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MAMMOGRAPHY SERVICES

Initial Impact of New Federal Law Has Been Positive

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The Honorable Nancy L. Kassebaum
Chairman, Committee on Labor and
Human Resources
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce
House of Representatives

Breast cancer is the second leading cause of cancer mortality among American women. The American Cancer Society has estimated that, in 1995, 46,000 women will die from breast cancer and an additional 182,000 will be diagnosed with the disease. The probability for survival increases significantly when the disease is discovered in its early stages. Currently, the most effective technique for early detection of breast cancer is mammography, an X-ray procedure that can detect small tumors and breast abnormalities. Research studies indicate that widespread use of mammography could reduce breast cancer mortality by one-third, especially among women aged 50 to 74.

The effectiveness of mammography as a cancer detection technique is directly related to the quality of mammography procedures. In response to concerns that many providers were using mammography procedures of insufficient quality, the Congress enacted the Mammography Quality Standards Act of 1992 (MQSA). The act established a number of requirements aimed at strengthening quality, such as certification and annual inspection of mammography facilities. The act also mandated that we assess the program established by the Food and Drug Administration (FDA) to implement these various requirements. We are required to issue an interim report in 1995 and a final report in 1997. This interim report is focused on assessing whether FDA's implementation of the act so far has had any effect on (1) the quality of mammography services and (2) access to such services. This interim report is based primarily on our analysis of outcome data from FDA's certification and annual inspection programs and on our interviews with officials from federal, state, and private organizations involved with the programs. We did our work from November 1994 through August 1995 in accordance with generally accepted government auditing standards. Details of our scope and methodology are presented in appendix I.

Results in Brief

Early indications are that the act has had a positive effect on the quality of mammography services. A set of uniform standards, substantially the same as those advocated by the American College of Radiology (ACR), a private, nonprofit professional association of radiologists, is now required in all states. Before the act, states varied widely in the standards they imposed, and only a few states had standards comparable to those established under MQSA. We also found that these standards are having more than a symbolic effect, because in order to become fully certified, many facilities have had to improve their practices. Annual inspections of certified facilities are helping to ensure that facilities are in compliance with standards on a day-to-day operating level.

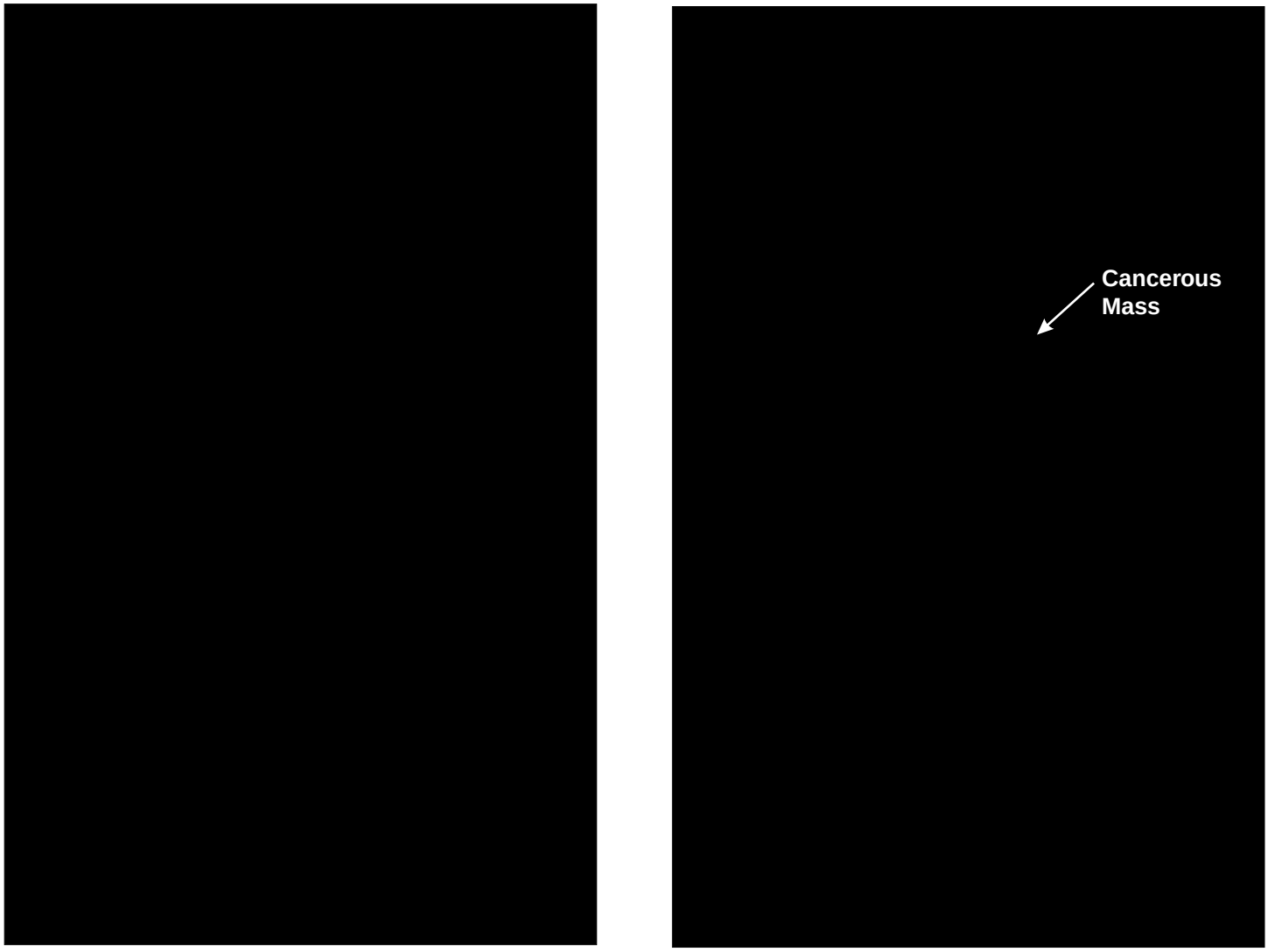
When the act was passed, the Congress was concerned that access to mammography services might be limited because many providers would choose to drop mammography services rather than upgrade operations to comply with the standards. Our work suggests that this does not appear to be the case. While some facilities have chosen to cease mammography services rather than comply with higher standards, the number that have done so is relatively small compared with the total number of facilities available to provide services. Those facilities that chose to stop delivering such services were generally small-volume providers located within 25 miles of another certified facility. FDA's gradual approach to implementing the act's requirements appears to have been a factor in minimizing adverse effects on access. FDA has not closed many facilities that have not met certification or inspection requirements. Instead, it has given facilities time and repeated opportunities to meet new quality assurance requirements and to correct problems found during inspections.

