



GAO

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

B-317727

January 30, 2009

The Honorable Edward M. Kennedy
Chairman
The Honorable Michael B. Enzi
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Office of the Secretary: Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards*

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), Office of the Secretary, entitled “Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards” (RIN: 0938-AM50). We received the rule on January 15, 2009. It was published in the *Federal Register* as a final rule on January 16, 2009. 74 Fed. Reg. 3296.

The final rule adopts updated versions of the standards for electronic transactions originally adopted under the Health Insurance Portability and Accountability Act of 1996. The final rule also adopts a transaction standard for Medicaid pharmacy subrogation, and two standards for billing retail pharmacy supplies and professional services. The final rule has an effective date of March 17, 2009, for most provisions of the rule.

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. Our review of the procedural steps taken indicates that HHS complied with the applicable requirements.

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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Vivian Stallion
Program Manager
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,
OFFICE OF THE SECRETARY
ENTITLED
"HEALTH INSURANCE REFORM; MODIFICATIONS TO THE
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)
ELECTRONIC TRANSACTION STANDARDS"
(RIN: 0938-AM50)

(i) Cost-benefit analysis

HHS performed a cost-benefit analysis of the final rule and anticipates that the benefits will outweigh the costs. In the final rule, HHS includes a detailed analysis of the costs and benefits of each of the rule's provisions on various segments of the health care industry, such as dentists, pharmacies, and government plans.

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

HHS certified that the final rule will not have a significant impact on a substantial number of small entities or 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

HHS determined that the final rule contains mandates that will impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, in excess of the current statutory threshold—approximately \$130 million. HHS incorporated the final rule's cost-benefit analysis to meet the Act's requirements, as allowed under 2 U.S.C. § 1532(c).

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

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

HHS promulgated this final rule using the notice and comment procedures found in the Administrative Procedure Act. 5 U.S.C. § 553. On August 22, 2008, HHS published a Notice of Proposed Rulemaking and Request for Comment regarding this rule. 73 Fed. Reg. 49,796. HHS received 192 timely public comments from all segments of the health care industry and responds to those comments in the final rule.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

The final rule contains new information collection requirements that have been submitted to the Office of Management and Budget (OMB) for approval.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority in sections 1171 through 1180 of the Social Security Act (42 U.S.C. §§ 1320d--1320d-9), as added by section 262 of Pub. L. No. 104-191, 110 Stat. 2021-2031, and section 105 of Pub. L. No. 110-233, 122 Stat. 881-922, and section 264 of Pub. L. No. 104-191, 110 Stat. 2033-2034 (42 U.S.C. § 1320d-2 note).

Executive Order No. 12,866 (Regulatory Planning and Review)

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the Order.

Executive Order No. 13,132 (Federalism)

The final rule does have federalism implications under the Order. HHS concluded the final rule will have a substantial direct effect on state or local governments, could preempt state law, or otherwise have a federalism implication.