U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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May 8, 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 Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 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 (PACE)

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 Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 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 (PACE)" (RINs: 0938-AV24 and 0938-AU96). We received the rule on April 4, 2024. It was published in the *Federal Register* as a final rule on April 23, 2024. 89 Fed. Reg. 30448. The effective date of the rule is June 3, 2024.

According to CMS, this final 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 Star Ratings, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans,

utilization management, network adequacy, and other programmatic areas. CMS also stated the rule 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 final rule was published in the *Federal Register* on April 23, 2024, and both we and Congress received the rule on April 4, 2024. 89 Fed. Reg. 30448; Email from Regulations Coordinator, HHS, to CRA Rules, GAO, *Subject: Official Submission - RIN 0938-AV24 and 0938-AU96*; 170 Cong. Rec. S2740 (daily ed. Apr. 5, 2024); 170 Cong. Rec. H2140 (daily ed. Apr. 5, 2024). The rule has a stated effective date of June 3, 2024, but provides various applicability dates up to and including January 1, 2026. Therefore, the stated effective date is less than 60 days from the publication 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.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human 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
ENTITLED
"MEDICARE PROGRAM; CHANGES TO THE MEDICARE ADVANTAGE
AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAM
FOR CONTRACT YEAR 2024—REMAINING PROVISIONS AND CONTRACT YEAR 2025
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 ELDERY (PACE)"
(RINS: 0938-AV24 & 0938-AU96)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) conducted an economic analysis of this final rule. CMS estimated that three provisions—two increasing enrollment in dual eligible special needs plans and one enhancing enrollee appeal rights—would reduce Medicare Trust Fund spending by $961 million, $1,341 million, and $6.8 million, respectively, for combined savings of $2.3 billion over a 10-year period. CMS explained that these savings are offset by various paperwork burden and some minor savings which, in aggregate, cost $2.2 billion over 10 years. According to CMS, the major cost drivers are enrollee mailings regarding unused supplemental benefits and medication therapy management.

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

CMS certified that this final rule does not have a significant economic impact on a substantial number of small entities. Additionally, CMS stated that it determined and the HHS Secretary certified that this 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 that this final 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.

(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.

CMS did not discuss the Act in this final rule. In its submission to us, CMS stated the Act does not apply to the rule because it meets one of the Act's exemptions—namely, that 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.*

On November 15, 2023, CMS published a proposed rule. 88 Fed. Reg. 78476. CMS stated that it received 3,463 timely pieces of correspondence containing one or more comments on the proposed rule. CMS responded to comments in this final rule but stated that it did not address some out-of-scope public comments.

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

CMS determined that this final rule contains information collection requirements under the Act. In total, CMS estimated the rule will impose an annual burden of 1,715,087 hours and costs of $227,178,194 for the first year and $225,128,585 for subsequent years. Additionally, CMS estimated that the provisions for the Drug Management Program reduce paperwork burden by $3 million annually, saving $30.5 million over 10 years.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to section 9701 of title 31 and various sections of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined that this final rule is economically significant under the Order and submitted it to OMB for review.

Executive Order No. 13132 (Federalism)

CMS determined that this final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Order.