



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

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December 20, 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 and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments*

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; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments” (RINs: 0938-AV33 & 0938-AU96). We received the rule on November 6, 2024. It was published in the *Federal Register* on December 9, 2024. 89 Fed. Reg. 97710. The stated effective date of the rule is January 1, 2025.

This rule addresses changes to the physician fee schedule; other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; updates to the Medicare Diabetes Prevention Program expanded model;

payment for dental services inextricably linked to specific covered medical services; updates to drugs and biological products paid under Part B including immunosuppressive drugs and clotting factors; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or a Medicare Advantage Prescription Drug plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act; update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2023 provisions; updates to Clinical Laboratory Fee Schedule regulations; updates to the diabetes payment structure and PHE flexibilities; expansion of colorectal cancer screening and Hepatitis B vaccine coverage and payment; establishing payment for drugs covered as additional preventive services; Medicare Parts A and B Overpayment Provisions of the Affordable Care Act and Medicare Parts C and D Overpayment Provisions of the Affordable Care Act.

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 received by the House of Representatives on November 6, 2024. 170 Cong. Rec. H5956 (daily ed. Nov. 12, 2024). The rule was received by the Senate on November 7, 2024. 170 Cong. Rec. S6525 (daily ed. Nov. 12, 2024). The rule was published in the *Federal Register* on December 9, 2024. 89 Fed. Reg. 97710. The stated effective date is January 1, 2025. *Id.* 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: Christina Kang
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;
CY 2025 PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE
AND OTHER CHANGES TO PART B PAYMENT AND COVERAGE POLICIES;
MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS; MEDICARE PRESCRIPTION
DRUG INFLATION REBATE PROGRAM; AND MEDICARE OVERPAYMENTS”
(RINS: 0938-AV33 & 0938-AU96)

(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 for this rule. See 89 Fed. Reg. 98498 (Dec. 9, 2024).

(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 stated that it certified this rule will not have a significant economic impact on a substantial number of small entities. However, in the rule, CMS stated that it determined that the rule will have a significant economic impact on substantial numbers of small entities, and prepared a Final Regulatory Flexibility Analysis. 89 Fed. Reg. 98499. CMS 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 governments, in the aggregate, or on the private sector, of \$100 million in 1995 dollars, updated annually for inflation, in any one year. 89 Fed. Reg. 98499.

(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 that it included a statement regarding compliance with the requirements of the Act.

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

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

On July 31, 2024, CMS published a proposed rule. 89 Fed. Reg. 61596. CMS responded to comments in this rule. See 89 Fed. Reg. 97713.

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. 98467.

Statutory authorization for the rule

CMS promulgated this rule pursuant to 42 U.S.C. §§ 1302, 1395hh, 1395w-5, and 1395kk-2; the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239 (Dec. 19, 1989); and the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508 (Nov. 5, 1990).

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that this rule is significant under the Order. See 89 Fed. Reg. 98499. CMS stated that the rule was submitted to OMB for review. *Id.*

Executive Order No. 13132 (Federalism)

CMS determined that this rule does not have federalism implications. See 89 Fed. Reg. 98499.