United States Government Accountability Office

GAO

Report to Congressional Requesters

July 2006

MAMMOGRAPHY

Current Nationwide Capacity Is Adequate, but Access Problems May Exist in Certain Locations

GAO-06-724

July 2006

MAMMOGRAPHY

Current Nationwide Capacity Is Adequate, but Access Problems May Exist in Certain Locations

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-06-724, a report to congressional requesters

Why GAO Did This Study

Mammography, an X-ray procedure that can detect small breast tumors, is an important tool for detecting breast cancer at an early stage and, when coupled with appropriate treatment, can reduce breast cancer deaths. In 2002, GAO reported in *Mammography: Capacity Generally Exists to Deliver Services* (GAO-02-532) that the capacity to provide mammography services was generally adequate, but that the number of mammography facilities had decreased by 5 percent from 1998 to 2001 and that about one-fourth of counties had no machines. GAO was asked to update its information on facility closures and mammography service capacity.

The Food and Drug Administration (FDA) regulates mammography quality and maintains a database on mammography facilities and other capacity elements. GAO reviewed FDA data on facility closures and examined reasons for closures in recent years. GAO analyzed changes in the nation's capacity for and use of mammography services using FDA capacity data and National Center for Health Statistics data on service use. GAO also interviewed state and local officials about the effects of the loss or absence of mammography machines on access, including access for medically underserved women, such as those who are poor or uninsured.

www.gao.gov/cgi-bin/getrpt?GAO-06-724.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

Closures of certified mammography facilities outpaced openings during a recent 3-year period, and financial considerations were most often cited as the reason for facility closures. FDA data show that from October 1, 2001, to October 1, 2004, the number of mammography facilities nationwide decreased from 9,306 to 8,768. During this period, 1,290 facilities closed and 752 began providing services, resulting in a net loss of 538 facilities, or 6 percent. Mammography facility officials most often cited financial considerations as the reason their facility closed. Experts said that another factor that could affect closures is difficulty recruiting and retaining radiologic technologists who perform mammography and physicians who interpret mammograms.

Although key elements that make up mammography capacity have decreased and the use of screening mammography has grown, current nationwide capacity is adequate. The numbers of mammography facilities, machines, radiologic technologists, and interpreting physicans decreased from 2001 to 2004. From 2000 to 2003, the estimated number of women who received a screening mammogram increased, mostly because of population growth. Based on GAO's calculation that the estimated number of mammograms performed in the United States in 2003 was substantially lower than the number that could have been performed, GAO found that current capacity is adequate. Most of the experts GAO interviewed believe the nation's current overall capacity is likely adequate, but all of the experts expressed concern that the flow of personnel into the field may be insufficient to serve the growing number of women needing screening. This potential development could result in access problems in the future.

The loss or absence of machines in certain locations may have resulted in access problems, including problems for women who are medically underserved, such as those who have a low income or lack health insurance. About one-fourth of counties had no mammography machines in 2004. The majority of officials GAO interviewed about access in their states, including access in 18 of the 117 counties that had lost over 25 percent of their machines from 2001 to 2004, said that machine losses had not resulted in access problems because women were able to obtain services at other facilities. However, some officials told GAO that the loss or absence of machines in certain counties resulted in access problems consisting of lengthy wait times or travel distances to obtain services. Lengthy travel distances may especially pose an access barrier for medically underserved women. Access problems for these women are of concern because uninsured and poor women have lower-than-average screening mammography rates.

In commenting on a draft of this report, FDA provided additional details and clarification regarding aspects of its regulation of mammography, which GAO incorporated as appropriate.

Contents

Tables

Figures

Abbreviations

ACR	American College of Radiology
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IDP	inspection demonstration program
MQSA	Mammography Quality Standards Act of 1992
MQSRA	Mammography Quality Standards Reauthorization Act
NCI	National Cancer Institute
NHIS	National Health Interview Survey
QIO	quality improvement organization

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

July 25, 2006

The Honorable Arlen Specter
Chairman
The Honorable Tom Harkin
Ranking Minority Member
Subcommittee on Labor, Health and Human
Services, Education, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Barbara A. Mikulski
Ranking Minority Member
Subcommittee on Retirement Security and Aging
Committee on Health, Education, Labor, and Pensions
United States Senate

Breast cancer is the most common cancer among women in the United States, excluding skin cancers, and is the second leading cause of cancer deaths among U.S. women. The American Cancer Society has estimated that in 2006, almost 213,000 new cases of breast cancer will be diagnosed in women and over 40,900 women will die from the disease. Early detection, however, when coupled with appropriate treatment, can reduce breast cancer mortality. Mammography, an X-ray imaging procedure that can detect small tumors and breast abnormalities, is an important tool for detecting breast cancer at an early stage. Mammography is performed for two different purposes: screening and diagnosis. Screening mammography is an examination of a woman without breast symptoms to detect a breast abnormality before it can be detected by physical examination. Diagnostic mammography is an examination of a woman who exhibits a symptom, such as a lump, that indicates the possible presence of breast cancer or whose screening mammogram indicated a possible cancer. The National Institutes of Health's National Cancer Institute (NCI) and the U.S. Preventive Services Task Force[1] recommend screening mammography every 1 to 2 years for women age 40 and over. Medically underserved

