



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

B-333876

February 16, 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: Most Favored Nation (MFN) Model*

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 “Most Favored Nation (MFN) Model” (RIN: 0938-AT91). We received the rule on December 27, 2021. It was published in the *Federal Register* as a final rule on December 29, 2021. 86 Fed. Reg. 73986. The effective date is February 28, 2022.

According to CMS, this final rule rescinds the Most Favored Nation Model interim final rule with comment period. CMS stated the interim final rule with comment period was published on November 27, 2020, in the *Federal Register*. 85 Fed. Reg. 76180.

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 Senate received this rule on January 14, 2022. 168 Cong. Rec. S674 (daily ed. Feb. 14, 2022). The final rule has an effective date of February 28, 2022. Therefore, based on the date the Senate received the rule, 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, reading "Shirley A. Jones". The signature is written in a cursive style with a large, stylized "S" and "J".

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
“MOST FAVORED NATION (MFN) MODEL”
(RIN: 0938-AT91)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) prepared an accounting statement for this final rule. The accounting statement presents two tables which reflect the estimated impacts from calendar year 2021 through calendar year 2028 as a result of the provisions of this final rule, based on estimates from the CMS Office of the Actuary (OACT), and the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE). CMS stated that both the OACT estimate and the ASPE estimate reflect, as a result of the provisions of this final rule, decreased costs to hospitals and physicians, and transferred costs from the federal government to hospitals, physicians, and plans, transferred costs from beneficiaries to hospitals, physicians, and plans, and transferred costs from states to hospitals, physicians, and plans.

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

The Secretary of HHS has certified that this final rule will have a significant economic impact on a substantial number of small entities. According to CMS, the Regulatory Flexibility Analysis presented in the *November 2020 IFR* describes the potential impact of the Most Favored Nation Model, if it had been implemented, on small entities. 85 Fed. Reg. 76180. CMS stated that this final rule prevents those impacts from being realized. CMS also stated that the lower drug payments and alternative add-on payments described in the *November 2020 IFR* will not occur. CMS stated further that payment for submitted claims will be made under the applicable Medicare payment methodology.

Additionally, CMS estimated that this final rule will have a significant impact on small rural hospitals by preventing the impacts described in the *November 2020 IFR* from being realized. CMS also stated that these rural entities will not experience drug payment reductions and overall payment reductions. CMS stated further that payment for submitted claims will be made under the applicable Medicare payment methodology.

(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 an analysis under the Act is not required for this final rule because it does not mandate any spending by state, local, or tribal governments, or by 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 August 10, 2021, CMS published a proposed rule to rescind the *November 2020 IFR*. 86 Fed. Reg. 43618. According to CMS, it received 34 timely items of correspondence from health care providers (such as health systems, hospitals, physician practices, and infusion centers), physician specialty groups, drug manufacturers, pharmaceutical industry groups, pharmacy benefit managers, patient advocacy groups, and individuals. CMS provided a summary of the public comments received as well as its response to the comments in this final rule.

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

CMS determined that this final rule does not impose information collection requirements.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to section 301 of title 5, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that the Office of Management and Budget's Office of Information and Regulatory Affairs determined that this final rule is economically significant.

Executive Order No. 13132 (Federalism)

CMS determined that this final rule does not impose any costs on state or local governments, preempt state law, or otherwise have Federalism implications, and the requirements of the Order are not applicable.