DELEGATION STATUS FOR PART 63 STANDARDS—STATE OF ARKANSAS [1]—Continued

Subpart	Source category	DEQ [2]
AAAAAA	(Reserved)	
BBBBBB	Gasoline Distribution Bulk Terminals, Bulk Plants, and Pipeline Facilities	
CCCCCC	Gasoline Dispensing Facilities	
DDDDDD	Polyvinyl Chloride and Copolymers Production Area Sources	
EEEEEE	Primary Copper Smelting Area Sources	X
FFFFFF	Secondary Copper Smelting Area Sources	X
GGGGGG	Primary Nonferrous Metals Area Sources: Zinc, Cadmium, and Beryllium	X
HHHHHH	Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources	
IIIIII	(Reserved)	
JJJJJJ	Industrial, Commercial, and Institutional Boilers: Area Sources	
KKKKKK	(Reserved)	
LLLLLL	Acrylic and Modacrylic Fibers Production Area Sources	
MMMMMM	Carbon Black Production Area Sources	X
NNNNNN	Chemical Manufacturing Area Sources: Chromium Compounds	X
OOOOOO	Flexible Polyurethane Foam Production and Fabrication Area Sources	
PPPPPP	Lead Acid Battery Manufacturing Area Sources	
QQQQQQ	Wood Preserving Area Sources	
RRRRRR	Clay Ceramics Manufacturing Area Sources	
SSSSSS	Glass Manufacturing Area Sources	X
TTTTTT	Secondary Nonferrous Metals Processing Area Sources	
UUUUUU	(Reserved)	
VVVVVV	Chemical Manufacturing Area Sources	X
WWWWWW	Plating and Polishing Operations Area Sources	
XXXXXX	Nine Metal Fabrication and Finishing Categories Area Sources	
YYYYYY	Ferroalloys Production Facilities Area Sources	
ZZZZZZ	Aluminum, Copper, and Other Nonferrous Foundries Area Sources	
AAAAAAA	Asphalt Processing and Asphalt Roofing Manufacturing Area Sources	
BBBBBBB	Chemical Preparations Industry Area Sources	
CCCCCCC	Paints and Allied Products Manufacturing Area Sources	
DDDDDDD	Prepared Feeds Manufacturing Area Sources	
EEEEEEE	Gold Mine Ore Processing and Production Area Sources	
FFFFFFF	Reserved	
GGGGGGG	Reserved	
HHHHHHH	Polyvinyl Chloride and Copolymers Production	X

[1] Program delegated to Arkansas Department of Energy and Environment, Division of Environmental Quality (DEQ).

[2] Authorities which may not be delegated include: § 63.6(g), Approval of Alternative Non-Opacity Emission Standards; § 63.6(h)(9), Approval of Alternative Opacity Standards; § 63.7(e)(2)(ii) and (f), Approval of Major Alternatives to Test Methods; § 63.8(f), Approval of Major Alternatives to Monitoring; § 63.10(f), Approval of Major Alternatives to Recordkeeping and Reporting; and all authorities identified in the subparts (*e.g.,* under ''Delegation of Authority'') that cannot be delegated.

[3] This subpart was vacated and remanded to EPA by the United States Court of Appeals for the District of Columbia Circuit. See, *Mossville Environmental Action Network* v. *EPA,* 370 F. 3d 1232 (D.C. Cir. 2004). Because of the DC Court's holding, this subpart is not delegated to DEQ at this time.

[4] This subpart was issued a partial vacatur on October 29, 2007 (72 FR 61060), by the United States Court of Appeals for the District of Columbia Circuit.

[5] Final rule. See 76 FR 15608 (March 21, 2011), as amended at 78 FR 7138 (January 31, 2013); 80 FR 72807 (November 20, 2015).

[6] Final promulgated rule adopted by the EPA. See 80 FR 65470 (October 26, 2015). Note that subpart KKKKK of this part was amended in response to a petition for reconsideration of the final rule. See 84 FR 58601 (November 1, 2019).

