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B-323517

May 31, 2012

The Honorable Max Baucus  
Chairman  
The Honorable Orrin G. Hatch  
Ranking Member  
Committee on Finance  
United States Senate

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

The Honorable Dave Camp  
Chairman  
The Honorable Sander Levin  
Ranking Member  
Committee on Ways and Means  
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation*

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, Centers for Medicare & Medicaid Services (CMS) entitled "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation" (RIN: 0938-AQ89). We received the rule on May 15, 2012. It was published in the *Federal Register* as a final rule on May 16, 2012. 77 Fed. Reg. 29,034.

The final rule revises the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. CMS describes these changes as an integral part of efforts to reduce procedural burdens on providers.

Enclosed is our assessment of CMS'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 CMS 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  
Managing 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  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
ENTITLED  
"MEDICARE AND MEDICAID PROGRAMS; REFORM OF HOSPITAL  
AND CRITICAL ACCESS HOSPITAL CONDITIONS OF PARTICIPATION"  
(RIN: 0938-AQ89)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis in conjunction with the final rule. CMS determined that the reductions in process and procedure requirements detailed in the final rule may allow hospitals and CAHs to redirect staff resources to areas of higher priority that they view as producing greater benefit to patients. The final rule could also enhance hospitals' abilities to flexibly deploy resources and reengineer internal processes. CMS estimated that the changes in the final rule could result in cost-reductions of approximately \$937,700,000 annually.

CMS noted that the amount of savings actually realized through these reforms will depend on the individual decisions of about 6,100 hospitals (including CAHs), over time. CMS stated that it could not predict the extent or speed of these elective changes. Finally, CMS noted that other factors, such as impending physician shortages and the growing use of other practitioners to perform many physician functions, will play a role as will state decisions on laws delineating scope of practice.

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

CMS has determined that the final rule will not have a significant economic impact on a substantial number of small entities. CMS determined that under the final rule no hospitals of any size will be negatively affected.

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

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates on state, local, or tribal governments in the aggregate, or on the private sector, require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. CMS determined that no analysis was required under the

UMRA, because the final rule would eliminate or reform existing requirements and would allow hospitals and CAHs to achieve substantial savings through staffing reforms.

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

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

On October 24, 2011, CMS published a notice of proposed rulemaking in the *Federal Register*. 76 Fed. Reg. 65,891. CMS received approximately 1,729 public comments in response to the proposed rule. CMS responded to the comments in the final rule. 77 Fed. Reg. 29,034.

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

The final rule impacts information collection requirements that had been approved by the Office of Management and Budget (OMB) under OMB control number 0938-0328. CMS stated in the final rule that it will revise the current burden estimated to be associated with the current regulations and adjust for any burden reductions resulting from the final rule once it is finalized.

Statutory authorization for the rule

The final rule was issued pursuant to the direction of Executive Order 13,563, which directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined. Under the Executive Order CMS has sought to reduce outmoded or unnecessarily burdensome rules issued under the authority of sections 1102, 1871, and 1881 of the Social Security Act, as amended.

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

CMS determined that the final rule is an “economically” significant regulatory action under section 3(f)(1) of Executive Order 12,866. The Office of Management and Budget has reviewed this final rule.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule would not significantly affect the rights, roles, or responsibilities of the states. CMS further determined that the final rule would not impose substantial direct requirement costs on state or local governments, preempt state law, or otherwise implicate federalism.