



441 G St. N.W.
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B-336761

October 24, 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 & Medicaid Services: Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*

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 Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027.” We received the rule on October 9, 2024, and it was issued by CMS as a memorandum on October 2, 2024. 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: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* (Final Guidance Rule). CMS published a notice in the *Federal Register* on October 10, 2024, announcing the availability of the Final Guidance Rule. 89 Fed. Reg. 82245. The effective date of the rule is December 9, 2024.

This rule provides CMS's final guidance of the second cycle of the Medicare Drug Price Negotiation Program and manufacturer effectuation of the maximum fair price in 2026 and 2027 for the implementation of the Inflation Reduction Act.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive style with a large, prominent "S" at the beginning.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Centers for Medicare & Medicaid 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 DRUG PRICE NEGOTIATION PROGRAM:
FINAL GUIDANCE, IMPLEMENTATION OF SECTIONS 1191–1198
OF THE SOCIAL SECURITY ACT FOR INITIAL PRICE APPLICABILITY YEAR 2027 AND
MANUFACTURER EFFECTUATION OF THE MAXIMUM FAIR PRICE IN 2026 AND 2027”

(i) Cost-benefit analysis

In its submission to us, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) indicated that it was not required to prepare an analysis of the costs and benefits of this rule.

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

In its submission to us, CMS indicated the Act is not applicable to this rule.

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

In its submission to us, CMS indicated the Act is not applicable to this 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.

In its submission to us, CMS indicated the Act is not applicable to this rule.

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

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

CMS published a notice of opportunity for the public to comment on its draft guidance. 89 Fed. Reg. 37229. In this rule, CMS stated that it could not have proceeded through notice-and-comment rulemaking and still provided interested parties with guidance sufficiently far in advance of the relevant statutory deadlines. Final Guidance Rule, at 161. CMS responded to comments in this rule. *Id.* at 9.

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

In its submission to us, CMS indicated the Act is not applicable to this rule.

Statutory authorization for the rule

In its submission to us, CMS indicated that sections 11001(c) and 11002(c) of the Inflation Reduction Act (IRA) direct the Secretary of HHS to implement the Negotiation Program provisions in sections 11001 and 11002 of IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance.

Executive Order No. 12866 (Regulatory Planning and Review)

In its submission to us, CMS indicated the Order is not applicable to this rule.

Executive Order No. 13132 (Federalism)

In its submission to us, CMS indicated the Order is not applicable to this rule.