[7] Initial final rule. See 77 FR 9304 (February 16, 2012), as amended 81 FR 20172 (April 6, 2016). Final supplemental finding that it is appropriate and necessary to regulate hazardous air pollutant (HAP) emissions from coal- and oil-fired electric utility steam generating units (EUSGU). See 81 FR 24420 (April 25, 2016).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 512

[CMS–5527–F2]

RIN 0938–AT89

Radiation Oncology (RO) Model

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

ACTION: Final rule.

SUMMARY: We are finalizing our proposal 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: These regulations are effective on October 28, 2022.

FOR FURTHER INFORMATION CONTACT: Genevieve Kehoe, *RadiationTherapy@cms.hhs.gov,* or 1–844–711–2664 Option 5, for questions related to the Radiation Oncology Model.

SUPPLEMENTARY INFORMATION:

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 Administration has taken a number of efforts to improve the care of Medicare cancer patients, most notably with the President's cancer agenda and the Cancer Moonshot, as well as the CMS Innovation Center's Oncology Care Model [1] and Enhancing Oncology Model,[2] which focus on patients with cancer who receive chemotherapy.

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 (the Act), we published a proposed rule, titled ''Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures'', which appeared in the **Federal Register** on July 18, 2019 (84 FR 34478), and included a proposal for implementing a mandatory model for radiation oncology services (hereinafter referred to as 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 (HOPDs), physician group practices (PGPs), 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. More specifically, as described in the 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 61115) (hereinafter referred to as the ''Specialty Care Models final rule''), the RO Model was designed to include prospective payments for certain RT services furnished during a 90-day RO episode for included cancer types for certain Medicare beneficiaries. The Model was designed to test the cost-saving potential of prospective episode payments for certain RT services furnished during an RO episode and whether shorter courses of RT (that is, fewer doses, also known as fractions) will encourage more efficient care delivery and incentivize higher value care.

In the Specialty Care Models 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 CY 2022 OPPS/ASC FC specified that if the RO Model was prohibited by law from beginning on January 1, 2022, 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 would start on January 1, 2023, because that date is the earliest date permitted by law. However, 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.

[1] *https://innovation.cms.gov/innovation-models/oncology-care.*

[2] *https://innovation.cms.gov/innovation-models/enhancing-oncology-model.*

In a proposed rule titled ''Radiation Oncology (RO) Model,'' which appeared in the **Federal Register** on April 8, 2022 (87 FR 20800) (hereinafter referred to as the ''April 2022 RO Model proposed rule''), we proposed 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 at 42 CFR 512.205 to provide that the start and end dates of the model performance period for the RO Model will be established in future rulemaking.

We solicited public comment on our proposal and received approximately 38 timely pieces of correspondence. We summarize and respond to public comments in this final rule.

II. Provisions of the Finalized Regulations

A. Model Performance Period

As stated in the April 2022 RO Model proposed rule, 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 (87 FR 20802). We believe the RO Model would provide payment stability and promote high-quality care for Medicare beneficiaries. We have heard that the RO Model is valuable and needed in the radiation oncology space from some interested parties 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 interested parties' comments that they would not support the RO Model unless specific changes were made, we proposed 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 noted that we would plan to propose the new 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. In the April 2022 RO Model proposed rule, we stated that we welcome additional dialogue with RO participants and interested parties about Medicare payment for RT services (87 FR 20802).

Further, RO participants and interested parties 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. As we have informed interested parties, 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 interested parties will not support the RO Model test moving forward with unchanged discounts and as noted previously, these interested parties have also requested that we not increase the geographic scope of the Model.

Thus, for these reasons, we proposed 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 proposed 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 proposed 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. Finally, in the April 2022 RO Model proposed rule, we noted 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 (87 FR 20802).

The following is a summary of comments we received on the proposal to delay the RO Model to a date to be determined through future rulemaking in section II.A. of the April 2022 RO Model proposed rule and our responses to these comments:

Comment: Many commenters supported the delay of the RO Model to a date to be determined in future rulemaking. CMS received a couple comments requesting a January 1, 2024 start date to allow for additional time to prepare for the Model.

Response: We appreciate the support for the delay of the RO Model to a date yet to be determined and that a couple commenters requested a specific alternative future date for the RO Model to begin. We will consider whether a January 1, 2024, start date or an alternative start date would be feasible and whether such a date is likely to provide enough time to address the current challenges associated with starting the RO Model as we contemplate future rulemaking.

Comment: Some commenters requested that the RO Model as it is currently designed be cancelled altogether. These commenters noted that they believe that the Model as currently designed does not align with the Biden Administration's Cancer Moonshot goal of increasing access to innovative and appropriate cancer care. Specifically, commenters were concerned the Model would impact equitable access to proton therapy and future innovation in radiation oncology. Some commenters stated that CMS should work with interested parties to redesign the Model with respect to, for example, the discounts, mandatory participation, billing requirements, quality and clinical reporting, included modalities, and the Advanced Alternative Payment Model (APM) bonus.

Response: We appreciate these comments. However, we do not agree with the comments that the RO Model should be cancelled. As noted previously, we continue to believe that the RO Model will address long-standing concerns related to delivery and payment of RT services and benefit RT providers and RT suppliers as well as beneficiaries, because of the RO Model's focus on financial predictability through prospective, site-neutral, episode-based payment and care improvement by linking payment to quality. The RO Model is designed to test an innovative approach to payment and service delivery in the field of radiation oncology. We welcome further dialogue with interested parties and RO participants about the design of the RO Model.

Comment: A few commenters opposed the delay of the RO Model to a date to be determined through future rulemaking. These commenters stated that the RO Model has been delayed long enough and should begin on January 1, 2023. A commenter noted its disappointment in the continued delay of the RO Model and its frustration with the starting and stopping of preparation efforts. The commenter provided support for value-based, bundled payment for RT services to ensure payment stability, and urged CMS to work with interested parties to make necessary final refinements to the RO Model and implement it as soon as possible. A commenter who requested that the RO Model start January 1, 2023 further stated that the only changes that should be considered with a January 1, 2023 start are those related to changes in the national base rates or the adjustment rates that would increase the revenue to RO participants, because the commenter believed that the cost of paying RO participants more would likely be less than the cost of continued delays.

Response: Although we continue to believe that the RO Model will address longstanding concerns related to delivery and payment of RT services as described in more detail in the Specialty Care Models final rule (85 FR 61347) and again in the CY 2022 OPPS/ASC FC (86 FR 63911 and 63912), such as the site-of-service payment differential that exists under the OPPS and PFS as well as the incentives built into the current fee-for-service payment system that promotes volume over the value of services, Congress has delayed the RO Model twice, and it is not known whether there may be further delays to the start of the RO Model that are out of CMS's control. As noted previously, there is a substantial cost to continue funding preparation for implementation of the RO Model in 2023, and the cost of such funding takes resources away from the development of other alternative payment models. A continued cycle of starting and stopping preparation efforts may also involve resources on the part of RO participants. Furthermore, as described in the Specialty Care Models final rule (85 FR 61152) and in the CY 2022 OPPS/ASC FC (86 FR 63928 and 63929), in order to be able to detect an impact of the Model, changes to RO Model payment methodology may require changes to other aspects of the Model, such as increasing the size of the Model. In light of the fact that it is unknown whether there may be further delays to the RO Model that are out of CMS's control, we believe that the best course of action is to delay the implementation of the RO Model to a future date. While we appreciate commenters' request to begin the RO Model as soon as possible on January 1, 2023, we believe that the delay will provide us with the opportunity for additional dialogue with RO participants and interested parties about Medicare payment for RT services.

Comment: We received a few comments requesting that CMS provide more than 6 months' notice in advance of the future RO Model start date.

Response: We appreciate these comments. We want to emphasize that we would plan to propose a new start date for the RO Model *at least* 6 months prior to that proposed start date, and the public would have an opportunity to comment on the new proposed start date as part of the rulemaking process. CMS is committed to the success of the RO Model and providing RO participants sufficient time to prepare before the RO Model begins. Should we receive comments indicating that a proposed start date provides insufficient time to prepare, CMS will consider any such comments in its decision of when to start the RO Model.

