



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

B-337402

May 2, 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 and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly*

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 and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" (RIN: 0938-AV40). We received the rule on April 17, 2025. It was published in the *Federal Register* on April 15, 2025. 90 Fed. Reg. 15792. The stated effective date of the rule is June 3, 2025.

According to CMS, this rule revises the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly regulations to implement changes related to prescription drug coverage, the Medicare Prescription Payment Plan, dual eligible special needs plans, Part C and D Star Ratings, and other programmatic areas, including the Medicare Drug Price Negotiation Program. CMS stated the rule also codifies existing sub-regulatory guidance in the Part C and Part D programs.

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). This rule was published in the *Federal Register* on April 15, 2025. 90 Fed. Reg. 15792. The *Congressional Record* reflects that the House of Representatives received the rule on April 17, 2025, and the Senate received it on April 23, 2025. 171 Cong. Rec. H1725, S2662–S2663 (daily ed. Apr. 29, 2025). The rule has a stated effective date of June 3, 2025, but provides various applicability dates up to and including January 1, 2027. Therefore, the rule does not have the required 60-day delay in its effective date.

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, flowing style.

Shirley A. Jones  
Managing Associate General Counsel

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 AND MEDICAID PROGRAMS; CONTRACT YEAR 2026 POLICY  
AND TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE PROGRAM,  
MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM, MEDICARE COST PLAN  
PROGRAM, AND PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY”  
(RIN: 0938-AV40)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) prepared an analysis of the costs and benefits for this rule. See 90 Fed. Reg. 15792, 15793–15794 (Apr. 15, 2025). CMS estimated that, among other things, a provision relating to insulin cost-sharing changes will increase federal transfers from the Medicare Supplementary Medical Insurance Trust Fund by approximately \$1.2 billion from 2026–2035. *Id.* at 15794.

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

CMS certified that this rule will not have a significant economic impact on a substantial number of small entities. See 90 Fed. Reg. at 15906. CMS prepared a Regulatory Flexibility Analysis. See *id.* at 15906–15908.

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

CMS stated that this rule is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$187 million or more. See 90 Fed. Reg. at 15908.

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

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

On December 10, 2024, CMS published a proposed rule. 89 Fed. Reg. 99340. CMS stated that they received approximately 31,227 timely pieces of correspondence containing multiple comments. 90 Fed. Reg. at 15795. CMS responded to comments in the rule. See *id.* at 15796–15908.

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

In its submission to us, CMS indicated that this rule contains information collection requirements under the Act. See *also* 90 Fed. Reg. at 15891–15902.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1302, 1306, 1395, 1395w-21 through 1395w-28, 1395w-101 through 1395w-152, 1395hh, 1395eee(f), 1396u-4(f), 300e, 300e-5, and 300e-9 of title 42, and section 9701 of title 31, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that the Office of Information and Regulatory Affairs has determined this rule is significant under the Order. See 90 Fed. Reg. at 15902.

Executive Order No. 13132 (Federalism)

CMS stated that because this rule does not impose any substantial costs on state or local governments, preempt state law, or have federalism implications, the requirements of the Order do not apply. See 90 Fed. Reg. at 15908.