U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

B-335200

April 17, 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
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; Contract Year 2024 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 (HHS), Centers for Medicare & Medicaid Services (CMS) entitled "Medicare Program; Contract Year 2024 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-AU96). We received the rule on April 5, 2023. It was published in the *Federal Register* as a final rule on April 12, 2023. 88 Fed. Reg. 22120. The effective date is June 5, 2023.

The final rule, according to CMS, revises the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare Cost Plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, marketing and communications, health equity, provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, and other programmatic areas. CMS stated that the rule will also codify regulations implementing section 118 of Division CC of the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, (Dec. 27, 2020), and section 11404 of the

Inflation Reduction Act of 2022, Pub. L. No. 117-169, (Aug. 16, 2022). Finally, CMS stated the rule includes provisions that will codify existing sub-regulatory guidance in the Part C, Part D, and PACE 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). Here, the *Congressional Record* does not yet reflect the date of receipt by the House of Representatives or the Senate. HHS sent us confirmation that the rule was received by the House of Representatives and the Senate on April 5, 2023. Email from Regulations Coordinator, HHS, to GAO, *Subject: Official Submission – RIN 0938-AU96* (Apr. 5, 2023). The rule was published in the *Federal Register* on April 12, 2023. 88 Fed. Reg. 22120. The rule has a stated effective date of June 5, 2023. Therefore, based on the date of publication, 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
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; CONTRACT YEAR 2024 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-AU96)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) summarized the costs and benefits of this final rule. Specifically, in the rule, CMS summarized quantitative and qualitative impacts of the below provisions of the rule:

- Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System
- Strengthening Translation Requirements for Medicare Advantage, Cost Plans, Part D, and D-SNP Enrollee Marketing and Communication Materials
- Health Equity in Medicare Advantage
- Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Mandate Annual Review of Utilization Management
- Medicare Advantage and Part D Marketing
- Behavioral Health in Medicare Advantage
- Enrollee Notification Requirements for Medicare Advantage Provider Contract Terminations
- Limited Income Newly Eligible Transition Program
- Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program

(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 would not have a significant impact on a substantial number of small entities.

(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 is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of $177 million or more.

(iv) 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 December 27, 2022. 87 Fed. Reg. 79452. CMS received nearly 1,000 timely pieces of correspondence containing multiple comments on the proposed rule. CMS responded to comments in this final rule.

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

CMS determined this final rule contained information collection requirements (ICRs) subject to PRA. CMS identified the associated Office of Management and Budget (OMB) control numbers and summarized the burden for each ICR in the rule. A description of the ICRs is provided below:

- ICRs Regarding Limited Income Newly Eligible Transition Program, OMB Control Number 0938-1441
- ICRs Regarding New Behavioral Specialty Types, OMB Control Number 0938-1346
- ICRs Regarding Medicare Advantage Provider Termination Notices, OMB Control Number 0938-0753
- ICRs Regarding Utilization Management Review Committee, OMB Control Number 0938-0964
- ICRs Regarding Medical Necessity Decisions, OMB Control Number 0938-0753
- ICRs Regarding Marketing Provisions, OMB Control Number 0938-1051
- ICRs Regarding PACE Service Determination, OMB Control Number 0938-0790
- ICRs Regarding Safeguarding Data, OMB Control Number 0938-0790

Statutory authorization for the rule

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

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that OMB's Office of Information and Regulatory Affairs determined that this final rule is significant as measured by having an annual effect of $100 million or more in any one year, and that the rule was reviewed by OMB.

Executive Order No. 13132 (Federalism)

CMS determined that the requirements of the Order are not applicable because it stated this final rule does not impose any substantial costs on state or local governments, preempt state law, or have federalism implications.