

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

B-332900

February 16, 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  
Republican Leader  
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 January 19, 2021. It was published in the *Federal Register* as a final rule on January 14, 2021. 86 Fed. Reg. 2987. The stated effective date of the rule is March 15, 2021.

According to CMS, this final rule establishes a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA). CMS stated that the Medicare Coverage of Innovative Technology (MCIT) pathway will result in 4 years of national Medicare coverage starting on the date of FDA market authorization or a manufacturer chosen date within 2 years thereafter. CMS stated that the rule also implements regulatory standards to be used in making reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act, Pub. L. No. 74-271, 49 Stat. 620 (Aug. 14, 1935), for items and services that are furnished under Part A and Part B.

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). This final rule was published on January 14, 2021. 86 Fed. Reg. 2987. The rule was received by the Senate on February 2, 2021. 167 Cong. Rec. S703 (daily ed. Feb. 12, 2021). The *Congressional Record* does not yet reflect when the House of Representatives received the rule. The rule has a stated effective date of March 15, 2021. Therefore, the final rule does not have the required 60-day delay in its 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.

A handwritten signature in cursive script that reads "Shirley A. Jones". The signature is written in black ink and is positioned above the typed name and title.

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  
“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), stated that the impact of implementing the Medicare Coverage of Innovative Technology (MCIT) pathway is difficult to determine without knowing the specific technologies that would be covered. CMS further stated that there is a range of potential impacts of the proposed MCIT coverage pathway, and estimates demonstrate how sensitive the impact is to the cost and utilization of these unknown devices. CMS stated that the impact of defining “reasonable and necessary” is hard to quantify without knowing the specific items and services that would be included in future National Coverage Determinations and Local Coverage Determinations and the criteria that CMS will use for determining which commercial insurers will be considered. CMS also stated that the definition it is finalizing provides consistency and flexibility regarding the role of commercial insurer coverage in the Medicare program.

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

The Secretary of the Department of Health and Human Services certified that this final rule will not have a significant negative economic impact on a substantial number of small entities because small entities are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business. The Secretary also certified that the rule will not have a significant impact on the operations of a substantial number of small rural hospitals because small rural hospitals are not being asked to undertake additional effort or take on additional costs outside of the ordinary course of business.

(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 will have no 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 September 1, 2020, CMS published a proposed rule. 85 Fed. Reg. 54327. CMS received comments on the proposed rule and responded to comments in this final rule.

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

CMS determined that this final rule contains information collection requirements under PRA. The proposed requirements and burden will be submitted to the Office of Management and Budget (OMB) under control number 0938-NEW.

Statutory authorization for the rule

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

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined that this final rule reaches the economic threshold (economically significant effects of \$100 million or more in any 1 year) and thus is considered a major rule. CMS stated that the rule was reviewed by OMB.

Executive Order No. 13132 (Federalism)

CMS determined that this final rule does not impose any costs on state or local governments and that the requirements of the Order are not applicable.