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General Accounting Office  
Washington, D.C. 20548**

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**Office of the General Counsel**

B-279684

April 17, 1998

The Honorable James M. Jeffords  
Chairman  
The Honorable Edward M. Kennedy  
Ranking Minority Member  
Committee on Labor and Human Resources  
United States Senate

The Honorable Thomas J. Bliley, Jr.  
Chairman  
The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Commerce  
House of Representatives

**Subject: Department of Health and Human Services, Health Resources and  
Services Administration: Organ Procurement and Transplantation  
Network**

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), Health Resources and Services Administration, entitled "Organ Procurement and Transplantation Network" (RIN: 0906-AA32). We received the rule on March 26, 1998. It was published in the Federal Register as a final rule on April 2, 1998. 63 Fed. Reg. 16296.

The final rule establishes performance goals to be achieved by the Organ Procurement and Transplantation Network to improve the effectiveness and equity of the Nation's transplantation system.

Enclosed is our assessment of HHS' 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 HHS complied with the applicable requirements.

If you have any questions about this report, please contact James Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation

work relating to the Department of Health and Human Services, Health Resources and Services Administration, is Bernice Steinhardt, Director, Health Services Quality and Public Health Issues. Ms. Steinhardt can be reached at (202) 512-7119.

Robert P. Murphy  
General Counsel

Enclosure

cc: The Honorable Donna E. Shalala  
The Secretary 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,  
HEALTH RESOURCES AND SERVICES ADMINISTRATION  
ENTITLED  
"ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK"  
(RIN: 0906-AA32)

(i) Cost-benefit analysis

HHS performed a Regulatory Impact Analysis which is included in the preamble to the final rule.

HHS recognizes in its analysis the difficulty of quantifying the costs and the benefits of the rule. There is a discussion of the current costs of transplantation and the analysis concludes that the final rule will not substantially raise the costs.

Regarding benefits, HHS discusses the use of the value of a statistical life as a quantifying benefit and the fact that, in the area of transplantation, the usefulness of such a measure is reduced because of the older average age of recipients and the substantial risk of either the graft or the patient not surviving. Another benefit of the rule is the public oversight and accountability of the organ transplant system, which will preserve public trust and confidence. Also, a system of patient-oriented information of transplant performance will allow easier comparison of transplant center performance and the use of performance goals will create equity in the system.

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

The Secretary of HHS has certified that the final rule will not have a significant impact on a substantial number of small entities.

However, because of concern over the effects of changes in allocation policies on smaller hospitals and because HHS considered, as an alternative, the possibility of imposing quality standards on transplant hospitals, a voluntary Regulatory Flexibility Analysis was prepared and is included in the rule's preamble.

The major portion of the analysis discusses the alternatives considered and the reasons why required volume or performance standards for transplant programs and imposing specific allocation standards focusing on geographic equity were rejected in favor of the performance standards adopted.

(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, according to HHS, does not impose a federal intergovernmental or private sector mandate of \$100 million or more, as defined in the Unfunded Mandates Act of 1995.

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

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

The final rule with comment period was promulgated using the notice and comment procedures in 5 U.S.C. § 553. HHS published a notice of proposed rulemaking on September 8, 1994 (59 Fed. Reg. 46482). In a notice published on November 13, 1996, HHS extended the comment period on the proposed rule and announced a public hearing to be held December 10-12, 1996.

HHS reports that 110 people testified at the public hearing and that it received 541 documents containing comments pertaining to the hearing, in addition to the 121 comment letters it received from the proposed rule notice. In the preamble to the final rule, HHS discusses these comments and addresses some misconceptions certain commenters had regarding the role and relationship of the Organ Procurement and Transplantation Network.

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

The final rule contains information collections which are subject to approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. Certain of the collections have been approved by OMB and were issued control number 0915-0184.

The preamble describes the information being collected, the need for the information, a description of the respondents, and the estimated annual burden hours. The total annual burden hours for all collections, both approved and pending approval, are estimated at 43,692 hours.

Written comments on the unapproved collections are requested and no one need respond to such collections until approved by OMB. OMB's approval will be announced by HHS in the Federal Register.

Statutory authorization for the rule

The final rule was promulgated under the authority contained in sections 215 and 371-376 of the Public Health Service Act (42 U.S.C. §§ 216 and 273-274d) and

sections 1102, 1106, 1138, and 1872 of the Social Security Act (42 U.S.C. §§ 1302, 1306, 1320b-8, and 1395ii).

**Executive Order No. 12866**

The final rule was determined to be an "economically significant" regulatory action under Executive Order No. 12866 and was reviewed by the Office of Management and Budget as complying with the requirements of the order.

**Executive Order No. 12612**

The final rule contains a Federalism Assessment under Executive Order No. 12612 (Federalism) and concludes that the preemption requirement of the final rule is necessary for the national organ sharing system to be effective across state lines.