 2021, we proposed to modify the definition of "model performance period" in 42 CFR 512.205 to provide for a 5-year model performance period starting on January 1, 2022, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. We also proposed other modifications both related to and unrelated to the timing of the RO Model in the proposed rule that appeared in the August 4, 2021 **Federal Register** titled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals" (86 FR 42018). These provisions were finalized in a final rule with comment period titled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model" that appeared in the November 16, 2021 **Federal Register** (86 FR 63458) (hereinafter referred to as the "CY 2022 OPPS/ASC FC").

On December 10, 2021, the Protecting Medicare and American Farmers from Sequester Cuts Act (Pub. L. 117-71) was enacted, which included a provision that prohibits implementation of the RO Model prior to January 1, 2023. The November 2021 final rule with comment specified that the model performance period would begin on January 1, 2022 unless the RO Model was prohibited by law from beginning on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1. As a result, under the current definition for model performance period at 42 CFR 512.205, the RO Model will start on January 1, 2023, because that date is the earliest date permitted by law. Given the multiple delays to date, and because both CMS and RO participants

must invest operational resources in preparation for implementation of the RO Model, we have considered how best to proceed under these circumstances.

II. Provisions of the Proposed Regulations

A. Proposed Model Performance Period

We continue to believe that the RO Model would address long-standing concerns related to RT delivery and payment, including the lack of site neutrality for payments, incentives that encourage volume of services over the value of services, and coding and payment challenges. We believe the RO Model would provide payment stability and promote high-quality care for Medicare beneficiaries. We note that we have heard that the RO Model is valuable and needed in the radiation oncology space from some stakeholders and that some RT providers and RT suppliers selected to be RO participants are dedicated to preparing for implementation of the RO Model.

However, given that there have been two legislative delays of the RO Model, the operational resources required of CMS and RO participants to continue to prepare for the RO Model before it can be implemented, and some stakeholders' comments that they would not support the RO Model unless specific changes were made, we are proposing to delay the start of the RO Model to a date to be determined through future rulemaking and to modify the definition of model performance period at 42 CFR 512.205 to reflect this policy. We would plan to propose a start date through rulemaking and modify the definition of model performance period at 42 CFR 512.205 to reflect this proposed start date no less than 6 months prior to that proposed start date.

As noted previously, Congress has delayed the RO Model twice. There is a substantial cost to continue funding preparation for implementation of the RO Model in 2023. For example, funding is needed for CMS to prepare for participant onboarding, claims systems changes, and updates to the data used in the Model's design and participant-specific payment amounts, among a number of other activities. The cost of the operational funding needed to continue to prepare to

implement the RO Model takes resources away from the development of other alternative payment models, particularly when it is not known whether there may be further legislative delays to the start of the RO Model.

Additionally, those entities selected to be RO participants continue to make good faith efforts to prepare to implement the RO Model, which may involve financial, operational, and administrative investment and resources. Given multiple delays and uncertainty about the timing of the RO Model, delaying the RO Model indefinitely will give RO participants the ability to pause their efforts to prepare for implementation of the RO Model. We welcome additional dialogue with RO participants and stakeholders about Medicare payment for RT services.

Further, RO participants and stakeholders have requested additional changes to the RO Model's payment methodology and to other aspects of the RO Model design and participation requirements, such as lower discounts while keeping the geographic scope of the Model the same. In the CY 2022 OPPS/ASC FC, we summarized comments regarding the discounts. No commenters agreed with the proposed discounts, and many commenters recommended that the discounts be set to 3 percent or less. Those commenters, recommending discounts of 3 percent or less, argued that this would be more in line with other payment models and ensure that RO participants have sufficient capital to remain operational and invest in the necessary resources (human and equipment) to increase efficiency and enhance beneficiary care. As we have informed stakeholders, if the discounts are lowered below 3.5 percent for the professional component and 4.5 percent for the technical component, we would need to expand the geographic scope of the RO Model to be larger than 30 percent of Core Based Statistical Areas (CBSAs) (86 FR 63928 and 63929). If the discount amounts are significantly smaller, all else equal, the projected savings will be smaller, and therefore, the number of CBSAs (and episodes) in the participant group may not be sufficient for CMS to detect an effect of the RO Model with statistical confidence. However, we believe that some stakeholders will not support the RO

Model test moving forward with unchanged discounts and as noted previously, these stakeholders have also requested that we not increase the geographic scope of the Model.

