U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

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October 13, 2020

The Honorable Chuck Grassley
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Ranking Member
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: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures*

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 "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures" (RIN: 0938-AT89). We received the rule on September 21, 2020. It was published in the *Federal Register* as a final rule on September 29, 2020. 85 Fed. Reg. 61114. The effective date of the rule is November 30, 2020.

According to CMS, this final rule implements two new mandatory Medicare payment models under section 1115A of the Social Security Act—the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model). Social Security Act, ch. 531, 49 Stat. 620 (Aug 14, 1935), 42 U.S.C. § 1315a. CMS stated that the RO Model will promote quality and financial accountability for providers and suppliers of radiotherapy (RT). CMS stated further that the RO Model will be a mandatory payment model and will test whether making prospective episode payments to hospital outpatient departments and freestanding radiation therapy centers for RT episodes of care preserves or enhances the quality of care furnished to Medicare beneficiaries while reducing Medicare program spending through enhanced financial accountability for RO Model participants. According to CMS, the ETC Model

will be a mandatory payment model focused on encouraging greater use of home dialysis and kidney transplants, in order to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. CMS stated that the ETC Model adjusts Medicare payments on certain dialysis and dialysis-related claims for participating ESRD facilities and clinicians caring for beneficiaries with ESRD—or Managing Clinicians—based on their rates of home dialysis transplant wait listing and living donor transplants. CMS asserted that the RO and ETC models will test ways to further its goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

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.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

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

ENCLOSURE

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
"MEDICARE PROGRAM; SPECIALTY CARE MODELS
TO IMPROVE QUALITY OF CARE AND REDUCE EXPENDITURES"
(RIN: 0938-AT89)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) conducted a regulatory impact analysis for this final rule. This analysis included (1) a statement of need; (2) the overall impact; (3) the anticipated effects; (4) a statement about reducing regulation and controlling regulatory costs; (5) alternatives considered; and (6) an accounting table.

CMS estimated the financial impact of the Radio Oncology Model and End-Stage Renal Disease Treatment Choices Model will net a federal savings of $253 million over a 6.5-year performance period (2021 through 2027).

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

CMS certified that this final rule will not have a significant economic impact on a substantial number of small entities. CMS also certified the final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. CMS prepared a Final Regulatory Flexibility Analysis. The analysis included: a description of the entities, including small entities, subject to the rule; an analysis of the effects of the Radio Oncology and End-Stage Renal Disease Treatment Choices models on small entities; public comments related to the RFA and the agency's response to those comments; and the projected reporting, recordkeeping, and other compliance requirements.

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

CMS determined that this final rule does not mandate any requirements for state, local, or tribal governments, or for the private sector of $100 million ($168 million, adjusted for inflation) or more.

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

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

On July 18, 2019, CMS published a proposed rule. *Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures*, 84 Fed. Reg. 34478. CMS received 330 timely comments. CMS stated that it is finalizing several of the provisions from the proposed rule, but there are a number of provisions from the proposed rule that CMS intends to address

later and a few that CMS does not intend to finalize. CMS addressed in-scope comments related to the provisions of the proposed rule it finalized in this final rule.

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

According to CMS, section 1115A(d)(3) of the Social Security Act states that, Chapter 35 of title 44, of the United States Code, shall not apply to the testing, evaluation, and expansion of models under section 1115A of the Act. Social Security Act, ch. 531, 49 Stat. 620 (Aug 14, 1935), *codified as amended at* 42 U.S.C. § 1315a. Thus CMS asserts that the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget (OMB).

Statutory authorization for the rule

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

Executive Order No. 12866 (Regulatory Planning and Review)

HHS determined that this final rule is economically significant and submitted it to OMB for review.

Executive Order No. 13132 (Federalism)

CMS determined that this rule would not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication.