U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

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October 11, 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: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate 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, Centers for Medicare & Medicaid Services (CMS) titled "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" (RIN: 0938-AU28). We received the rule on September 18, 2024. It was published in the *Federal Register* on September 26, 2024. 89 Fed. Reg. 79020. The stated effective date of the rule is November 19, 2024.

According to CMS, this final rule implements policies in the Medicaid Drug Rebate Program (MDRP) related to the new legislative requirements in the Medicaid Services Investment and Accountability Act of 2019 (MSIAA), which address drug misclassification, as well as drug pricing and product data misreporting by manufacturers. *See generally* MSIAA, Pub. L. No. 116-16, 133 Stat. 852 (Apr. 18, 2019). CMS stated that it is finalizing, through this rule, several other proposed program integrity and program administration provisions or modifications, including revising and finalizing key definitions used in the MDRP.

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). Both houses of Congress received the rule on September 18, 2024. 170 Cong. Rec. H5845 (daily ed. Oct 1, 2024); 170 Cong. Rec. S6364 (daily ed. Sept. 24, 2024). The rule was published in the *Federal Register* on September 26, 2024. 89 Fed. Reg. 79020. The stated effective date of the rule is November 19, 2024. Therefore, the stated effective date is less than 60 days from the date of publication in the *Federal Register*.

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.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Centers for Medicare & Medicaid Services

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
TITLED
"MEDICAID PROGRAM; MISCLASSIFICATION OF DRUGS,
PROGRAM ADMINISTRATION AND PROGRAM INTEGRITY UPDATES
UNDER THE MEDICAID DRUG REBATE PROGRAM"
(RIN: 0938-AU28)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) prepared an accounting table with costs and benefits for this final rule. CMS stated that the benefits include, for example, aiding states in development of managed care plan capitation rates, resulting in more accurate Medicaid spending. Regarding costs, CMS notes in some situations there will be no cost or minimal costs to the states. 89 Fed. Reg. 79020, 79071–79079 (Sept. 26, 2024).

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

According to CMS, the Secretary of HHS has certified that this rule will not have a significant economic impact on a substantial number of small entities. 89 Fed. Reg. at 79080. CMS also stated that the Secretary of HHS has certified that the rule will not have a significant impact on the operations of a substantial number of small rural hospitals. *Id*.

(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 government, in the aggregate, or on the private sector, of $100 million in 1995 dollars, updated annually for inflation. *See* 89 Fed. Reg. at 79081.

(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 the 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.

CMS did not discuss the Act in the rule. In its submission to us, CMS stated that the requirements of the Act do not apply because it will not result in an increase of federal government direct spending exceeding $100 million in any given year.

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

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

On May 26, 2023, CMS published a proposed rule. 88 Fed. Reg. 34238. CMS stated that they received 128 comments. 89 Fed. Reg. at 79021. CMS responded to comments in the rule.

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

CMS determined that this rule contains information collection requirements under the Act. 89 Fed. Reg. at 79066.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1302 and 1396r-8 of title 42, United States Code. 89 Fed. Reg. at 79081.

Executive Order No. 12866 (Regulatory Planning and Review)

The Office of Information and Regulatory Affairs, OMB, determined that this rule is significant under the Order and stated that OMB has reviewed the rule. 89 Fed. Reg. at 79071.

Executive Order No. 13132 (Federalism)

CMS determined that this rule does not have federalism implications. 89 Fed. Reg. at 79081.