Thus, for these reasons, we are proposing to delay the current start date of the RO Model, and to establish the start and end dates for the model through future rulemaking, which may also involve modifications to the model design. We are proposing to modify the definition of the model performance period at 42 CFR 512.205 to reflect this proposed delay, by removing the provision that the RO Model begins on January 1, 2022 and ends on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period begins on the earliest date permitted by law that is January 1, April 1, or July 1. We are proposing to modify the definition of model performance period to instead specify that CMS will establish the start and end dates of the model performance period for the RO Model through future rulemaking. We note that if we do not finalize this proposal and instead proceed with a start date of January 1, 2023, we do not plan to change the CBSAs selected for participation before that start date.

We are soliciting comments on the proposed delay of the RO Model to a date to be determined through future rulemaking, as well as on our proposed amendments to the definition of the model performance period at 42 CFR 512.205 to reflect this proposed delay.

III. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Social Security Act, Chapter 35 of title 44, United States Code, shall not apply to the testing, evaluation, and expansion of CMS Innovation Center Models. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

IV. Regulatory Impact Analysis

A. Statement of Need

The purpose of this proposed rule is to propose to delay the start of the RO Model to a date yet to be determined, and to modify the definition of model performance period at 42 CFR

512.205. Delaying the start of the RO Model to a date yet to be determined does not change the statement of need for the RO Model as described in the Specialty Care Models final rule (85 FR 61347) and the CY 2021 OPPS/ASC IFC (85 FR 86296) and again in the CY 2022 OPPS/ASC FC (86 FR 63458).

B. Overall Impact

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

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 1 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.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory actions or with economically significant effects ($100 million or more in any 1 year).

Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is "significant". Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

Delaying the start of the RO Model to a later undetermined date and modifying the regulatory text at 42 CFR 512.205 to reflect this would mean that the annualized/monetarized estimates of costs and transfers policy for the RO Model presented in the CY 2022 OPPS/ASC FC (86 FR 63986) would not be realized at this time.

Similarly, the burden estimates related to implementation of the RO Model presented in the Specialty Care Models final rule (85 FR 61358), the CY 2021 OPPS/ASC IFC (85 FR 86297), and the CY 2022 OPPS/ASC FC (86 FR 63987) would not be realized at this time.

The regulatory impact analysis of the CY 2022 OPPS/ASC FC estimated that on net the RO Model would reduce Medicare spending by $150 million over the 5-year model performance period. This amount is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a Federal outlay under the policy. These potential impacts were estimated to occur beginning on January 1, 2022 through December 31, 2026, in alignment with a January 1, 2022 model start. Table 1 summarizes the estimated impact of the RO Model with a model performance period that would have begun January 1, 2022, and ended December 31, 2026. Table 2 provides additional information about those expected impacts by year. However, because the RO Model was not implemented on January 1, 2022, as contemplated in the CY 2022 OPPS/ASC FC, such effects have yet not occurred.

