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November 29, 2023

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 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health 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) entitled “Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program” (RIN: 0938-AV07). We received the rule on November 1, 2023. It was published in the *Federal Register* as a final rule on November 16, 2023. 88 Fed. Reg. 78818. The effective date is January 1, 2024.

According to CMS, the final 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; payment for dental services inextricably linked to specific covered medical services; 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 certain Medicare and Medicaid provider and supplier enrollment policies, electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA-PD plan under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (Oct. 24, 2018); updates to the Ambulance Fee Schedule regulations and the Medicare Ground Ambulance Data Collection System; codification of the Inflation Reduction Act, Pub. L. No. 117-169, 136 Stat. 1818 (Aug. 16, 2022), and Consolidated Appropriations Act, 2023, provisions, Pub. L. No. 117-328, 136 Stat. 4459 (Dec. 29, 2022); expansion of the diabetes screening and diabetes definitions; pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation expansion of supervising practitioners; appropriate use criteria for advanced diagnostic imaging; early release of Medicare Advantage risk adjustment data; and a social determinants of health risk assessment in the annual wellness visit and Basic Health Program.

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). In its submission to us, CMS indicated both Houses of Congress received the final rule on November 1, 2023. Email from Regulations Coordinator, CMS, to CRA Rules, GAO, *Subject: Official Submission - RIN 0938-AV07* (Nov. 1, 2023). It was published in the *Federal Register* as a final rule on November 16, 2023. 88 Fed. Reg. 78818. The final rule has a stated effective date of January 1, 2024. Therefore, the final 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.



Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Centers for Medicare & Medicaid Services
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 2024 PAYMENT POLICIES
UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER CHANGES TO PART B PAYMENT
AND COVERAGE POLICIES; MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS;
MEDICARE ADVANTAGE; MEDICARE AND MEDICAID PROVIDER AND SUPPLIER
ENROLLMENT POLICIES; AND BASIC HEALTH PROGRAM”
(RIN: 0938-AV07)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated a decrease in payments from the federal government to physicians, other practitioners and providers and suppliers who receive payments under Medicare in the amount of \$2.4 billion for the physician fee schedule conversion factor update. CMS further estimated a reduction in payments from the beneficiaries to the federal government in the amount of \$0.6 billion. Finally, CMS estimated a reduction in payments from the federal government to accountable care organizations in the amount of \$15 million at the seven percent discount rate and \$25 million at a three percent discount rate.

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

CMS stated it provided analysis that complied with RFA’s requirements in the final rule. Additionally, CMS certified the final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

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

CMS determined the final rule imposes no mandates on state, local, or tribal governments or the private sector.

(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 stated the Act does not apply to this rule because it meets one of the Act’s exemptions; specifically, the direct spending is less than \$100 million in any given year during such 10-year period.

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

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

CMS published a proposed rule on August 7, 2023. 88 Fed. Reg. 52262. CMS received comments and addressed them in the final rule.

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

CMS determined the final rule contained information collection requirements (ICRs) subject to PRA. CMS stated the ICRs are associated with several OMB control numbers, and CMS provided estimates on the burden of the ICRs in the final rule.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 263a, 405, 1302, 1306, 1320a-7j, 1320b-12, 1395i-3, 1395m, 1395w-22 through 1395w-28, 1395w-101 through 1395w-152, 1395x, 1395y, 1395aa, 1395cc, 1395ff, 1395hh, 1395kk, 1395nn, 1395rr, 1395ww, 1395ddd, and 1395jjj of title 42, United States Code, as well as Public Laws 111-148 and 111-152.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated OMB had reviewed the rule and determined the final rule is significant under the Order, as amended.

Executive Order No. 13132 (Federalism)

CMS stated the final rule would not impose costs on states or local governments, so the requirements of the Order do not apply.