U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
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February 20, 2024

The Honorable Bernard Sanders
Chairman
The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Office of the Secretary: Medications for the Treatment of Opioid Use Disorder*

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, Office of the Secretary (HHS) entitled "Medications for the Treatment of Opioid Use Disorder" (RIN: 0930-AA39). We received the rule on January 31, 2024. It was published in the *Federal Register* as a final rule on February 2, 2024. 89 Fed. Reg. 7528. The effective date of this final rule is April 2, 2024, and the compliance date is October 2, 2024.

HHS states that the final rule modifies and updates certain provisions of 42 C.F.R. part 8 related to Opioid Treatment Program (OTP) accreditation, certification, and standards for the treatment of Opioid Use Disorder (OUD) with Medications for Opioid Use Disorder (MOUD) in OTPs. HHS also states that the final rule makes flexibilities put forth during the COVID-19 Public Health Emergency (PHE) permanent, as well as expands access to care and evidence-based treatment for OUD. Finally, HHS states that the final rule removes all language and rules pertaining to the Drug Addiction and Treatment Act (DATA) Waiver from 42 C.F.R. part 8 pursuant to the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 136 Stat. 4459 (Dec. 29, 2022).

Enclosed is our assessment of HHS'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,
OFFICE OF THE SECRETARY
ENTITLED
"MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER"
(RIN: 0930-AA39)

(i) Cost-benefit analysis

The Department of Health and Human Services, Office of the Secretary (HHS), conducted a cost-benefit analysis of the final rule. HHS's analysis included an overview of the estimated costs of Opioid Use Disorder (OUD), a discussion of the estimated costs and reporting burdens for Opioid Treatment Programs (OTP) and Accreditation Bodies, a discussion of the costs pertaining to recordkeeping, and a consideration of regulatory alternatives.

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

HHS certifies that the final rule will not have a significant economic 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

HHS stated that it does not anticipate that the final rule will result in the expenditure by state, local, and tribal governments, taken together, or by the private sector, of $165 million or more in any one year.

(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, HHS stated that it did not prepare a statement pursuant to the Act.

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

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

On December 16, 2022, HHS published a proposed rule. 87 Fed. Reg. 77330. HHS stated that it received 373 comments in response to the proposed rule. On February 13, 2023, HHS published a supplemental proposed rule. 88 Fed. Reg. 9221. HHS received 27 additional comments in response to the supplemental proposed rule. HHS responded to comments in the final rule.

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

HHS states that the final rule does not add or alter any new requirements under the Act, but that it implicates information collections for which HHS has previously submitted burden estimates to OMB. HHS estimates a total OTP burden associated with all information collections of 1,868.95 hours and a total number of burden hours for Accreditation Body respondents of approximately 394.70 hours each year.

Statutory authorization for the rule

HHS promulgated the final rule pursuant to section 823 of title 21 and sections 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a), and 300y-11 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS stated that it has examined the impact of the final rule as required by the Order.

Executive Order No. 13132 (Federalism)

HHS stated that it does not believe the final rule will have any significant federalism implications, impose significant costs on state or local governments, or preempt state law.