U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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December 8, 2020

The Honorable Chuck Grassley
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
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: 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 November 24, 2020. It was published in the *Federal Register* as an interim final rule with comment period (IFC) on November 27, 2020. 85 Fed. Reg. 76180. The effective date of this IFC is November 27, 2020.

According to CMS, this IFC implements the Most Favored Nation (MFN) Model, a new Medicare payment model under section 1115A of the Social Security Act (the Act). *See* the Act, ch. 531, § 1115A, 49 Stat. 620 (Aug. 14, 1935), 42 U.S.C. § 1315A. CMS stated that the MFN Model will test whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as drugs) with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.

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 60-day delay in effective date can be waived, however, if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. §§ 553(b)(3)(B), 808(2). Here, although CMS did not specifically mention CRA's 60-day delay in effective date requirement, CMS stated that notice and comment procedures are unnecessary for this IFC and the agency finds good cause to waive such procedures under section 553(b)(3)(B) of the Administrative Procedure Act. CMS asserted that it found that there is good cause to waive the notice and comment because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic. CMS stated that implementation of this model will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost-sharing on the alternative add-on payment. CMS stated further that it is waiving the 30-day delay in effective date under 5 U.S.C. § 553(d) because it asserts that delaying implementation of this IFC is contrary to the public interest for the same reasons that it found good cause to waive prior notice and comment.

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
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) provided a summary of cost and benefits for this interim final rule with comment period (IFC). CMS stated that it believes the Most Favored Nation (MFN) Model will substantially lower drug payment amounts for the most costly Medicare Part B drugs, thereby lowering program expenditures and out-of-pocket costs for beneficiaries. CMS also stated it estimates that the MFN Model will result in substantial overall Medicare savings during the 7-year model performance period (that is, 28 calendar quarters). CMS stated further that it estimates an overall savings of $85.5 billion, net of the associated change in the Part B premium, in Medicare Part B spending. In addition, CMS asserts that all beneficiaries will save an estimated total of $28.5 billion from a reduction in the Medicare Part B premium as a result of the MFN Model, and will also see their coinsurance reduced. CMS explained that HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) roughly estimated a net reduction of $87.8 billion in spending on MFN Model drugs by the federal government, state governments, and beneficiaries over the 7 years of the model. CMS noted that there is much uncertainty around the assumptions for these estimates and that the agency included a Regulatory Impact Analysis of this IFC for a more complete discussion of potential impacts of the MFN Model.

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

CMS prepared a Final Regulatory Flexibility Analysis, but noted that some of the analysis and discussion of the mandates under RFA are discussed throughout the IFC. According to CMS, the vast majority of MFN participants are considered to be small entities, based upon Small Business Administration standards, and there are over 20,000 MFN model participants that will be included or affected by the MFN Model. CMS provided an analysis (table 3 in the IFC) showing the number of entities and type of provider or suppliers that will most likely be impacted by the IFC. CMS stated that the potential impact on an MFN participant's revenue will be driven by the proportion of Medicare payments to the MFN participant that is related to administering Medicare Part B drugs, rather than its size. CMS also stated that the IFC provides financial protection for MFN participants by including a financial hardship exemption for MFN participants (regardless of size) that experience significant financial hardship as a result of the model test. CMS stated further that it is likely that many, if not all, included providers and suppliers will see an overall decrease in revenue for MFN Model drugs of 3 percent or more over the course of the model. CMS asserted that it has and will continue to take steps to minimize the impact of this IFC on administrative and reporting burdens for small businesses. Lastly, CMS noted, rural entities will experience drug payment reductions and overall payment reductions similar to urban entities under the MFN Model.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

CMS determined this IFC 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.*

CMS stated that notice and comment procedures are unnecessary for this IFC and the agency found good cause to waive such procedures under section 553(b)(3)(B) of the Administrative Procedure Act. CMS asserted that it found that there is good cause to waive the notice and comment because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic. CMS stated that implementation of this model will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost-sharing on the alternative add-on payment. CMS stated further that it has waived the delay in effective date under 5 U.S.C. § 553(d) because it asserts that delaying implementation of this IFC is contrary to the public interest for the same reasons that it found good cause to waive prior notice and comment.

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

CMS asserted that under section 1115A(d)(3) of the Social Security Act, PRA does not apply to the testing and evaluation of CMS Innovation Center Models. *See* Social Security Act, ch. 531, § 1115A(d)(3), 49 Stat. 620 (Aug. 14, 1935), 42 U.S.C. § 1315A(d)(3). As a result, according to CMS, the information collection requirements contained in this IFC need not be reviewed by the Office of Management and Budget. Even so, CMS provided an analysis of the estimated cost incurred through the information collection in this IFC. CMS stated that it assumes the "patient experience survey" provided for in this IFC will be administered to 75,000 beneficiaries and be completed by 30,000 beneficiaries per year. CMS also stated, the survey will take approximately 30 minutes to complete. Therefore, according to CMS, the annual total number of hours for this information collection will be 15,000 hours (30,000 beneficiaries multiplied by 0.5 hours per beneficiary responding), and the estimated cost for this information collection will be $385,800 (15,000 hours multiplied by $25.72).

Statutory authorization for the rule

CMS promulgated this IFC pursuant to section 301 of title 5, and sections 1302, 1351, and 1395hh of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that this IFC is economically significant under the Order.

Executive Order No. 13132 (Federalism)

CMS determined this IFC will not have a direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication.