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B-298382

June 14, 2006

The Honorable Charles E. Grassley  
Chairman  
The Honorable Max Baucus  
Ranking Minority Member  
Committee on Finance  
United States Senate

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

The Honorable William M. Thomas  
Chairman  
The Honorable Charles B. Rangel  
Ranking Minority Member  
Committee on Ways and Means  
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)*

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 and Medicaid Services (CMS), entitled “Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)” (RIN: 0938-AK81). We received the rule on May 31, 2006. It was published in the Federal Register as a final rule on May 31, 2006. 71 Fed. Reg. 30982.

The final rule establishes new conditions for coverage for organ procurement organizations (OPOs) that include multiple new outcome and process performance measures based on organ donor potential and other related factors in each service area of qualified OPOs.

Enclosed is our assessment of the 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 indicates that CMS complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7101.

signed

Kathleen E. Wannisky  
Managing Associate General Counsel

Enclosure

cc: Ann Stallion  
Regulations Coordinator  
Department of Health and  
Human Services

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
ENTITLED  
"MEDICARE AND MEDICAID PROGRAMS; CONDITIONS FOR  
COVERAGE FOR ORGAN PROCUREMENT ORGANIZATIONS (OPOS)"  
(RIN: 0938-AK81)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule. CMS states that the first-year cost of implementing the final rule would be \$4,815,182, and the average first-year cost to each of the 58 certified OPOs is approximately \$83,000.

The benefits of the final rule would be increased organ donation and transplantation with the results of life years gained, improvements in quality of life, resumption of employment for some patients, and an increase in access to dialysis as more patients receive kidney transplants. CMS has calculated a benefit of \$1.38 billion in terms of life years saved, which it did not include in the cost analysis.

The total estimated impact of this rule, assuming a 2 percent increase in organ transplants, is \$66 million in the first year and \$247 million over 5 years. Assuming that Medicare transplants comprise 55.3 percent of all transplants, the estimated impact of the rule on the Medicare program is \$37 million in the first year and \$136 million over 5 years.

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

The Administrator of CMS has certified that the final rule will not have a significant economic 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

The final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than \$120 million (\$100 million in 1995 adjusted for inflation) in any one year.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On February 4, 2005, CMS published a Notice of Proposed Rulemaking in the Federal Register. 70 Fed. Reg. 6086. In response, CMS received 129 comments on the proposed rule and discusses the comments in the preamble to the final rule.

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

The final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. CMS has submitted the required information, including the annual burden hours and costs, for the various collections to OMB for approval.

Statutory authorization for the rule

The final rule is promulgated under the authority found in the Organ Procurement Organization Certification Act of 2000 (section 701 of Pub. L. 106-505) and section 1138 of the Social Security Act (42 U.S.C. 1320b-8).

Executive Order No. 12866

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.

Executive Order No. 13132 (Federalism)

CMS states that the final rule does not have federalism implications under the order.