Background

An estimated 23.5 million mammograms were performed in the United States in 1992 at a cost of about $2.5 billion. Both the National Cancer Institute (NCI) and the American Cancer Society recommend that all women over the age of 50 have annual screening mammograms, though the two organizations are not in total agreement on the recommended frequency of screening mammography for women under the age of 50. Utilization rates for the technology have continuously increased over the years. According to the Centers for Disease Control and Prevention, the percentage of women aged 50 and above who had received mammograms in the past year increased from 26 percent in 1987 to 54 percent in 1993. The demand for mammography services has resulted in significant growth in the number of mammography facilities, currently numbering over 10,000 nationwide.

Mammography is one of the most technically challenging radiological procedures, and ensuring the quality of the radiologic image is difficult. If the image is poor, tumors and abnormalities may go undetected. To illustrate, two images of the same patient who had a cancerous tumor are presented in figure 1. The tumor is visible in the picture on the right, where the image is of higher quality, but it is blurred and indecipherable in the picture on the left.

Figure 1: Example of Low- and High-Quality Mammography Images of the Same Patient



Source: Dr. Carolyn Kimme-Smith, UCLA Department of Radiology, Los Angeles, California.

Accurate interpretation of mammograms is equally as important as image quality. According to radiological experts, mammograms are the most

difficult radiographic images to read. Misreading mammograms can have considerable consequences. A mammogram that is incorrectly read as showing an abnormality could cause a woman to go through unnecessary and costly follow-up procedures, such as ultrasound or biopsies. A mammogram that is read as normal when an abnormality is actually present could result in missed diagnosis of early lesions and delayed treatment, which could cost a woman's life.

MQSA contains a number of provisions designed to ensure the quality of the image and its interpretation. Among other things, MQSA requires that

- FDA establish quality standards for mammography equipment, personnel, and practices;
- all mammography facilities be accredited by an FDA-approved accrediting body (either a nonprofit organization or a state agency) and obtain a certificate from FDA in order to legally provide mammography services after October 1, 1994; and
- all mammography facilities be evaluated annually by a certified medical physicist and be inspected annually by FDA-approved inspectors.

FDA issued interim regulations in December 1993 that established requirements for accrediting bodies and quality standards and certification requirements for mammography facilities. Since early 1994, FDA has been working with the National Mammography Quality Assurance Advisory Committee[1] to develop the final regulations. FDA officials estimate that they will publish the proposed final regulations for public comment in October 1995 and issue the final regulations in October 1996. As of October 1, 1994, FDA had approved ACR and the states of California, Arkansas, and Iowa as official accrediting bodies. Because of ACR's pre-MQSA involvement in establishing a voluntary accreditation program, it serves as the major accrediting body, responsible for over 95 percent of

[1]MQSA also required that the Secretary of Health and Human Services establish a National Mammography Quality Assurance Advisory Committee. The Secretary delegated the responsibility to FDA. Among other things, the Committee is responsible for advising FDA on the appropriateness of quality standards for mammography facilities and accrediting bodies and for studying (1) the effect of MQSA on access to services in rural and health-professional-shortage areas, (2) the costs and benefits of compliance with MQSA, and (3) the sufficiency of medical physicists after October 1, 1999, to ensure compliance with MQSA. The Committee was required to report the findings of the first two studies by October 1993, but as of July 15, 1995, it had not done so.

the current MQSA accreditation workload.[2] To minimize duplicate submission of application information to FDA and accrediting bodies, under FDA's interim rules facilities need only submit application information to the accrediting bodies. On the basis of accrediting bodies' notification, FDA automatically issues certificates to facilities that pass accreditation review.

Quality of Mammography Services Has Improved

Early indications point to a general improvement in the quality of mammography services under the act. This improvement is mainly the result of setting national quality assurance standards and establishing enforcement mechanisms to ensure that the standards are met by all mammography providers.

Standards Are Now in Place

Before MQSA, wide variations existed in oversight provided at the state level. To provide an indication of these variations, we asked a panel of experts[3] to develop a list of mammography standards they considered most important. Eighteen quality assurance requirements were selected and then used as a benchmark for evaluating state oversight before MQSA took effect. These requirements, listed in appendix II, include such items as the quality of clinical image evaluations and the use of equipment designed especially for mammography. Before MQSA was implemented, only two states—Michigan and Texas—had enacted legislation and regulations that included all 18 requirements.[4] Nine states—Alabama, Connecticut, Kansas, Louisiana, Montana, Nebraska, North Dakota, West Virginia, and Wyoming—plus the District of Columbia made no mention of any of these requirements in state laws or regulations. See appendix III for state-by-state results.

Our interviews with officials from 20 states indicated that the impact of MQSA on quality of mammography services was greatest in states that had

[2]Concerned about the quality of mammography services, ACR began in 1987 a voluntary mammography accreditation program to provide assurance of quality to patients seeking services at ACR-accredited facilities. The program involved a number of facility procedures and image quality requirements, including an evaluation of clinical images produced by each facility. The program did not include on-site inspections of each facility and, because it was a voluntary program, only facilities that were seeking accreditation were subjected to ACR review.

[3]The experts came from five agencies or organizations: FDA, NCI, ACR, the Conference of Radiation Control Program Directors, and the Medical Center of the University of California at Los Angeles.

[4]Information about state mammography quality assurance requirements was obtained from an NCI study entitled Legislative and Regulatory Mandates for Mammography Quality Assurance. The study involved detailed review of state-enacted legislation and regulations on mammography quality assurance. It did not assess the extent to which states enforce their regulations.

no or few pre-MQSA standards. For example, officials from four states that had no pre-MQSA standards told us that they believed MQSA would greatly improve the quality of mammography services in their states. Officials from Michigan, which already had well-developed standards, welcomed the additional authority and resources that MQSA gave them to enforce the standards, but said the act's effect would not be as significant as it would in states without such standards already in place.

Another measure of variation in quality standards before MQSA was the level of voluntary participation in mammography quality assurance activities developed by ACR. ACR has managed a voluntary accreditation program since 1987, but, according to NCI and ACR records, only between 37 and 44 percent of the nation's mammography units were accredited by ACR as of July 1993.

The MQSA standards, as currently prescribed in FDA's interim regulations, include all 18 requirements chosen by our panel as well as a number of other requirements. Thus, the October 1994 implementation of MQSA had a substantial effect in that all providers, regardless of location or setting, became responsible for complying with a single, minimum standard of care. In all, FDA's interim regulations contain more than 30 requirements covering such matters as personnel qualification and radiation safety. In implementing these requirements, FDA adopted the standards that had been set by ACR in its voluntary compliance program. These standards have been endorsed by professional organizations as well as industry and government experts. FDA officials chose these standards because they believed the standards were based on sound scientific principles and clinical judgment gained through extensive experience; further, the legislative history of MQSA indicates that the Congress intended to use the ACR program as the model for accreditation.[5]

The current standards include specific requirements to control image quality, but the requirement for monitoring the accuracy of image interpretation is less specific. The regulations include a general requirement that each facility have a system to review outcome data, including follow-up on positive mammograms (those identified as showing tumors or abnormalities) and their correlation to biopsy results. However, the regulations do not include standards for evaluating the outcome data. How to develop a quality assurance system to monitor the accuracy of

[5]Under ACR's program, facilities are required to have a quality assurance system that includes qualified personnel (interpreting physician, medical physicist, and radiologic technologist) with adequate continuing education in mammography, as well as appropriate equipment, quality control, and quality assurance procedures.

image interpretation is a controversial issue in the medical community. On one hand, several academic studies have shown wide variation in the interpretation of the same films by different radiologists, and some experts suggest that peer reviews of films or proficiency tests of radiologists are needed to ensure accuracy. On the other hand, others, including FDA, believe that those measures are too difficult and costly to implement and that a system of tracking the mammography outcomes is a better approach to achieve the goal of quality interpretation.

FDA officials told us that, after consulting with the National Mammography Quality Assurance Advisory Committee, they are considering expanding the outcome data requirement in the proposed final regulations. The option under consideration is for each facility to designate at least one interpreting physician to review the outcome data at least annually, and for the facilities to use the data to evaluate the performance of each interpreting physician and the facility as a whole. FDA officials told us this option would allow facilities discretion in defining outcome standards. They said such discretion was needed because no consensus existed on appropriate outcome measures and because more research was needed before outcome standards could be prescribed.

Accreditation Process Has Produced Change at Many Facilities

MQSA called for facilities to comply with the new standards through an accreditation process. In adopting ACR standards in its interim regulations, FDA granted automatic certification to any facility that had already demonstrated compliance with ACR requirements by being accredited under ACR's voluntary program. All other facilities had to apply for accreditation by completing an application package and submitting materials for testing to provide evidence of meeting the standards. Accreditation was performed by one of the FDA-approved accrediting bodies. While the accreditation procedures established by Arkansas, California, and Iowa are somewhat different from ACR's,[6] the four accrediting bodies enforce the same FDA standards. Because ACR accounts for more than 95 percent of the current MQSA accreditation workload, we focused our review on ACR's accreditation process.

When MQSA initially took effect, many mammography units did not meet its mammography standards. According to ACR records, between October 1,

[6]For example, ACR allows facilities to submit materials for review only twice and will deny accreditation to facilities that fail the second review. Arkansas and Iowa, on the other hand, allow facilities to resubmit materials three times and, instead of denying accreditation if a facility fails the second review, continue to work with the facility to bring it into compliance with accreditation requirements.

1994, and August 1, 1995, 7,525 different mammography units from approximately 5,510 facilities went through ACR's first review for accreditation, and 2,598 units (35 percent) from roughly 1,900 facilities failed to meet the accreditation requirements.[7] After a second review process, ACR found about two-thirds of these units to be in compliance and granted them full accreditation.[8] Of those that were denied accreditation after failing the second review, 277 facilities have since taken sufficient corrective actions to qualify for reinstatement. These data suggest that the accreditation process has resulted in improvement at these facilities.

Inspection Process Is Designed to Enforce Compliance

MQSA inspection authority provides FDA with another means to ensure that facilities comply with standards on a day-to-day operating level. While accreditation is a mail-in process that involves the submission and review of application materials, inspections are conducted on site, allowing inspectors to verify information provided during the accreditation process.

Actual inspections began somewhat later than initially planned. FDA entered into agreements with states to train state inspectors for annual inspections and reimburse states for their inspection costs. FDA had planned to have 200 inspectors trained by June 1995, but only 159 inspectors were trained by that date. Because of these delays in training, annual inspections did not begin until January 1995, although they had been planned to start in October 1994.

Early results from annual inspections indicated that many facilities fell short of full compliance with MQSA requirements. As of June 9, 1995, inspectors had inspected 1,843 facilities and found that 601—or 33 percent—had deficiencies that needed to be corrected. Of these, 119 facilities were considered to be in serious noncompliance with MQSA standards. As table 1 shows, the most common violations noted in the serious noncompliance group involved the facilities' use of personnel who did not meet FDA's qualification requirements.

[7]ACR uses mammography units rather than facility counts to compute these percentages. In reviewing a facility's application for accreditation, ACR requires facilities to submit materials for each mammography unit and reviews each unit separately to determine if it meets accreditation requirements. Thus, a facility that has more than one mammography unit could have some of its units pass and some of its units fail.

