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February 2, 2009

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Minority Member
Committee on Finance
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: HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS*

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 “HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD-10-CM and ICD-10-PCS” (RIN: 0958-AN25). 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. 3328. The rule has a stated effective date of March 17, 2009, and a compliance date of October 1, 2013.

The final rule modifies two standard medical data code sets for coding diagnoses and inpatient hospital procedures. The rule adopts the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding, including the Official ICD-10-CM Guidelines for Coding and Reporting, and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, including the Official ICD-10-PCS Guidelines for Coding and Reporting. These two code sets are maintained and distributed by HHS. These new codes replace earlier editions of the code sets.

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
"HIPAA ADMINISTRATIVE SIMPLIFICATION: MODIFICATIONS
TO MEDICAL DATA CODE SET STANDARDS TO
ADOPT ICD-10-CM AND ICD-10-PCS"
(RIN: 0958-AN25)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) analyzed the costs and benefits of this final rule. The costs include the cost of training, productivity losses, and the costs of system changes. The benefits include more accurate payments for new procedures, fewer rejected claims, fewer improper claims, better understanding of new procedures, and improved disease management. HHS made low, high, and primary estimates for the costs and benefits at 3- and 7-percent discount rates. At a 3-percent discount rate, the low cost estimate was \$122.41 million, the high cost estimate was \$555.5 million, and the primary cost estimate was \$248.5 million. At a 7-percent discount rate, the low cost estimate was \$160.45 million, the high cost estimate was \$722.06 million, and the primary cost estimate was \$325.68 million. At a 3-percent discount rate, the low benefit estimate was \$190.14 million, the high benefit estimate was \$760.54 million, and the primary benefit estimate was \$380.26 million. At a 7-percent discount rate, the low benefit estimate was \$249.22 million, the high benefit estimate was \$996.85 million, and the primary benefit estimate was \$498.42 million.

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

HHS determined that this final rule will not have a significant 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 anticipates that this final rule will impose costs on the private sector exceeding the Act's current \$130 million per year threshold beginning in 2012, and ending in 2015. HHS determined that the states' share of implementation costs would not exceed \$130 million over a 1-year period. In addition, local or tribal governments will not experience costs exceeding \$130 million over a 1-year period. HHS based its assessment on the fact that it received no comments from local governments indicating cost impacts exceeding \$130 million over a 1-year period in response to

the August 22, 2008, proposed rule and the Indian Health Service estimate of costs to tribal governments totaling \$12.3 million. HHS discussed in the final rule the three alternatives it considered and concluded that the provisions in this final rule are the most cost-effective alternative for implementing HHS's statutory objective of administrative simplification.

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

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

This final rule was issued using the notice and comment procedures found in the Administrative Procedure Act. 5 U.S.C. § 553. On August 22, 2008, HHS published the proposed rule. 73 Fed. Reg. 49,796. HHS received 3,115 timely public submissions from the health care industry, including providers, physician practices, hospitals, coders, standards development organizations, vendors, state Medicaid agencies, state agencies, corporations, tribal representatives, healthcare professional and industry trade associations, and disease-related advocacy groups. HHS responded to relevant and timely comments in the final rule. 74 Fed. Reg. 3331–3341.

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

The burden associated with the implementation and continued use of the newly required code sets is the time and effort required to update information systems for use with updated transaction and code set standards. Specifically, entities impacted by these requirements must comply with the ASC X12 Technical Reports Type 3, Version 005010 standards. With regard to these standards, HHS has submitted to the Office of Management and Budget (OMB) a revised version of an existing information collection request with OMB Control Number 0938-0866 for review under the Act.

Statutory authorization for the rule

HHS promulgated this final rule under the authority of sections 1320d through 1320d-9 of title 42, United States Code.

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

HHS determined that this final rule is an economically significant rule under the Order because it will have an impact of over \$100 million on the economy. Accordingly HHS prepared a regulatory impact analysis and OMB reviewed the rule.

Executive Order No. 13,132 (Federalism)

HHS consulted with appropriate local, state, and federal agencies, including tribal authorities and Native American groups, as well as private organizations. HHS has examined the effects of provisions in this final rule as well as the opportunities for input by the states. HHS invited states to comment on the proposed rule.