TABLE 1: ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR RADIATION ONCOLOGY MODEL (STARTING JANUARY 1, 2022)

	Year of Model					
	2022	**2023**	**2024**	**2025**	**2026**	**Total***
Net Impact to Medicare Program Spending	-20	-30	-20	-40	-40	-150
Changes to Incurred FFS Spending	-20	-20	-20	-30	-30	-120
Changes to MA Capitation Payments	0	-20	-20	-20	-30	-80
Part B Premium Revenue Offset	0	10	10	10	10	50
Total APM Incentive Payments	0	0	10	0	0	10
Episode Allowed Charges	830	860	900	930	970	4,490
Episode Medicare Payment	650	670	700	730	750	3,500
Total Number of Episodes	53,300	54,900	56,400	58,000	59,600	282,200
Total Number of Beneficiaries	51,900	53,500	54,900	56,500	58,100	250,200

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

TABLE 2: RADIATION ONCOLOGY MODEL PGP (INCLUDING FREESTANDING RADIATION THERAPY CENTERS) VS HOPD ALLOWED CHARGE IMPACTS 2022 TO 2026 AS COMPARED TO THOSE NOT PARTICIPATING IN THE RO MODEL

% Impact	**2022**	**2023**	**2024**	**2025**	**2026**	**2022 to 2026**
PGP (including freestanding radiation therapy centers)	3.1%	4.5%	6.0%	7.4%	8.9%	6.3%
HOPD	-7.8%	-8.8%	-9.6%	-10.6%	-11.6%	-9.9%

Nevertheless, and notwithstanding the RO Model delay, the analysis uses a baseline in which the RO Model provisions of the CY 2022 OPPS/ASC FC were effective on January 1, 2022, to calculate the monetized estimates of the effects of this proposed rule. We maintain the analytical approach described in the regulatory impact analysis of the CY 2022 OPPS/ASC FC, and, for the purposes of quantifying the effects of this proposed rule, we assume that the regulations at 42 CFR part 512 subpart B as amended by the CY 2022 OPPS/ASC FC will be in full effect if this proposed rule is not finalized. As a result of the delay of the start of the RO Model to a date yet to be determined, this proposed rule would, if finalized, prevent the occurrence of the estimated savings presented in Table 90 of the CY 2022 OPPS/ASC FC at this time. We summarize this result in Table 1 in this section, which illustrates, inversely, the net monetized estimates contained in Table 90 of the CY 2022 OPPS/ASC FC. The period covered shown in Table 1 begins January 2022 in alignment with Table 90 of the CY 2022 OPPS/ASC FC.

As required by OMB Circular A-4 (available at the Office of Management and Budget

website at: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 3 showing the classification of the impact associated with the provisions of this proposed rule.

TABLE 3: ACCOUNTING STATEMENT: ESTIMATED IMPACTS FROM CY 2022 TO CY 2026 AS A RESULT OF PROVISIONS OF THIS PROPOSED RULE

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	$27 million	2020	7%	2022 – 2026
	$29 million	2020	3%	2022 – 2026
From Whom to Whom	From the Federal Government to healthcare providers			

D. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other health care providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. For details, see the Small Business Administration's "Table of Small Business Size Standards" at https://www.sba.gov/document/support--table-size-standards.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. If finalized, the impact in this proposed rule as described the CY 2022 OPPS/ASC FC would not occur. Instead, payment for submitted claims would be made under the applicable Medicare payment methodology. As a result, the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an 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 of a

Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that the RO Model will not have a significant impact on the operations of a substantial number of small rural hospitals.

We welcome comments on our estimate of significantly affected providers and suppliers and the magnitude of estimated effects for this proposed rule.

E. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This proposed rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

F. 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 the RO Model is a Federal payment model impacting Federal payments only and does not implicate local governments or state law. Therefore, the requirements of Executive Order 13132 are not applicable.

V. 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.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 31, 2022.

List of Subjects in 42 CFR 512

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble and under the authority at 42 U.S.C. 1302, 1315a, and 1395hh, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV part 512 as set forth below:

PART 512 – RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

1. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

2. Section 512.205 is amended by revising the definition of "model performance period" to read as follows:

§ 512.205 Definitions

* * * * *

Model performance period means the 5 performance years (PYs) during which RO episodes initiate and terminate. CMS will establish the start and end dates of the model performance period for the RO Model through future rulemaking.

* * * * *

Dated: April 5, 2022.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2022-07525 Filed: 4/6/2022 4:15 pm; Publication Date: 4/8/2022]