[8]ACR's accreditation process allows facilities to go through two reviews. Facilities that fail the first accreditation review can correct deficiencies and resubmit the materials for a second review. If a facility fails the second review, ACR denies accreditation.

Table 1: Number of Facilities With Serious Noncompliance Violations (as of June 1995)

Type of violation	Number of facilities
Medical physicist did not meet MQSA qualification requirements.	40
Interpreting physician did not meet MQSA qualification requirements.	34
Radiological technologist did not meet MQSA qualification requirements.	19
Not all interpreting physicians had a state medical license.	16
Facility had not been surveyed by medical physicist.	12
Other	8

Note: Total number of facilities shown exceeds 119 because some facilities had more than one serious violation.

Under the current inspection program, FDA issues a warning letter to facilities in serious noncompliance, such as those listed above. Facilities are required to respond in writing within 15 days, listing specific steps they plan to take to correct violations. Failure to promptly correct the deficiencies could result in regulatory action by FDA, such as fines, suspension or revocation of the facility's certificate, or a court injunction prohibiting the facility from performing mammography.

Early Indications Show No Significant Adverse Impact on Access to Services

While many facilities had problems meeting FDA's quality standards and deadlines for compliance, FDA and the accrediting bodies made significant efforts to work with facilities to avoid large-scale facility closures or discontinuance of services. As a result, although some facilities have discontinued services, so far the number of closures is relatively small and access to services has not been significantly affected.

FDA Has Taken a Gradual Approach to Bringing Facilities Into Compliance

To prevent widespread facility closures, FDA has been working with facilities to bring them into compliance with MQSA. From the start, FDA was concerned that many facilities would need time to upgrade their practices. To provide facilities lead time for preparation, FDA issued its interim regulations in December 1993, more than 10 months before the certification deadline of October 1, 1994, and began to send quarterly newsletters to facilities informing them about MQSA requirements.

Even with advance notice, however, almost 4,700 of the more than 10,000 mammography facilities nationwide failed to complete the accreditation process in time to receive full certification by the October 1 deadline. The

two main reasons for this outcome, according to ACR officials, were the failure of facilities to submit materials in a timely manner and the submission of applications that did not meet the accreditation requirements. Using the maximum time allowed by MQSA, FDA issued provisional certificates to these facilities, giving them 6-month extensions. FDA also granted 90-day extensions for facilities whose provisional certificates expired before accreditation requirements could be met. In April, more than 1,500 90-day extensions were granted. On July 17, 1995, 242 facilities were still in the 90-day extension status, indicating that they still had problems satisfying all accreditation requirements (see table 2).

Table 2: Status of Facility Certification

	10/1/94		4/12/95		7/17/95	
Status	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Full certification	5,338	53	8,421	80	9,406	93
Provisional certification	4,692	47	576	5	522[a]	5
90-day extension			1,557	15	242	2
Total	**10,030**	**100**	**10,554**	**100**	**10,170**	**100**

Note: The total number of facilities changed because (1) many facilities did not send in their accreditation applications until the final week before the October 1, 1994, deadline and, thus, did not receive their provisional certificates until some time after October 1, 1994, and (2) some facilities were decertified as a result of withdrawal or failing the accreditation process after April 1995.

[a]Includes 279 facilities that have been provisionally reinstated.

To minimize the need for shutting down facilities permanently, in February 1995, FDA established a reinstatement process. This process allows a facility that has had to stop performing mammography because it has failed to meet accreditation requirements to apply for reinstatement by submitting a corrective action plan and applying for accreditation as a new facility.[9] As of July 17, 1995, 279 facilities have been granted such reinstatement, which has allowed them to resume mammography services while pursuing accreditation under a new provisional certificate.

As a result of FDA's approach, although some facilities did have to cease performing mammography for some period of time, many of them have

[9]To be eligible for reinstatement, a facility must submit to its accreditation body a corrective action plan that details how the facility has corrected or intends to correct deficiencies. If the accreditation body and FDA approve the plan, the facility becomes eligible for a new provisional certificate, which allows it to operate legally for 6 months while pursuing full accreditation. In June 1995, FDA worked with ACR to revise its reinstatement protocol to allow both failing facilities and those that did not complete the accreditation process when their 90-day extension expired to apply for reinstatement.

been able to reopen. According to ACR records, between October 1, 1994, and August 1, 1995, a total of 488 facilities were denied accreditation (for failing to pass the second review or to complete submission requirements) and had to suspend mammography services. As of August 1, 1995, 301 of these had either passed accreditation on appeal or had been reinstated. For these facilities, the average time from notification of denial until reinstatement was about 15 days. Only six of these denied facilities had notified ACR that they did not intend to resume providing mammography services. ACR officials said that most of the remaining facilities are in the process of evaluating the causes of their deficiencies and assessing the costs of correcting them. ACR officials expected that a substantial majority would apply for reinstatement within 30 days.

