



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

B-334211

June 6, 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: Medicare Program; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards*

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; Maximum Out-of-Pocket (MOOP) Limits and Service Category Cost Sharing Standards” (RIN: 0938-AT97). We received the rule on April 13, 2022. It was published in the *Federal Register* as a final rule with comment period on April 14, 2022. 87 Fed. Reg. 22290. The effective date is June 13, 2022.

According to CMS, the final rule finalizes the two remaining proposals from the proposed rule titled “Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” which appeared in the *Federal Register* on February 18, 2020. 85 Fed. Reg. 9005. CMS stated the two proposals being finalized here include the MOOP limits for Medicare Parts A and B services and cost sharing limits for Medicare Parts A and B services, including service category cost sharing limits and per member per month actuarial equivalence cost sharing.

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 April 14, 2022. 87 Fed. Reg. 22290. The *Congressional Record* does not yet reflect receipt by the House of Representatives, but it does show the Senate received the final rule on April 25, 2022. 168 Cong. Rec. S2418 (daily ed. May 10, 2022). The final rule has a stated effective date of June 13, 2022. Therefore, 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.

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  
“MEDICARE PROGRAM; MAXIMUM OUT-OF-POCKET (MOOP) LIMITS  
AND SERVICE CATEGORY COST SHARING STANDARDS”  
(RIN: 0938-AT97)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) stated the final rule has no cost. According to CMS, a combination of three reasons drives the conclusion that, in aggregate, the final rule has no cost: (1) the Medicare Advantage requirement of actuarial equivalence to coverage in original Medicare, implying that plans can shift costs, but not create additional out-of-pocket costs for enrollees compared to the original Medicare program; (2) many of the provisions of the final rule are codifications of existing practice, which because of the annual bid cycle and review, CMS is confident plans are complying with; and (3) with regard to the maximum out-of-pocket (MOOP) limits provisions, analysis of bid changes shows that plans in general have not been charging the highest MOOP amount. CMS stated that, as a result, although in aggregate there is no estimated impact, Medicare Advantage plans may shift cost sharing costs provided they do not create additional costs.

(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 economic impact on a substantial number of small entities. CMS further certified the final rule does not impose a burden on 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 is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$158 million or more.

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

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

On February 18, 2020, CMS published a proposed rule. 85 Fed. Reg. 9005. CMS received 44 timely pieces of correspondence containing multiple comments from health plans, provider associations, beneficiary and other advocacy organizations, and pharmaceutical companies.

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

CMS stated the final rule contains no new information collection requirements subject to PRA.

Statutory authorization for the rule

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

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated the final rule is economically significant under the Order.

Executive Order No. 13132 (Federalism)

CMS determined the final rule will not impose substantial direct requirement costs on state and local governments, preempt state law, or have any federalism implications.