



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

B-337905

December 4, 2025

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

The Honorable Brett Guthrie
Chairman
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 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*

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 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028.” We received the rule on November 17, 2025. It was issued by CMS as a memorandum on September 30, 2025. See Memorandum from Chris Klomp, CMS Deputy Administrator and Director of the Center for Medicare, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (Final Guidance Rule). The stated effective date of the rule is January 1, 2026.

This rule provides interested parties with the final Medicare Drug Price Negotiation Program guidance for the initial price applicability year 2028 and manufacturer effectuation of the maximum fair price in 2026, 2027, and 2028.

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 Guidance Rule was issued on September 30, 2025. The House of Representatives received the rule on November 17, 2025. 171 Cong. Rec. H4768 (daily ed. Nov. 18, 2025). The Senate received the rule on November 19, 2025. 171 Cong. Rec. S8271 (daily ed. Nov. 20, 2025). The stated effective date of the rule is January 1, 2026. Therefore, the stated effective date is less than 60 days from the date of receipt of the rule by Congress.¹

Enclosed is our assessment of HHS'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 Will Shakely, Acting Assistant General Counsel, at (202) 512-3363.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Shirley A. Jones
Managing Associate General Counsel

¹ The 60-day delay in effective date does not apply if the agency finds for good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates the finding and a brief statement of its reasons in the rule. 5 U.S.C. § 808(2). Although CMS did not specifically mention CRA's delayed effective date requirement, the agency found good cause to waive notice-and-comment procedures and incorporated a brief statement of reasons in the rule. Final Guidance Rule, at 154. Specifically, CMS stated that to the extent the Final Guidance Rule establishes or changes any substantive legal standard, notice and public procedure would be impracticable, unnecessary, and contrary to the public interest in light of the statutory requirement to implement sections 11001 and 11002 of the Inflation Reduction Act of 2022 for 2026, 2027, and 2028 by program instruction and in light of the complexity of the preparations that must be undertaken in advance of the publication by February 1, 2026, of the selected drug list for initial price applicability year 2028 and to establish the mechanisms necessary for manufacturers to provide access to any maximum fair price agreed upon for drugs selected for initial price applicability year 2026 starting on January 1, 2026. Final Guidance Rule, at 154. However, CMS issued draft guidance on May 12, 2025, see 90 Fed. Reg. 20674 (May 15, 2025), solicited public comment on all sections of the rule other than section 90.3, and addressed the comments in the final guidance. Final Guidance Rule at 2–3. GAO has previously stated that the good cause exception to CRA's 60-day delayed effective date requirement only applies where the agency has not undertaken notice-and-comment procedures. See OGC-97-32 (Mar. 28, 1997); B-336904, Dec. 12, 2024.

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 DRUG PRICE NEGOTIATION PROGRAM: FINAL GUIDANCE,
IMPLEMENTATION OF SECTIONS 1191–1198 OF THE SOCIAL SECURITY ACT
FOR INITIAL PRICE APPLICABILITY YEAR 2028 AND MANUFACTURER EFFECTUATION
OF THE MAXIMUM FAIR PRICE IN 2026, 2027, AND 2028”

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

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

CMS stated that this rule is not subject to the notice-and-comment requirements of the Act. Final Guidance Rule, at 153. However, CMS published draft guidance on May 12, 2025. 90 Fed. Reg. 20674 (May 15, 2025). CMS stated that they received comments from various interested parties. Final Guidance Rule, at 2. CMS responded to comments in the rule. *Id.* at 3.

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

CMS determined that this rule contains information collection requirements under the Act. Final Guidance Rule, at 178.

Statutory authorization for the rule

In its submission to us, CMS indicated that sections 11001(c) and 11002(c) of the Inflation Reduction Act of 2022 (IRA) direct the Secretary of HHS to implement the Negotiation Program provisions in sections 11001 and 11002 of the 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.