FDA has adopted a similarly gradual approach to resolving deficiencies identified in annual inspections. As a result, as of July 26, 1995, FDA had not closed any facilities for noncompliance found during inspections.

Most Closures Did Not Limit Access

Facility closures, both in anticipation of the act and since the act took effect, appear to have had a limited effect on access to mammography services. Of the 10,000-plus facilities that were providing mammography services before MQSA, FDA identified 404 facilities, or about 4 percent, that had ceased to provide mammography services between October 1993 and October 1994, when MQSA became effective. FDA contracted with a private research firm to study the impact of these closures on access to mammography services. The study found that about 97 percent of the closed facilities were within 25 miles of a certified facility; 62 percent were within 1 mile of such a facility. In May 1995, FDA asked the contractor to update the study by adding into the closure population those facilities that had been denied accreditation or had voluntarily withdrawn from the process since the act took effect. The update, which covered about 350 such facilities, showed almost identical results.

In addition, officials in the eight states (plus Puerto Rico) that had at least 10 percent of their facilities identified as closed consistently told us that the closures did not adversely affect access to quality mammography services in their states. This lack of negative impact may be related to the fact that most of the closed facilities were low-volume operations in independent doctors' offices: we have previously documented that quality assurance is more difficult to maintain in low-volume facilities.[10]

[10]Screening Mammography: Low-Cost Services Do Not Compromise Quality (GAO/HRD-90-32, Jan. 10, 1990), and Screening Mammography: Federal Quality Standards Are Needed (GAO/T-HRD-92-39, June 5, 1992).

Several of these state officials also told us that the main reason that many low-volume providers in their states ceased to perform mammography was that their volume could not support the costs for system upgrades necessary to meet MQSA standards. The costs associated with a system upgrade vary depending on the type and the extent of changes that are required. For example, FDA estimated that, for facilities that have to upgrade or replace equipment, the average cost would be about $50,000. FDA does not have reliable data on costs and has not been able to assess the economic impact of its interim regulations on facilities. It has contracted with a private research group to develop an industry profile and a cost model. FDA officials told us that they plan to assess the total cost impact of MQSA when the final regulations are issued.

Besides the cost of upgrades, facilities also have to pay accreditation fees and annual inspection fees. To obtain ACR accreditation, a facility has to pay a fee of $700 for the first mammography unit and $600 for each additional unit. In addition, facilities must pay inspection fees, and MQSA requires that such fees entirely cover inspection costs. For fiscal year 1995, FDA established a fee schedule of $1,178 for the first unit and $152 for each additional unit for annual inspection; follow-up inspections cost $670 each. The inspection fee assessment is based on FDA's calculation of the amount needed to cover the costs of inspections.[11] See appendix IV for more information on total and per-inspection costs.

Michigan's Experience Shows Access Unaffected

To provide an additional perspective on how regulations might affect access, we examined whether any studies had been conducted in states where mammography standards had been strengthened before MQSA. One unpublished study by NCI staff had looked at Michigan, which enacted stringent quality standards almost 5 years before the implementation of MQSA. According to the principal researcher, access to mammography services in Michigan was not adversely affected by the tighter standards. NCI staff analyzed the number of mammography facilities and machines in Michigan between 1989 and 1994 and found that while the stringent standards had caused some facilities to discontinue mammography, there were still sufficient facilities in the state to provide services. In addition, longitudinal mammography utilization data examined through 1994

[11]On March 17, 1995, FDA issued a notice in the Federal Register announcing the inspection fee assessment of fiscal year 1995. In calculating the fee assessment, FDA included specific costs, such as the cost of contracts with states to conduct annual inspections and FDA personnel and equipment costs associated with the inspections. Of the total costs included in the 1995 fee assessment, over 80 percent came from the costs of state contracts. In this interim report, we did not determine the reasonableness of these costs and the fee assessment.

indicated that Michigan was outperforming most of the country in mammography usage and was among the very few states with the best rates of mammography screening compliance. NCI staff also concluded that, after the implementation of the Michigan standards, the technical quality of mammograms in Michigan improved in comparison with that of other states.

