U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

B-338910

November 20, 2026

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 and Medicare Prescription Drug Benefit Program*

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 (HHS), Centers for Medicare & Medicaid Services (CMS) entitled "Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program" (RIN: 0938-AV90). We received the rule on November 9, 2026. It was published in the *Federal Register* on November 9, 2026. 91 Fed. Reg. 72176. The stated effective date of the rule is December 5, 2026.

According to CMS, this rule finalizes and codifies the Medicare Drug Price Negotiation Program (Negotiation Program) and establishes certain new policies for the Negotiation Program and the Medicare Prescription Drug Benefit Program (Part D Program) as required by the Inflation Reduction Act of 2022. CMS stated that the rule also finalizes a proposed policy for specific fixed combination drugs that are new formulations.

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 rule was published in the *Federal Register* on

November 9, 2026. 91 Fed. Reg. 72176. The Senate and House of Representatives received the rule on November 9, 2026. 172 Cong. Rec. H6145 (daily ed. Nov. 10, 2026); 172 Cong. Rec. S5756 (daily ed. Nov. 18, 2026). The rule has a stated effective date of December 5, 2026. Therefore, the stated effective date is less than 60 days from the date of publication in the *Federal Register* and less than 60 days from the date of receipt by Congress.[1] However, CMS stated that the rule applies to the Negotiation Program beginning with initial price applicability year 2029 and to Part D Program coverage beginning January 1, 2029.

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 me at (202) 512-8156.



Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human Services

[1] CMS stated in the rule that it found good cause to waive the 60-day delay in effective date to allow it to meet the statutory deadline of February 1, 2027, for publication of the selected drug list. 91 Fed. Reg. 72179–80. The exception in section 808(2) only applies when the agency has found good cause to waive notice and public procedure requirements when promulgating the rule and incorporates the finding and a brief statement therefor in the rule. 5 U.S.C. § 808(2). Here, CMS's good cause finding relates to waiving the delay in effective date, not to waiving the notice and public procedure requirements. Further, CMS published a notice of proposed rulemaking on June 16, 2026, 91 Fed. Reg. 36236, on which it solicited comments. Therefore, this exception does not apply.

ENCLOSURE

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 AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM"
(RIN: 0938-AV90)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) prepared an analysis of the costs and benefits of this rule. 91 Fed. Reg. 72176, 72348–56 (Nov. 9, 2026). CMS estimated that the rule will result in annualized costs of $8.38 million in calendar year 2029. *Id.* at 72356. CMS further stated that the rule will result in transfers from the federal government and Medicare enrollees to pharmaceutical manufacturers during calendar years 2028 to 2034 of $9.976 billion, at a three percent discount rate, and $8.695 billion, at a seven percent discount rate. *Id.*

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

The Secretary of HHS certified that this rule will not have a significant economic impact on a substantial number of small entities. 91 Fed. Reg. at 72357. The Secretary further certified that the rule will not have a significant impact on the operations of a substantial number of small rural hospitals. *Id.* at 72358.

(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 this rule will not have an effect on state, local, or tribal governments, in the aggregate, or on the private sector, of $100 million in 1995 dollars, updated annually for inflation, in any one year. 91 Fed. Reg. at 72358.

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

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

On June 16, 2026, CMS published a proposed rule. 91 Fed. Reg. 36236. CMS stated that they received comments from various interested parties. *See* 91 Fed. Reg. at 72178–79. CMS responded to comments in the rule. *See id.*

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

CMS determined that this rule contains information collection requirements under the Act. 91 Fed. Reg. at 72341–48.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1191 to 1198 of the Social Security Act.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that this rule is significant under the Order. 91 Fed. Reg. at 72349.

Executive Order No. 13132 (Federalism)

CMS determined that this rule does not have federalism implications. 91 Fed. Reg. at 72358.