[1]The U.S. Preventive Services Task Force is a committee of medical experts convened by the Department of Health and Human Services to evaluate evidence and make recommendations for screening services, such as mammography.

women—such as those who have low incomes, lack health insurance coverage, or are in certain racial or ethnic minority groups—have been less likely to obtain screening mammography than have other women. In addition, studies have found that diagnoses of breast cancer for minority women have occurred at a more advanced stage than for white women and that differences in mammography use, such as a lower likelihood of obtaining regular screening among minority women, may explain this disparity.[2]

Although mammography is the most effective tool for detection of early-stage breast cancer, it is not a perfect test. For example, mammograms are among the most difficult radiographic images to interpret because very early-stage breast cancer appears similar to noncancerous breast tissue in the mammographic image. If a mammogram is interpreted as normal when an abnormality is actually present, this could result in a missed diagnosis and delayed treatment, which could cost a woman her life. Conversely, if a mammogram is incorrectly interpreted as showing an abnormality, this could cause a woman to undergo unnecessary and costly follow-up procedures and experience unnecessary anxiety.

The Mammography Quality Standards Act of 1992 (MQSA) and the Mammography Quality Standards Reauthorization Acts (MQSRA) of 1998 and 2004 established national quality standards for mammography to help ensure the quality of the images and image interpretations that mammography facilities produce.[3] MQSA required the Secretary of Health and Human Services to establish and enforce quality standards for mammography equipment, personnel, and recordkeeping practices. The Food and Drug Administration (FDA) administers the requirements of MQSA on behalf of the Department of Health and Human Services (HHS).

Before a mammography facility can legally perform mammography services, it must receive an MQSA certificate indicating that it meets FDA's quality standards. To begin this process, the facility must be accredited by an FDA-approved accreditation body, which assesses whether the facility

[2]See, for example, Rebecca Smith-Bindman et al., "Does Utilization of Screening Mammography Explain Racial and Ethnic Differences in Breast Cancer?" *Annals of Internal Medicine*, vol. 144, no. 8 (2006), and Asma Ghafoor et al., "Trends in Breast Cancer by Race and Ethnicity," *CA: A Cancer Journal for Clinicians*, vol. 53, no. 6 (2003).

[3]Pub. L. No. 102-539, 106 Stat. 3547; Pub. L. No. 105-248, 112 Stat. 1864; Pub. L. No. 108-365, 118 Stat. 1738 (codified at 42 U.S.C. § 263b).

meets the quality standards. FDA has approved one nonprofit organization—the American College of Radiology (ACR)—and state agencies in three states—Arkansas, Iowa, and Texas—to serve as accreditation bodies.[4] ACR serves as the major accreditation body and is responsible for over 90 percent of the accreditation workload. State accreditation bodies may accredit facilities only within their own state; facilities may apply for accreditation to either their state body or ACR. Accreditation bodies must establish measures that FDA approves to avoid conflicts of interest—such as an accreditation body employee's financial interest in a facility being reviewed—as the bodies carry out their work. Upon receiving notification from an accreditation body that a facility meets the quality standards and has therefore achieved accreditation, FDA or a state certification body issues an MQSA certificate to the facility, which allows it to legally operate for up to 3 years. To operate subsequent to the 3-year period, the facility must apply for reaccreditation prior to the expiration of its certificate. FDA has approved state agencies in three states—Illinois, Iowa, and South Carolina—as certification bodies.[5] As with state accreditation bodies, state certification bodies may certify facilities only within their own state[6] and are to establish FDA-approved measures to avoid conflicts of interest. FDA and the state certification bodies are also responsible for ensuring that all facilities they certify receive an annual MQSA compliance inspection.[7] For most states where FDA certifies the facilities, it contracts with the state to have state

[4]FDA approved ACR and state agencies in Arkansas and Iowa to serve as accreditation bodies in 1994. FDA approved a state agency in Texas to serve as an accreditation body in 1999. These bodies are currently approved to serve as accreditation bodies through April 28, 2013. FDA approved a state agency in California to operate as an accreditation body in 1994, but California withdrew its application to continue operating as an accreditation body on May 5, 2004. FDA required that facilities previously accredited by California obtain accreditation from ACR within 1 year of California's withdrawal as an accreditation body.

[5]FDA approved state agencies in Illinois and Iowa to serve as certification bodies in 1998. In April 2005, FDA approved a state agency in South Carolina to serve as a state certification body. These state certification bodies are currently approved to serve in that capacity for an indefinite period.

