



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

B-333254

May 26, 2021

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
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: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policies and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*

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: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policies and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (RIN: 0938-AU01). We received the rule on May 3, 2021. It was published in the *Federal Register* as a final rule on May 3, 2021. 86 Fed. Reg. 23496. The effective date is July 2, 2021.

According to CMS, the final rule extends the length of the Comprehensive Care for Joint Replacement (CJR) model through December 31, 2024, by adding an additional 3 performance years (PYs). CMS stated PY 6 will begin on October 1, 2021, and end on December 31, 2022; PY 7 will begin on January 1, 2023, and end on December 31, 2023; and PY 8 will begin on January 1, 2024, and end on December 31, 2024. In addition, CMS stated the final rule revises certain aspects of the CJR model including the episode of care definition, the target price

calculation, the reconciliation process, the beneficiary notice requirements, and the appeals process. CMS further stated that for PY 6 through 8, this final rule eliminates the 50 percent cap on gainsharing payments, distribution payments, and downstream distribution payments for certain recipients. Lastly, CMS stated this final rule extends the additional flexibilities provided to participant hospitals related to certain Medicare program rules consistent with the revised episode of care definition.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). The final rule was published in the *Federal Register* on May 3, 2021. 86 Fed. Reg. 23496. The Senate received the rule on May 18, 2021; however, the *Congressional Record* does not indicate when the House of Representatives received it. 167 Cong. Rec. S3333 (daily ed. May 24, 2021). The final rule has an effective date of July 2, 2021. Therefore, the final rule does not have the required 60-day delay.

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 fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Vanessa Jones
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

“MEDICARE PROGRAM: COMPREHENSIVE CARE FOR JOINT REPLACEMENT
MODEL THREE-YEAR EXTENSION AND CHANGES TO EPISODE DEFINITION AND
PRICING; MEDICARE AND MEDICAID PROGRAMS; POLICIES AND REGULATORY
REVISIONS IN RESPONSE TO THE COVID-19 PUBLIC HEALTH EMERGENCY”
(RIN: 0938-AU01)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would lead to \$86 million in savings to the federal government at the 3 percent discount rate and \$83 million at the 7 percent discount rate, annually, for the period from 2021 to 2024. CMS also estimated under an alternative scenario that the final rule would result in an annual savings of \$63 million to the federal government at the 3 percent discount rate and \$59 million at the 7 percent discount rate for the same time period.

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

CMS stated the final rule would have an economic impact on a substantial number of small entities, but it estimated the impact would not exceed the 3 or 5 percent thresholds necessary for that impact to be classified as either substantial or significant, respectively. CMS certified the final rule would not have a significant economic impact on 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 the final rule would not have any consequential effect on state, local, or tribal governments or on 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 February 24, 2020, CMS published a proposed rule. 85 Fed. Reg. 10516. CMS received approximately 66 pieces of timely correspondence containing approximately 810 discrete comments. CMS stated the comments came from groups representing medical societies, hospital associations, hospitals, and medical centers, as well as from individual physicians, and individual commenters. CMS addressed the comments in the final rule.

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

CMS determined the final rule does contain information collection requirements (ICRs) but that these ICRs are not subject to the Act. CMS summarized the ICRs in the Regulatory Impact Analysis section of the final rule.

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 final rule was reviewed by the Office of Management and Budget and determined to be economically significant.

Executive Order No. 13132 (Federalism)

CMS stated the final rule does not impose any costs on state or local governments so the requirements of the Order are inapplicable.