



441 G St. N.W.
Washington, DC 20548

B-334577

September 9, 2022

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Richard Neal
Chairman
The Honorable Kevin Brady
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Radiation Oncology (RO) Model*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) entitled "Radiation Oncology (RO) Model" (RIN: 0938-AT89). We received the rule on August 29, 2022. It was published in the *Federal Register* as a final rule on August 29, 2022. 87 Fed. Reg. 52698. The effective date is October 28, 2022.

According to CMS, the final rule finalizes its proposal to delay the current start date of the RO Model to a date to be determined through future rulemaking. CMS stated the final rule also modifies 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.

Enclosed is our assessment of CMS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the

subject matter of the rule, please contact Shari Brewster, Assistant General Counsel, at (202) 512-6398.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive, flowing style.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
“RADIATION ONCOLOGY (RO) MODEL”
(RIN: 0938-AT89)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule will increase transfers from the federal government to health care providers in the amount of \$29 million at the three percent discount rate and \$27 million at the seven percent discount rate for the period from 2022 to 2026.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603–605, 607, and 609

CMS determined the final rule will not have a significant economic impact on a substantial number of small entities. CMS further certified the final rule will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

CMS determined this final rule does not mandate any requirements for state, local, or tribal governments, or for the private sector.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

On April 8, 2022, CMS published a proposed rule. 87 Fed. Reg. 20800. CMS received approximately 38 timely pieces of correspondence in response to the rule. CMS responded to the comments in the final rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

CMS determined PRA does not apply to the final rule because, according to CMS, PRA does not apply to the testing, evaluation, and expansion of CMS Innovation Center Models.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1315a, and 1395hh of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated the Office of Management and Budget reviewed the final rule and determined it was economically significant.

Executive Order No. 13132 (Federalism)

CMS determined the final rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication because the Radiation Oncology Model is a federal payment model impacting federal payments only and does not implicate local governments or state law.