February 23, 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; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability 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; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program” (RIN: 0938-AU87). We received the rule on January 31, 2024. It was published in the Federal Register as a final rule on February 8, 2024. 89 Fed. Reg. 8758. The effective date is April 8, 2024.
According to CMS, the final rule improves the electronic exchange of health care data and streamline processes related to prior authorization through new requirements for Medicare Advantage organizations, state Medicaid fee-for-service (FFS) programs, state Children’s Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan issuers on the Federally-Facilitated Exchanges. CMS additionally stated this final rule will also add new measures for eligible hospitals and critical access hospitals to report under the Medicare Promoting Interoperability Program and for Merit-based Incentive Payment System (MIPS) eligible clinicians to report under the Promoting Interoperability performance category of the MIPS. According to CMS, these policies, taken together, will reduce overall payer and provider burden and improve patient access to health information while continuing CMS’s drive toward interoperability in the health care market.

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; PATIENT PROTECTION
AND AFFORDABLE CARE ACT; ADVANCING INTEROPERABILITY AND IMPROVING
PRIOR AUTHORIZATION PROCESSES FOR MEDICARE ADVANTAGE ORGANIZATIONS,
MEDICAID MANAGED CARE PLANS, STATE MEDICAID AGENCIES, CHILDREN’S HEALTH
INSURANCE PROGRAM (CHIP) AGENCIES AND CHIP MANAGED CARE ENTITIES,
ISSUERS OF QUALIFIED HEALTH PLANS ON THE FEDERALLY-FACILITATED
EXCHANGES, MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS) ELIGIBLE
CLINICIANS, AND ELIGIBLE HOSPITALS AND CRITICAL ACCESS HOSPITALS
IN THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM”
(RIN: 0938-AU87)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would cause annual costs of $159 million per year at the seven percent discount rate and $157.2 million at the three percent discount rate to state Medicaid and Children's Health Insurance Program plans, Medicare Advantage plans, and individual market plans from 2024–2033. CMS additionally estimated the final rule would lead to transfers from the federal government to enrollees in the amount of $22.7 million at the seven percent discount rate and $22.5 million at the three percent discount rate for the same period.

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

CMS stated the analysis provided in the final rule satisfied the requirements of the RFA.


CMS concluded this final rule will not impose an unfunded mandate that results in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $177 million ($100 million, adjusted for inflation) or more in any one year.


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 the Act does not apply to the final rule as the direct spending effects of the final rule are less than $100 million in any given year during the 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 December 13, 2022, CMS published a proposed rule. 87 Fed. Reg. 76238. CMS received nearly 900 timely pieces of correspondence on the proposed rule. CMS addressed the comments in the final rule.

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

CMS determined the final rule contains information collection requirements (ICRs) subject to PRA. CMS provided estimates of the cost and burden for each ICR in the final rule.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to section 36B of title 26 and sections 1302, 1395hh, 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, and 18082 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that OMB reviewed the final rule and determined it was significant under the Order.

Executive Order No. 13132 (Federalism)

CMS concluded the final rule does not impose substantial costs on state or local governments, preempt state law, or have federalism implications.