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July 7, 1998

The Honorable William V. Roth
Chairman
The Honorable Daniel Patrick Moynihan
Ranking Minority Member
Committee on Finance
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 Care Financing Administration: Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals' Provision of Transplant-Related Data

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, Health Care Financing Administration (HCFA), entitled "Medicare and Medicaid Programs; Hospital Conditions of Participation; Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals' Provision of Transplant-Related Data" (RIN: 0938-AI95). We received the rule on June 22, 1998. It was published in the Federal Register as a final rule on June 22, 1998. 63 Fed. Reg. 33856.

The final rule revises current hospital conditions of participation relating to organ procurement by modifying the relationship between hospitals and Organ Procurement Organizations (OPOs) in order to increase the number of organs available for donation and transplantation.

One of the requirements is that a hospital must have an agreement with an OPO, under which it will contact the OPO in a timely manner about individuals who die or whose death is imminent in the hospital. The OPO will then determine the

individual's medical suitability for donation. Hospitals are also required to have an agreement with at least one tissue bank and one eye bank for tissue and eye referrals. The final rule also requires hospitals to collaborate with the OPO in notifying families of potential donors of their donation options and work cooperatively with OPOs, tissue, and eye banks, in educating hospital staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while testing and placement of organs occurs. In addition, the final rule requires transplant hospitals to provide organ-transplant-related data as requested by the Organ Procurement and Transplantation Network, the Scientific Registry, and OPOs.

Enclosed is our assessment of HCFA'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 HCFA 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 Care Financing Administration, is William Scanlon, Director, Health Financing and Systems Issues. Mr. Scanlon can be reached at (202) 512-7114.

Robert P. Murphy
General Counsel

Enclosure

cc: The Honorable Donna E. Shalala
The Secretary of Health and
Human Services

ENCLOSURE

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 CARE FINANCING ADMINISTRATION
ENTITLED
"MEDICARE AND MEDICAID PROGRAMS; HOSPITAL CONDITIONS OF PARTICIPATION; IDENTIFICATION OF POTENTIAL ORGAN, TISSUE, AND EYE DONORS AND TRANSPLANT HOSPITALS' PROVISION OF TRANSPLANT-RELATED DATA"
(RIN: 0938-AI95)

(i) Cost-benefit analysis

HCFA performed a cost-benefit analysis of the final rule and concluded that the estimated cost to the Medicare program would be as follows:

-- $35 million in fiscal year 1999,
-- $75 million in fiscal year 2000,
-- $115 million in fiscal year 2001,
-- $160 million in fiscal year 2002,
-- $200 million in fiscal year 2003, and
-- $240 million in fiscal year 2004.

These estimates include the cost of the transplants and follow-up medical care, adjusted for patient survival.

The benefits from the projected 4,118 additional non-renal transplants during a 5-year period were estimated to be 49,416 additional life-years and $5,732,256,000 additional social benefits.

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

The Administrator of HCFA has certified that the final rule will not have a substantial economic impact on a significant number of small entities and, therefore, has not prepared a Final Regulatory Impact Analysis. However, HCFA recognizes that a general discussion of the impact of the final rule on the various entities involved in the field of organ donation and transplant would be useful and has included such a discussion in the final rule's preamble.

(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 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 was issued using the notice and comment procedures contained in 5 U.S.C. § 553. On December 19, 1997, HCFA published a notice of proposed rulemaking which contained revisions to many current conditions of participation for hospitals. The portion of the proposed rule dealing with organ donations is the subject of this final rule. HCFA received 150 comments from hospitals, OPOs, tissue and eye banks, professional organizations, transplant organizations, medical practitioners, donor family organizations, and other organizations and individuals. HCFA has summarized and responded to the comments in the preamble to the final rule.

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

The final rule contains information collections which are subject to review and approval by the Office of Management and Budget under the Paperwork Reduction Act. The preamble to the final rule describes the information required by the Paperwork Reduction Act, including the need for and use of the information collections, a description of and the number of respondents, and an estimate of the annual burden hours.

For example, for the collection involving a hospital's organ procurement responsibilities, the burden associated with the requirement for a hospital to notify an OPO of every death is estimated to be approximately 400 calls per year for the average hospital (5,200 hospitals). This is multiplied by 5 minutes per call for an annual estimated burden of 34 hours per hospital or a total annual burden of 176,800 hours.

Statutory authorization for the rule

The final rule was promulgated pursuant to the authority of sections 1102 and 1871 of the Social Security Act (42 U.S.C. §§ 1302 and 1395hh).

Executive Order No. 12866

The final rule has been found to be an "economically significant" regulatory action under Executive Order No. 12866 and has been reviewed and approved by the Office of Management and Budget.