



United States Government Accountability Office  
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B-323515

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 Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction*

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 Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" (RIN: 0938-AQ96). 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. 29,002.

The final rule reforms Medicare and Medicaid regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries. The final rule is intended to increase the ability of health care professionals to devote resources to improving patient care, by eliminating or

reducing requirements that impede quality patient care or that divert providing high quality patient care.

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 PROGRAM; REGULATORY PROVISIONS  
TO PROMOTE PROGRAM EFFICIENCY, TRANSPARENCY,  
AND BURDEN REDUCTION"  
(RIN: 0938-AQ96)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis in conjunction with the final rule. CMS determined that the final rule will result in cost savings in many areas. CMS estimates that one-time savings to End Stage Renal Disease facilities are likely to range from about \$47.5 to \$217 million; however, CMS used \$108.7 million as the estimate. Second, CMS also estimated a one-time savings of \$18.5 million to Ambulatory Surgical Centers through reduced emergency equipment requirements. CMS determined that the final rule will also result in many types of recurring savings, including avoidance of business and payment losses for physicians and other providers that are difficult to estimate but likely to be in the tens of millions of dollars annually through the reforms proposed for re-enrollment and billing processes. Taking all of the reforms included in the final rule together, CMS estimated that the overall cost savings that the final rule will create will exceed \$200 million in the first year.

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

CMS certified that this final rule will not have a significant economic impact on a substantial number of small entities. CMS voluntarily prepared a final regulatory flexibility analysis because it determined that the final rule will create a significant positive economic impact by reducing burden on small entities. CMS also certified that the final rule will not have a significant impact on the operations of 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

CMS determined that the final rule did not contain any mandates on state, local, or tribal governments, or on the private sector.

(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. 65,909. CMS received comments in response to the proposed rule. CMS responded to the comments in the final rule. 77 Fed. Reg. 29,002.

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

The final rule contains information collection requirements under the Paperwork Reduction Act. Many of the changes in the final rule will not increase or decrease existing information collection burdens. The final rule requires that Ambulatory Surgical Centers (ASCs) coordinate, develop, and revise ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. CMS estimates that approximately 5,200 ASCs are subject to this requirement and that a one-time burden of 2 hours is imposed by this requirement, for a total cost of \$468,000. CMS is submitting revisions to the Office of Management and Budget (OMB) for the information collection approved by OMB control number 0938-1071, expiring October 31, 2012. The final rule also removes the time limited agreements for intermediate care facilities, which CMS projects will result in an annual national savings of state Medicaid administrative expenditures totaling \$445,700, of which 75 percent consists of federal funds and 25 percent of state funds. CMS is submitting a revision to OMB control number 0938-0062. Finally, CMS is revising the wording on two forms, CMS-3070G and CMS-3070H, which are approved under OMB control number 0938-0062, expiring April 30, 2013, and the revisions will not result in any changes to the information collection burden.

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 205(a), 1102, 1138, 1860D-4(e), 1861, 1862(a), 1866(j), 1869, 1871, 1874, 1881, and 1886(k) 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 because the final rule does not impose any costs on state or local governments, CMS is not required to perform a federalism analysis.