Conclusion

To date, MQSA's effects appear generally positive. Mammography quality standards are now in place in all states, and these standards do not appear to have had a negative effect on access to services. However, to avoid large-scale closures of facilities, FDA settled on an approach that allowed some delay in meeting the certification requirements. For this and other reasons, such as the availability of outcome data, more time will be needed before MQSA's full impact can be determined. MQSA mandates that we assess the effects of MQSA again in 2 years and issue a report in 1997.

Agency Comments

We provided FDA and ACR officials with a draft copy of the report for review and comment. FDA responded that the draft was accurate and reflective of the program. While ACR did not provide formal comments, officials provided some technical comments, which we incorporated as appropriate. Appendix V contains FDA's written response.

We will send copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, the Director of NCI, the Director of the Office of Management and Budget, and other interested parties. We will also make copies available to others on request.

Please contact me at (202) 512-7119 if you or your staff have any questions. Major contributors to this report are listed in appendix VI.

Mark V. Nadel
Associate Director, National
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Contents

Abbreviations

ACR	American College of Radiology
FDA	Food and Drug Administration
GAO	U.S. General Accounting Office
MQSA	Mammography Quality Standards Act of 1992
NCI	National Cancer Institute

Scope and Methodology

To develop general information about how FDA has implemented MQSA, we analyzed data from FDA's certification and annual inspection programs and from ACR's accreditation program. To specifically address our objective of assessing the initial effect of MQSA on the quality of mammography services, we relied on two analyses: a comparison of MQSA standards with existing state standards and an outcome analysis of ACR's accreditation and FDA's inspection results. Because FDA's inspection program was just getting under way at the time of our review, our analysis of FDA inspection results was limited to summary data provided by FDA from its first 4 months of inspection. The analysis of state standards was primarily based on data from an NCI study of state mammography legislation.[12] Although we did not directly measure the quality of mammography images, the accreditation process does involve an evaluation of a facility's quality assurance system, including a review of clinical images.

To address our objective of assessing MQSA's effect on accessibility, we examined an FDA contractor's study on facility closures and an unpublished study by NCI staff of Michigan's experience in implementing stringent quality standards prior to MQSA. We supplemented this work by interviewing 6 members of FDA's National Quality Assurance Advisory Committee and 32 officials from 20 states and Puerto Rico to obtain their views on the initial impact of MQSA on quality and accessibility of mammography services. We did our work from November 1994 through August 1995 in accordance with generally accepted government auditing standards.

[12]Lou Fintor, Marianne Haenlein-Alciati, and Ruth Fischer, "Legislative and Regulatory Mandates for Mammography Quality Assurance," Journal of Public Health Policy, Vol. 16, No. 1, Spring 1995.

Mammography Quality Assurance Requirements Used in Assessing States' Pre-MQSA Programs

Requirement	Purpose of requirement
Dedicated equipment	To ensure the use of equipment specifically designed for mammography
Technical exposure factors	To ensure optimal picture quality and radiation control
Compression device	To uniformly reduce the thickness of the breast so that it is evenly penetrated by the X ray for the best image of all breast tissue
Grid capability	To control scatter radiation
Automatic exposure control	To administer the appropriate radiation exposure for each woman's unique breast size
kVp accuracy and reproducibility	To ensure the accuracy and consistency of electrical current
Half-value layer	To ensure an accurate picture is produced at the minimum level of radiation
Collimation assessment	To protect the patient from excess radiation
Screen-film contact	To ensure a sharp mammography image
Average glandular dose	To ensure the radiation dose to the patient does not exceed government standards
Phantom image review	To evaluate the ability of the equipment to produce images of sufficient quality
Processor sensitometry and densitometry	To ensure the processor is producing high-quality images
Repeat analysis	To identify the cause of and correction for rejected mammograms
Clinical image evaluation	To identify problems related to technique or equipment
Outcome data	To evaluate the effectiveness of mammography in screening and detecting breast cancer
Mammogram retention	To ensure an adequate period of film retention in case it is necessary to compare future mammograms
Mammogram report	To ensure complete and unambiguous mammography reports
Personnel requirements	To establish minimum qualifications for education, training, experience, and professional certification of mammography personnel

