



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

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December 30, 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: Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard*

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) titled “Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Modification of the Medicaid Pharmacy Subrogation Standard” (RIN: 0938-AU19). We received the rule on December 11, 2024. It was published in the *Federal Register* on December 13, 2024. 89 Fed. Reg. 100763. The effective date of the rule is February 11, 2025.

According to HHS, this final rule adopts updated versions of the retail pharmacy standards for electronic transactions adopted under the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). See *generally* HIPAA, Pub. L. No. 104-191, 110 Stat. 1936, (Aug. 21, 1996). HHS stated that these updated versions are modifications to the currently adopted standards for the following retail pharmacy transactions: health care claims or equivalent encounter information; eligibility for a health plan; referral certification and authorization; and coordination of benefits. HHS also stated that the rule adopts a modification to the standard for the Medicaid pharmacy subrogation transaction.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.

A handwritten signature in cursive script that reads "Shirley A. Jones". The signature is written in black ink and is positioned above the typed name and title.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II  
Regulations Coordinator  
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  
TITLED

“ADMINISTRATIVE SIMPLIFICATION: MODIFICATIONS OF HEALTH INSURANCE  
PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) NATIONAL COUNCIL  
FOR PRESCRIPTION DRUG PROGRAMS (NCPDP) RETAIL PHARMACY STANDARDS;  
AND MODIFICATION OF THE MEDICAID PHARMACY SUBROGATION STANDARD”  
(RIN: 0938-AU19)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) prepared an accounting statement for this rule. HHS estimates the annualized monetized costs of the rule to be \$97 million at a 2 percent discount rate. HHS stated that the benefits of the rule include wider adoption of standards; increased productivity due to decrease in manual processing; and reduced delays in patient care. 89 Fed. Reg. 100783, 100784 (Dec. 13, 2024).

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

HHS determined that this rule will have a significant economic impact on substantial numbers of small entities and prepared a Final Regulatory Flexibility Analysis. 89 Fed. Reg. at 100784–100787. HHS also stated that the Secretary has certified that the rule will not have a significant impact on the operations of a substantial number of small rural hospitals. 89 Fed. Reg. at 100787.

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

HHS determined that this 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, in any one year. 89 Fed. Reg. at 100787.

(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.

HHS did not discuss the Act in this rule or in its submission to us.

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

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

On November 9, 2022, HHS published a proposed rule. 87 Fed. Reg. 67634. HHS reported receiving 47 comments from a variety of commenters on the proposed rule. 89 Fed. Reg. at 100767. HHS summarized and responded to comments in this rule. *Id.*

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

HHS determined that this rule contains information collection requirements under PRA. 89 Fed. Reg. at 100773.

Statutory authorization for the rule

HHS promulgated this rule pursuant to sections 1302 and 1395hh of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS stated that OMB's Office of Information and Regulatory Affairs has determined that this rule is significant under the Order. 89 Fed. Reg. at 100774.

Executive Order No. 13132 (Federalism)

HHS determined that this rule does not have federalism implications. 89 Fed. Reg. at 100787.