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November 29, 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
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: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary''*

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; Medicare Coverage of Innovative Technology (MCIT) and Definition of ''Reasonable and Necessary''" (RIN: 0938-AT88). We received the rule on November 16, 2021. It was published in the *Federal Register* as a final rule on November 15, 2021. 86 Fed. Reg. 62944. The effective date is December 15, 2021.

According to CMS, the final rule repeals the "Medicare Coverage of Innovative Technology and Definition of 'Reasonable and Necessary'" final rule, which was published on January 14, 2021, 86 Fed. Reg. 2987, and was to be effective on December 15, 2021.

The Congressional Review Act (CRA) requires a 60-day delay in 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 on November 15, 2021. 86 Fed. Reg. 62944. The Congressional Record does not indicate when the final rule was received by Congress. The final rule has a stated effective date of December 15, 2021.

Therefore, based on the date of publication in the *Federal Register*, the final rule does not have the required 60-day delay in effective date.

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: Vanessa Jones
Regulations Coordinator

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; MEDICARE COVERAGE OF
INNOVATIVE TECHNOLOGY (MCIT) AND DEFINITION OF
''REASONABLE AND NECESSARY''"
(RIN: 0938-AT88)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated a reduction of Medicare Coverage of Innovative Technology transfers from the federal government to Medicare providers in the amount of $34 million to $1.044 billion annually at a seven percent discount rate and $34.9 million to $1.071 billion annually at a three percent discount rate for the period from 2022 to 2025. CMS further estimated a reduction of transfers because of the repeal of the "Reasonable and Necessary Definition" from the federal government to Medicare providers in the amount of $51 million to $880 million annually at both the seven and three percent discount rates for the same period.

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

CMS certified the final rule would not have a significant negative economic impact on a substantial number of small entities. CMS also certified the final rule would not have a significant impact on the operations of a substantial number of 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 impose a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $158 million in any one year.

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

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

On September 15, 2021, CMS published a proposed rule. 86 Fed. Reg. 51326. CMS received approximately 115 timely items of correspondence in response to the proposed rule. CMS received comments from physicians, professional societies, manufacturers, manufacturer associations, venture capital firms, and patient advocates. CMS responded to the comments in the final rule.

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

CMS did not discuss the PRA in the final rule. In its submission to us, CMS indicated that the rule does not contain a collection of information requiring approval by the Office of Management and Budget (OMB) under the PRA.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 263a, 405, 1302, 1320b-12, 1395x, 1395y, 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated OMB determined the final rule was economically significant.

Executive Order No. 13132 (Federalism)

CMS determined the final rule was not subject to the requirements of the Order because it does not impose any costs on state or local government.