Comment: Many commenters provided feedback not directly related to our proposal to delay the start date of the RO Model to a date to be determined through future rulemaking. These comments concerned a range of issues, including participation requirements and criteria, the geographic size of the Model, included modalities, Advanced APM incentive payment under the Quality Payment Program (QPP), and the Model's pricing methodology (for example, the national base rates, trend factor, case mix and historical experience adjustments, blend, and discount rates). Commenters also provided feedback related to the RO Model's potential impact on rural practices, health equity, and health disparities, as well as the burden of collecting and reporting the clinical data elements and the quality measures, and the burden of the RO Model's billing requirements. Commenters also discussed patient navigation tools, the beneficiary notification letter, and how the RO Model does or does not align with the goals of the Biden Administration's cancer agenda and the Cancer Moonshot.

Response: We appreciate these additional comments, which we may further consider as we evaluate how best to proceed with the RO Model going forward. As noted previously, we continue to welcome further feedback and dialogue with interested parties and RO participants on the design of the RO Model.

After considering public comments, we are finalizing our proposal to delay the start of the RO Model to a date to be determined through future rulemaking. Specifically, we are finalizing our proposed revisions to the definition of model performance period at 42 CFR 512.205, to specify that model performance period means the 5 performance years (PYs) during which RO episodes initiate and terminate, and that CMS will establish the start and end dates of the model performance period for the RO Model through future rulemaking.

III. 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 CMS Innovation Center Models. Consequently, there is no need for review by the Office of Management and Budget (OMB) 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 final rule is 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 regulatory actions 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 ''economically significant'' as measured by the $100 million threshold, and hence is also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). 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 means 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) will 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) will 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 PHYSICIAN GROUP PRACTICE (PGP) (INCLUDING FREESTANDING RADIATION THERAPY CENTERS) VS HOSPITAL OUTPATIENT DEPARTMENT (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 final 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 final rule, we assumed that the regulations at 42 CFR part 512, subpart B, as amended by the CY 2022 OPPS/ASC FC were otherwise in full effect. As we are finalizing the delay of the start of the RO Model to a date yet to be determined, the estimated savings presented in Table 90 of the CY 2022 OPPS/ASC FC will not occur at this time. We summarize this result in Table 3 later 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 3 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 final rule.

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

Category	Estimates (million)	Units		
		Year dollar	Discount rate (%)	Period covered
Transfers:				
Annualized Monetized ($million/year)	$27	2020	7	2022–2026
	29	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. Because we are finalizing our proposal, the estimated impact of the RO Model as described in the CY 2022 OPPS/ASC FC will not occur. Instead, payment for submitted claims will be made under the applicable Medicare payment methodology. As a result, the Secretary has determined that this final 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside 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 requested comments on our estimate of significantly affected providers and suppliers and the magnitude of estimated effects for the proposed rule. We did not receive any comments.

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 final 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 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.

List of Subjects in 42 CFR Part 512

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

For the reasons set forth in the preamble and under the authority at 42 U.S.C. 1302, 1315a, and 1395hh, the Centers for Medicare & Medicaid Services amends 42 CFR 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: August 24, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–18541 Filed 8–25–22; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[RTID 0648–XC196]

Pacific Island Fisheries; 2022 U.S. Territorial Longline Bigeye Tuna Catch Limits for American Samoa

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Announcement of a valid specified fishing agreement.

SUMMARY: NMFS announces a valid specified fishing agreement that allocates up to 1,500 metric tons (t) of the 2022 bigeye tuna limit for American Samoa to U.S. longline fishing vessels. The agreement supports the long-term sustainability of fishery resources of the U.S. Pacific Islands, and fisheries development in American Samoa.

DATES: The specified fishing agreement was valid as of July 20, 2022. The start date for attributing 2022 bigeye tuna catch to American Samoa was August 25, 2022.

ADDRESSES: The Fishery Ecosystem Plan for Pelagic Fisheries of the Western Pacific (FEP) describes specified fishing agreements and is available from the Western Pacific Fishery Management Council (Council), 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, or *http://www.wpcouncil.org.*

NMFS prepared environmental analyses that describe the potential impacts on the human environment that would result from the action. The analyses, identified by NOAA–NMFS–2021–0076, are available from *https://www.regulations.gov/search/docket?filter=NOAA-NMFS-2021-0076,* or from Sarah Malloy, Acting Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

FOR FURTHER INFORMATION CONTACT: Lynn Rassel, NMFS PIRO Sustainable Fisheries, 808–725–5184.

SUPPLEMENTARY INFORMATION: In a final rule published on December 29, 2021, NMFS specified a 2022 limit of 2,000 t of longline-caught bigeye tuna for each of the U.S. Pacific Island territories of American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (86 FR 73990). NMFS allows each territory to allocate up to 1,500 t of the 2,000 t limit to U.S. longline fishing vessels identified in a valid specified fishing agreement, but the overall allocation limit among all territories may not exceed 3,000 t.

On June 24, 2022, NMFS received from the Council, through its Executive Director, a specified fishing agreement between American Samoa and the Hawaii Longline Association providing an initial allocation to U.S. fishing of 1,300 t followed by a subsequent allocation, upon notification by HLA to American Samoa at a later date, of any unallocated portion of American Samoa's 1,500 mt allocation limit to U.S. fishing vessels identified in the agreement for 2022. The Council's Executive Director advised that the agreement is consistent with the FEP and its implementing regulations. On July 20, 2022, NMFS reviewed the agreement and determined that it is consistent with the FEP, implementing regulations, the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable laws.

On March 29, 2022, NMFS determined that the U.S. longline fishery exceeded the 3,554 t 2021 U.S. bigeye tuna catch limit established in regulations at 50 CFR 300.224 by 196 t. Western and Central Pacific Fisheries Commission (WCPFC) Conservation and Management Measures (CMM) 2021–01, Paragraph 37, states that where the limit has been exceeded, any overage of the limit shall be deducted from the catch limit for the following year. In accordance with U.S. obligations as a WCPFC member, NMFS must reduce the 2022 U.S. bigeye tuna limit by the amount of the overage of 196 t. NMFS is preparing a separate regulatory package that would revise the 2022 U.S. bigeye tuna limit to 3,358 t. Although the revised limit is not yet effective, NMFS is basing its decisions for attributing bigeye catch under valid specified fishing agreements with U.S. participating territories pursuant to 50 CFR 665.819(c)(9)(i) on this 3,358 t limit to ensure compliance with CMM 2021–01.

At the time NMFS determined the American Samoa specified fishing agreement was consistent with applicable laws, U.S. longline vessels operating in the area of application of the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPO) still had about 9 percent of the 3,358 t U.S. catch limit left, so NMFS waited for a later projection to determine the date for attributing catch to the 2022 American Samoa limit and agreement.

In accordance with 50 CFR 300.224(d) and 50 CFR 665.819(c)(9), vessels in the agreement may retain and land bigeye tuna in the WCPO under the American Samoa attribution specified in the fishing agreement. Based on logbook data submitted by U.S. longline vessels in the WCPFC Convention Area, NMFS forecasts that the U.S. longline fishery will reach the U.S. bigeye tuna limit of 3,358 t by September 1, 2022. Regulations at 50 CFR 665.819(c)(9)(i) direct NMFS to begin attributing catch to the applicable U.S. territory starting seven days before the date NMFS forecasts the U.S. limit to be reached, or upon the effective date of the agreement, whichever is later. Therefore, on August 25, 2022, NMFS began attributing bigeye tuna caught by vessels in the agreement to American Samoa. If NMFS determines that the fishery will reach the overall 2,000 t territorial catch limit or the 1,500 t allocation limit, NMFS will restrict the catch and retention of longline-caught bigeye tuna by vessels in order to not exceed these limits, unless the vessels are included in a subsequent specified fishing agreement with another U.S. territory.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: August 23, 2022.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–18499 Filed 8–26–22; 8:45 am]

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