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July 21, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Office of the Secretary:
Administrative Simplification: Adoption of Operating Rules for Eligibility for a
Health Plan and Health Care Claim Status Transactions*

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 “Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions” (RIN: 0938-AQ12). We received the rule on June 30, 2011. It was published in the *Federal Register* as an interim final rule with comment period on July 8, 2011. 76 Fed. Reg. 40,458.

Section 1104(b)(2) of the Patient Protection and Affordable Care Act requires HHS to establish operating rules for each Health Insurance Portability and Accountability Act of 1996 (HIPAA) transaction.¹ This interim final rule with comment period adopts operating rules for two HIPAA transactions: eligibility for a health plan and health care claim status. This rule also defines the term “operating rules” and explains the role of operating rules in relation to the adopted transaction standards. In general, transaction standards adopted under HIPAA enable electronic data interchange

¹ Pub. L. No. 111-148, § 1104(b)(2), 124 Stat. 119, 147 (Mar. 23, 2010).

through a common interchange structure, thus minimizing the industry's reliance on multiple formats. Operating rules, in turn, attempt to define the rights and responsibilities of all parties, security requirements, transmission formats, response times, liabilities, exception processing, error resolution and more, in order to facilitate successful interoperability between data systems of different entities.

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.

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). This interim final rule with comment period was received by the House of Representatives on June 29, 2011, and by the Senate on July 1, 2011.² It was published on July 8, 2011. This rule has a stated effective date of June 30, 2011, and a compliance date of January 1, 2013. However, any rule that an agency for good cause finds that notice and public comment procedures are impractical, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. 5 U.S.C. § 808(2). HHS found good cause to waive the delay for this 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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Program Manager
Department of Health
and Human Services

² 157 Cong. Rec. H4669 (July 6, 2011); 157 Cong. Rec. S4393 (July 6, 2011).

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
"ADMINISTRATIVE SIMPLIFICATION: ADOPTION OF
OPERATING RULES FOR ELIGIBILITY FOR A HEALTH PLAN
AND HEALTH CARE CLAIM STATUS TRANSACTIONS"
(RIN: 0938-AQ12)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) anticipates that the adoption of this interim final rule with comment period will result in benefits that outweigh the costs to providers and health plans. HHS estimates that within 10 years of implementation of the operating rules for eligibility for a health plan and health care claim status transactions, providers will experience \$7.9 billion to \$9.5 billion in savings at a cost of up to \$855 million. HHS estimates that health plans will see a savings of, conservatively, \$5 billion to \$5.8 billion within 10 years of the implementation for a cost of \$2.6 billion to \$5.1 billion.

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

Using a baseline threshold of 3-percent revenues, HHS determined that it could certify that this interim final rule with comment period would not have a significant economic impact on a substantial number of small entities. However, because of the relative uncertainty in the data, the lack of consistent industry data, and HHS's general assumptions, HHS invited public comments on the analysis and requested any additional data that would help HHS determine more accurately the impact on the various categories of small entities affected by this rule. HHS also determined that this rule will not have a significant impact on 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 analyzed this interim final rule with comment period under the Act and anticipates that the private sector would incur costs exceeding \$136 million per year in the first 2 years following publication of the rule. HHS has also concluded that the provisions in this rule are the most cost effective alternative for implementing HHS's statutory obligation of administrative simplification.

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

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

HHS determined that under the Patient Protection and Affordable Care Act it is statutorily required to proceed with an interim final rule with comment period, dispensing with normal APA notice and comment procedures.³ HHS therefore waived those procedures for good cause. HHS also found good cause for waiving the 30-day delay in the effective date of this rule because the statutory compliance date is January 1, 2013.

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

In this interim final rule with comment period, HHS is soliciting public comment on the information collection requirement “Specifications: Companion Guides Template.” HHS estimated the one-time conversion to the template will cost industry \$3,028,000.

Statutory authorization for the rule

HHS promulgated this rule under the authority of section 552 of title 5 and sections 1302(a) and 1320d to 1320d-8 of title 42, United States Code, and section 264 of Public Law 104-191 (110 Stat. 2033-2034), sections 13400 and 13402 of Public Law 111-5 (123 Stat. 258-263), and section 1104 of Public Law 111-148 (124 Stat. 146-154).

Executive Order Nos. 12,866 and 13,563 (Regulatory Planning and Review)

HHS determined that this interim final rule with comment period is an economically significant rule under the Order because it will have an impact of over \$100 million on the economy in any 1 year. The Office of Management and Budget reviewed this rule.

³ 42 U.S.C. § 1320d-2(g)(4)(C).