Key Mammography Quality Assurance Requirements, by State, as of December 1993

	Equipment											Develop.	Image Analysis		Records and Tracking			Pers.
	Mammography																	
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
Michigan	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Texas	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Rhode Island	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●
Massachusetts	●	●	●	●	●	●	●	●	●	●	●	●	●			●	●	●
Indiana	●	●	●	●	●	●	●	●	●	●	●	●	●			●	●	●
Mississippi	●	●	●	●	●	●	●	●	●	●	●	●	●			●		●
Iowa	●	●	●	●	●		●	●	●	●	●	●	●			●	●	●
Missouri	●	●	●	●	●	●	●		●	●	●	●	●			●	●	●
Nevada	●	●	●	●	●	●	●	●	●	●	●	●	●					●
Arkansas	●	●	●	●	●		●			●	●	●	●			●	●	●
California	●	●	●		●	●	●		●	●	●	●	●				●	●
Pennsylvania	●	●	●	●	●		●			●	●	●	●			●	●	●
Colorado	●	●	●	●	●	●	●	●	●		●	●	●					●
New Jersey	●	●	●		●	●	●	●	●	●	●	●	●					●
Washington	●	●	●		●	●	●	●	●	●	●	●	●					●
Idaho	●	●	●	●	●	●	●	●	●	●	●	●	●					
Utah	●	●	●	●	●		●			●				●	●	●	●	●
New York	●	●	●		●	●	●			●	●	●	●			●		●
Maine	●				●	●	●	●	●	●	●	●	●					●
South Carolina	●	●	●		●	●	●			●	●	●	●					●
Illinois	●	●	●			●	●		●	●	●	●				●		●
Florida	●		●	●			●	●		●	●	●				●		●
Minnesota	●	●			●	●	●	●		●	●					●		
Kentucky	●		●										●	●	●	●	●	●
Vermont	●		●										●	●	●	●	●	●
Maryland	●	●	●										●			●	●	●
Ohio	●		●										●	●	●	●	●	
Georgia	●												●	●	●	●	●	●
New Mexico	●												●	●	●	●	●	
Delaware	●												●	●	●	●	●	
Oklahoma	●		●								●					●		●
North Carolina	●												●			●	●	●
Virginia	●		●													●		●
South Dakota	●		●															●
Oregon	●															●		●
Arizona	●														●			●
Wisconsin	●		●															
New Hampshire	●		●															
Hawaii	●		●															
Alaska	●		●															
Tennessee	●																	
Alabama																		
Connecticut																		
District of Columbia																		
Kansas																		
Louisiana																		
Montana																		
Nebraska																		
North Dakota																		
West Virginia																		
Wyoming																		

Legend

A = Dedicated Equipment
B = Technical: KV, MA, Exposure, Compression Device
C = Compression Device
D = Grid Capability
E = Automatic Exposure Control Performance Capability
F = kVp Accuracy and Reproducibility
G = Half-Value Layer
H = Collimation Assessment
I = Screen-Film Contact
J = Average Glandular Dose
K = Phantom Image Review
L = Processor Sensitometry and Densitometry
M = Repeat Analysis
N = Clinical Image Evaluation
O = Outcome Data
P = Mammogram Retention
Q = Mammogram Report
R = Personnel Requirements

Basis of FDA's Calculation of Fiscal Year 1995 Annual Inspection Fees for Mammography Facilities

Breakdown of MQSA inspection fee costs	Cost	Cost per unit[a]	
		First unit	Additional unit
Contracts with states to conduct inspections	$10,480,556	$958	$123
FDA personnel to conduct inspections	351,439	32	4
Equipment, development of calibration procedures, and instrument calibration	611,199	56	7
Design, programming, and maintenance of data systems necessary to schedule inspections and track results	566,643	52	7
Training and certification of inspectors (FDA and state)	894,305	81	10
Total FY 95 annual inspection costs	**$12,904,142**	**$1,178[b]**	**$152[b]**

Source: FDA, MQSA inspection fees, November 1994.

[a]The unit cost is based on the following assumptions: (1) the total number of mammography units subject to inspection in 1995 was 10,666; (2) on average, each facility had 1.24 mammography units; (3) 7.76 hours are required for an annual inspection of a facility with a single mammography unit; and (4) each additional unit adds one hour to the annual inspection.

[b]Totals do not add due to rounding.

Comments From the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 23 1995

Mr. Mark Nadel
Associate Director, National and Public Health Issues
Health, Education, and Human Services Division
U.S. General Accounting Office
Room 500
1 Massachusetts Avenue
Washington, D.C. 20001

Dear Mr. Nadel:

The Food and Drug Administration has reviewed the draft report entitled, "MAMMOGRAPHY SERVICES: Initial Impact of New Federal Law Has Been Positive," and finds it to be generally accurate and reflective of the program. We, therefore, have no comments. Thank you for the opportunity to review the draft report.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

GAO Contacts and Staff Acknowledgments

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Staff Acknowledgments

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