U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

B-336022

February 29, 2024

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Jason Smith
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*

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 and Medicaid Services (CMS), titled "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." We received the rule on June 30, 2023, and it was issued by CMS as a memorandum on the same date. *See* Memorandum from Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare to interested parties, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year* 2026 (Revised Guidance Rule). On February 13, 2024, CMS informed us that the Revised Guidance Rule will not be published in the *Federal Register*.[1] The stated effective date of the Revised Guidance Rule is June 30, 2023.

[1] CMS also stated that it published a notice in the *Federal Register* on July 3, 2023, announcing the availability of the Revised Guidance Rule. Email from CMS, to Paralegal Specialist, GAO,

The Revised Guidance Rule provides interested parties with revised Medicare Drug Price Negotiation Program (Program) guidance for Initial Price Applicability Year 2026. CMS stated that the Revised Guidance Rule includes the following sections: 1) an introduction; 2) a summary of changes and clarifications to the initial memorandum released on March 15, 2023; 3) a summary of the public comments received in response to the initial memorandum, and CMS's responses; and 4) revised guidance that establishes final policies on the topics discussed for Initial Price Applicability Year 2026. CMS also stated that they may supplement the Revised Guidance Rule with further program instruction to explain how these policies will be implemented during Initial Price Applicability Year 2026 (e.g., technical instructions for data submissions).

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 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. *See* 5 U.S.C. §§ 553(b)(3)(B), 808(2). Here, CMS did not specifically mention CRA's 60-day delay in effective date requirement. But CMS asserts that notice-and-comment procedures provided for under the Administrative Procedure Act (APA) do not apply to the Revised Guidance Rule because sections 11001(c) and 11002(c) of the Inflation Reduction Act (IRA) state that CMS "shall implement" the Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." *See generally* 42 U.S.C. §§ 1320f note, 1320f-1 note (sections 11001(c) and 11002(c) of the IRA). CMS explained that the terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. Thus, according to CMS, the statutory directive in sections 11001(c) and 11002(c) requires it to follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under APA.

Additionally, CMS stated that even if APA applied, notice-and-comment for the Revised Guidance Rule would be impracticable, unnecessary, and contrary to the public interest. Accordingly, CMS stated, it found good cause to waive notice-and-comment procedures under APA. Specifically, CMS stated that complex actions must be undertaken in advance of the statutorily mandated publication of the selected drug list by September 1, 2023, hence there was good cause to issue the Revised Guidance Rule as final without soliciting public comment and without a delayed effective date. CMS also stated that it could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far enough in advance of statutory deadlines to allow them adequate time to complete their preparations for potential participation in the Program.

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

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Subject: XVIII Rx $ Negotiation Program: Revised Guidance Implementation of § 1191–1198 of the SSA for Initial Price Applicability Year 2026 (Feb. 13, 2024); *See* 88 Fed. Reg. 42723.

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: Samuel A. Shipley
Senior Regulatory and Policy Coordinator
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEATH AND HUMAN SERVICES,
CENTERS FOR MEDICARE AND MEDICAID SERVICES
TITLED
"MEDICARE DRUG PRICE NEGOTIATION PROGRAM:
REVISED GUIDANCE, IMPLEMENTATION OF SECTIONS 1191-1198
OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2026"

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) did not prepare a cost-benefit analysis for this rule. In its submission to us, CMS indicated that the preparation of a cost-benefit analysis is not applicable to its Revised Guidance Rule.

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

CMS did not address RFA in the rule. In its submission to us, CMS indicated that RFA is not applicable to the Revised Guidance Rule.

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

CMS did not address the Act in the rule. In its submission to us, CMS indicated that the Act is not applicable to the Revised Guidance Rule.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO's major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: "the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act's exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act's requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the OMB Director as required by section 263(a) or (b) of the Act" in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive Departments and Agencies,* Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

The Revised Guidance Rule was issued and submitted to GAO before OMB released its guidance to implement the Act. OMB guidance did not go into effect until September 1, 2023.

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

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

CMS asserts that notice-and-comment procedures provided for under the Administrative Procedure Act (APA) do not apply to the Revised Guidance Rule because sections 11001(c) and 11002(c) of the Inflation Reduction Act (IRA) state that CMS "shall implement" the Program "for 2026, 2027, and 2028 by program instruction or other forms of program guidance." *See generally* 42 U.S.C. §§ 1320f note, 1320f-1 note (sections 11001(c) and 11002(c) of the IRA). CMS explained that the terms "program instruction" and "program guidance" are terms of art that Congress routinely uses in Medicare statutes to refer to agency pronouncements other than notice-and-comment rulemaking. Thus, according to CMS, the statutory directive in sections 11001(c) and 11002(c) requires it to follow policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under APA.

Additionally, CMS stated that even if APA applied, notice-and-comment for the Revised Guidance Rule would be impracticable, unnecessary, and contrary to the public interest. Accordingly, CMS stated, it found good cause to waive notice-and-comment procedures under APA. Specifically, CMS stated that complex actions must be undertaken in advance of the statutorily mandated publication of the selected drug list by September 1, 2023, hence there was good cause to issue the Revised Guidance Rule as final without soliciting public comment and without a delayed effective date. CMS also stated that it could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far enough in advance of statutory deadlines to allow them adequate time to complete their preparations for potential participation in the Program.

On March 15, 2023, CMS issued an initial memorandum for implementation of the Medicare Drug Price Negotiation Program (Program) for Initial Price Applicability Year 2026. Memorandum from Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare, to interested parties*, Medicare Drug Price Negotiation Program: Initial Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 and Solicitation of Comments.* CMS stated that it solicited comments on the initial memorandum and that it received more than 7,500 comments in response to its request. CMS also stated that the comments represented a wide range of views from academic experts and thought leaders, consumer and patient organizations, data vendors/software technology entities, health plans, health care providers, health systems, individuals, labor unions, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers, state governments, trade associations, venture capital firms, and wholesalers. CMS stated further that it provided a summary of significant comments that it received as well as the agency's response to those significant comments.

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

CMS determined that this final rule contains information collection requirements (ICRs). CMS stated that it released a Negotiation Data Elements ICR (CMS-10847 / OMB Control Number 0938-NEW) to detail the specific data CMS is requesting for purposes of implementing the negotiation process to determine the maximum fair price.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 1320f note and 1320f-1 note of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS did not address the Order in the rule. In its submission to us, CMS indicated that the Order is not applicable to the Revised Guidance Rule.

Executive Order No. 13132 (Federalism)

CMS did not address the Order in the rule. In its submission to us, CMS indicated that the Order is not applicable to the Revised Guidance Rule.