U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

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April 3, 2023

The Honorable Bernard Sanders
Chairman
The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Mammography Quality Standards Act*

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 "Mammography Quality Standards Act" (RIN: 0910-AH04). We received the rule on March 21, 2023. It was published in the *Federal Register* as a final rule on March 10, 2023. 88 Fed. Reg. 15126. The effective date is September 10, 2024.

According to FDA, the final rule issues updates to modernize the regulations by incorporating current science and mammography best practices. FDA stated these updates are intended to improve the delivery of mammography services by strengthening the communication of healthcare information; allowing for more informed decision-making by patients and providers (by requiring facilities to provide them with additional health information); helping to ensure the availability of qualified mammography personnel; bolstering the medical outcomes audit to provide feedback to improve mammography interpretations; modernizing technological aspects of the standards; and adding additional tools to deal with noncompliant facilities.

Enclosed is our assessment of 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. 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Megan Andersen
Regulatory Policy Analyst
Food and Drug Administration
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"MAMMOGRAPHY QUALITY STANDARDS ACT"
(RIN: 0910-AH04)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) estimated the final rule would create benefits from $12.99 to $232.69 million per year at the seven percent discount rate. FDA also estimated the benefits would be $8.5 to $266.09 million per year at the three percent discount rate. FDA also stated the final rule would lead to improvements in the accuracy of mammography and better management of mammography facilities. In addition to those estimates, FDA estimated the final rule would lead to costs ranging from $28.87 to $45.42 million at the seven percent discount rate, or $27.61 to $44.16 million at the three percent discount rate per year.

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

FDA determined the final rule would have a significant economic impact on a substantial number of small entities. FDA estimated the effect of the final rule to range from $416 to $727 per small entity, annually, which would represent about 1.2 percent of gross receipts.

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

FDA determined the final rule would not result in an expenditure by a state, local, or tribal government, in the aggregate, or by the private sector of $165 million ($100 million, adjusted for inflation) or more.

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

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

FDA published a proposed rule on March 28, 2019. 84 Fed. Reg. 11669. FDA received comments from several entities, including medical device associations, industry, medical and healthcare professional associations, public health advocacy groups, law firms, and individuals. FDA addressed the comments in the final rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

FDA concluded the final rule contained information collection requirements (ICRs) subject to PRA. The ICRs are associated with Office of Management and Budget (OMB) Control Number 0910-0309. FDA estimated the burdens of the ICRs to be 140,496 hours with a capital cost of $2,496,452 and an operating and maintenance cost of $5,807,650 for recordkeeping

requirements. FDA also estimated the burdens for third-party disclosures to be 1,099,674 hours with a capital cost of $44,010,473 and an operating and maintenance cost of $111,364.

Statutory authorization for the rule

FDA promulgated the final rule pursuant to sections 360i, 360nn, and 374 of title 21; and section 263b of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA stated OMB determined the final rule to be economically significant.

Executive Order No. 13132 (Federalism)

FDA stated it believed the final rule was consistent with the Order.