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December 8, 2008

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 John D. Dingell
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services: Patient Safety and Quality Improvement*

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), entitled "Patient Safety and Quality Improvement" (RIN: 0919-AA01). We received the rule on November 20, 2008. It was published in the *Federal Register* as a final rule on November 21, 2008, with a stated effective date of January 19, 2009. 73 Fed. Reg. 70,732.

The final rule implements certain provisions of the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (July 29, 2005). The rule establishes a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events. The final rule outlines the requirements that entities must meet to become PSOs and the processes by which HHS will review and accept certifications and list PSOs. It also describes the privilege and confidentiality protections for the information that is assembled and developed by providers and PSOs, the exceptions to these privilege and confidentiality protections, and the procedures for the imposition of civil money penalties for the knowing or reckless impermissible disclosure of patient safety work product.

The Congressional Review Act requires major rules to have a 60-day delay in their effective date following publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). Although this rule was received on November 20, 2008, it was not published until November 21, 2008. The final rule has an announced effective date of January 19, 2009. Therefore, this final rule will not have the required 60-day delay in its effective date.

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 indicates that, except for the delay in the effective date, 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 Michael R. Volpe, Assistant General Counsel, at (202) 512-8236.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Ann 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
ENTITLED
"PATIENT SAFETY AND QUALITY IMPROVEMENT"
(RIN: 0919-AA01)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) analyzed the costs and benefits of this final rule. HHS estimated the costs and cost savings from reductions in adverse events, and net benefits for the years 2009 to 2013. The estimated costs of this rule for each year from 2009 to 2013 are, respectively, \$68.9 million, \$122.1 million, \$167.8 million, \$179.0 million, and \$186.5 million. The estimated cost savings from reduced adverse events for each year from 2009 to 2013 are, respectively, \$11.5 million, \$69 million, \$138 million, \$215.6 million, and \$293.3 million. HHS estimates that the rule will have net costs at a 3-percent discount rate of \$55.7 million in 2009, \$50.0 million in 2010, and \$27.3 in 2011. However, HHS estimates the rule will have net benefits at a 3-percent discount rate of \$32.5 million in 2012 and \$92.1 million in 2013. HHS also made these estimates using a 7-percent discount rate: -\$53.6 million (2009), -\$46.4 million (2010), -\$24.3 (2011), \$27.9 million (2012), and \$76.1 million (2013).

(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 determined that this final rule does not impose any mandates on any state, local, or tribal governments or on the private sector within the meaning of the Act.

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

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

CMS promulgated this final rule using the notice and comment procedures found in the Administrative Procedure Act. 5 U.S.C. § 553. On February 12, 2008, HHS published a notice of the proposed rule. 73 Fed. Reg. 8112. HHS received 161 comments on the proposed rule from a variety of entities, including small providers,

large institutional providers, hospital associations, medical associations, accrediting bodies, medical liability insurers, and government agencies. HHS responded to those comments in the final rule. 73 Fed. Reg. 70,733–70,793.

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

This final rule contains information collection requirements under the Act. HHS has published the proposed information collection forms for public comment and has submitted them to the Office of Management and Budget for review. 73 Fed. Reg. 9336 (Feb. 20, 2008); 73 Fed. Reg. 21,349 (April 21, 2008). HHS estimates that the burden associated with certification forms for Patient Safety Organizations will be 30 minutes per entity per year.

Statutory authorization for the rule

HHS promulgated this final rule under the authority of sections 216, 299b-21 to 299b-26 and 299c-6 of title 42, United States Code.

Executive Order No. 12,866

HHS has determined that this final rule may be economically significant under the Order because the economic impact may approach \$100 million. HHS also determined that this rule is significant under the Order because it raises novel legal and policy issues, and the rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

To the extent that the Patient Safety and Quality Improvement Act of 2005 is inconsistent with any state law, including state court decisions, the statute preempts such state law. HHS determined that this final rule will not have any greater preemptive effect on state or local governments than that imposed by the statute. HHS held public listening sessions prior to drafting the proposed rule to which representatives of several states attended. Following publication of the proposed rule, HHS consulted with state officials and organizations specifically seeking input on federalism issues.