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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, Food and Drug Administration: Quality Mammography Standards

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, Food and Drug Administration (FDA), entitled "Quality Mammography Standards" (RIN: 0910-AA24). We received the rule on November 14, 1997. It was published in the Federal Register as a final rule on October 28, 1997. 62 Fed. Reg. 55852.

The final rule amends FDA regulations governing mammography including the requirements for accreditation bodies; procedures for facility certification; and quality standards for mammography personnel, equipment, and practices, including quality assurance. The final rule replaces existing interim rules and will, according to the FDA, provide increased assurance of adequate and consistent evaluation of mammography facilities on a nationwide level and compliance of the facilities with quality standards.

Enclosed is our assessment of the FDA'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 the FDA 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, Food and Drug 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

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,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"QUALITY MAMMOGRAPHY STANDARDS"
(RIN: 0910-AA24)

(i) Cost-benefit analysis

The FDA performed a cost-benefit analysis concerning the impact of the final rule. The analysis is summarized in the preamble to the final rule while a complete copy of the Economic Impact Analysis was furnished to our Office.

The analysis projects a range of yearly expenditures for compliance by mammography facilities from a high of $156.2 million in the second year to $9.5 million during the 10th year due to phased implementation dates. Over the 10-year period at a 7-percent discount rate, the average yearly cost is about $38.2 million. This cost consists of $28.5 million for replacement units, $4.6 million for medical reports and records, $3.4 million for quality assurance systems, $1.6 million for personnel qualifications, and $0.1 million for consumer complaint mechanisms.

FDA states that it is difficult to determine the increase in the quality of mammograms which the final rule will cause. However, FDA calculates the following benefits assuming a 5-percent improvement. This degree of improvement would prevent 75 women per year from dying of breast cancer within a 20-year period. At $5 million per life saved, the discounted value of this outcome would be $234 million per year. FDA points out that an improvement of quality as low as 2 percent would result in the benefits outweighing the costs of the final rule.

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

FDA has concluded that the final rule may have a significant economic impact on a substantial number of small entities and has included a Final Regulatory Flexibility Analysis as part of the Economic Impact Analysis accompanying the final rule. An Initial Regulatory Flexibility Analysis was part of the proposed rule as required by the Regulatory Flexibility Act.

The FDA notes that the Small Business Administration considers any (1) doctor's office, clinic, or hospital with $5 million or less in revenue and (2) not-for-profit-enterprise that is independently owned and operated and not dominant in its field to

be small. Under this standard, 4,800 small doctors' offices or clinics and 5,000 small hospitals offer mammograms, comprising 98 percent of mammography facilities.

The cost of a mammogram is expected to increase 3.4 percent in an average facility and by 4.2 percent in the smallest 10 percent of the facilities. The fixed costs of compliance for equipment improvements increase the cost per mammogram relatively more at low-volume facilities.

The analysis discusses the alternatives considered to implementation of the final rule and uses both quantifiable and general descriptions of the effects of the final rule on small entities.

Numerous small entities participated in the rulemaking, as required by section 609, by submitting comments on the proposed rule.

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

The FDA utilized its Economic Impact Analysis to comply with the requirements of the Unfunded Mandates Reform Act of 1995 (as permitted by section 202(c) of the act) since the final rule is expected to result in private sector expenditures of $100 million or more in at least one year.

The preamble to the final rule gives the statutory authority for the rule, a summary of the costs and benefits contained in the Economic Impact Analysis, and a description of the regulatory alternatives FDA considered and why it finds the rule to be the most cost-effective alternative.

(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 of 5 U.S.C. 553.

The FDA issued interim rules regarding mammography services on December 21, 1993 (58 Fed. Reg. 67558 and 58 Fed. Reg. 67565).

The proposed rule was published in the Federal Register on April 3, 1996 (61 Fed. Reg. 14856) and comments were requested. A copy of the proposed rule was mailed to each certified mammography facility. In total, 17,000 copies were made available to the public and 1,900 comments were received.

In the preamble to the final rule, the FDA responds to the comments and the actions it took in response to those comments.

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

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

The collections include requiring each accreditation body to submit applications and establish a quality assurance program. Mammography facilities need to maintain a medical reporting and recordkeeping system, a medical outcomes audit program, a consumer compliant mechanism, and records documenting personnel qualifications.

As required by the act, the FDA has estimated the annual burden hours of the collections at 184,510 hours. This represents an increase of 63,566 hours over the burden imposed by the interim rule. However, FDA points out that the overall burden attributable to the final rule is a reduction from the estimate contained in the proposed rule based on FDA's actions taken in response to comments it received.

The collections have been submitted to OMB for approval and no reporting or recordkeeping is required until approval is given and an OMB control number has been issued.

Statutory authorization for the rule

The Mammography Quality Standards Act (Pub. L. 102-539, Oct. 27, 1992) required the Secretary of Health and Human Services to approve and certify mammography facilities; that authority was delegated to the FDA. The mammography quality standards were issued under section 354(f) of the Public Health Service Act (42 U.S.C. § 263b(f)).

Executive Order No. 12866

The final rule was reviewed by the OMB under Executive Order No. 12866 and found to be an economically significant regulatory action. OMB approved the rule as complying with the requirements of the order.