[6]Facilities in states with certifying bodies may receive certification only from their state body, not from FDA.

[7]MQSA requires the annual inspection of mammography facilities to ensure compliance with the act's requirements. 42 U.S.C. § 263b(g).

inspectors perform MQSA compliance inspections.[8] FDA is responsible for overseeing accreditation and certification bodies' compliance with MQSA and MQSA regulations.

To determine if the frequency of MQSA compliance inspections could be reduced for facilities that had previously been found to be in compliance with MQSA, FDA implemented an inspection demonstration program (IDP) as authorized under MQSRA of 1998.[9] The IDP tested whether moving to a biennial inspection schedule would affect the facilities' compliance levels. FDA implemented the IDP in November 2001 and ended it in August 2004.

We reported in 2002 that key elements that make up mammography capacity—the numbers of mammography facilities, machines, and radiologic technologists—were generally adequate to meet the demand for services.[10] We also reported that the number of mammography facilities had decreased by 5 percent from 1998 to 2001 and that over one-fourth of the nation's counties had no machines in 1998 and in 2001. You asked us to update this information and to provide information on state accreditation and certification bodies. In this report, we examine (1) mammography facility closures and factors that have contributed to closures in recent years; (2) changes in the nation's capacity for and use of mammography services in recent years and whether current capacity is adequate; (3) the effects of the loss or absence of mammography machines on access to services, including access for medically underserved women; and (4) the measures state accreditation and certification bodies have taken to avoid conflicts of interest and FDA's oversight of state bodies' performance in this area. You also asked us to provide information on the results of FDA's MQSA compliance inspection IDP; this information is in appendix I.

To examine mammography facility closures, we analyzed data from FDA's Mammography Program Reporting and Information System database on

[8]In addition to contracting with states, FDA also contracts with New York City and Puerto Rico to have their inspectors perform MQSA compliance inspections. As of June 2006, FDA did not have contracts with Nebraska, New Hampshire, and the District of Columbia, according to FDA officials. FDA inspectors are responsible for conducting inspections in these jurisdictions and in federal facilities.

[9]Pub. L. No. 105-248, § 8, 112 Stat. 1864, 1865-66.

[10]GAO, *Mammography: Capacity Generally Exists to Deliver Services*, GAO-02-532 (Washington, D.C.: Apr. 19, 2002).

the total numbers of certified facilities as of October 1, 2001, and October 1, 2004. To examine the factors that have contributed to mammography facility closures, we reviewed data from ACR and state accreditation bodies in Arkansas, Iowa, and Texas on closures and reasons for closure, and interviewed eight radiologists who are experts in mammography about factors that contribute to facility closures.

To examine changes in the nation's capacity for and use of mammography services in recent years and whether current capacity is adequate, we first defined the key elements that make up mammography capacity as the numbers of certified mammography facilities; machines; radiologic technologists who perform mammography; and physicians who interpret mammograms, who are usually radiologists.[11] We then analyzed data from FDA's mammography facility database on the total numbers of these capacity elements as of October 1, 2001, and October 1, 2004. To examine changes in the nationwide use of mammography services, we analyzed data from the 2000 and 2003 National Health Interview Survey (NHIS), administered by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics, to estimate the number of women age 40 and older who received a screening or diagnostic mammogram within the previous year.[12] To examine changes in the population of women age 40 and older, we used population estimates from the Census Bureau. To determine the adequacy of current capacity, we asked mammography experts for estimates of the amount of time it takes to perform a screening mammogram and to perform a diagnostic mammogram. We used those estimates and FDA data on the number of machines available in 2003 to calculate the number of screening mammograms that potentially could have been performed in 2003. We compared this estimate of capacity to the estimated number of women age 40 and older who received a screening mammogram, based on the 2003 NHIS, and also took into account 2003 NHIS data on diagnostic mammograms. In addition, we interviewed the following individuals about issues related to mammography closures, mammography capacity, and

[11]In our last report, we examined three of these elements. In this report we added physicians who interpret mammograms as a fourth element of capacity.

[12]NHIS is the principal source of information on the health of the civilian noninstitutionalized population of the United States and is one of the major data collection programs for the National Center for Health Statistics. In 2000 and 2003, NHIS asked women age 30 and older about the length of time since their last mammogram and about the reason for the mammogram. NHIS data on the use of mammography services are based on data that are self-reported by respondents. The 2003 data were the most recent data available on the use of mammography services at the time we conducted our analysis.

access to mammography services: officials from FDA, CDC, NCI, and the Centers for Medicare & Medicaid Services (CMS); representatives from several professional organizations, such as the American Board of Radiology, American Cancer Society, ACR, and the American Society of Radiologic Technologists; and mammography experts.

To examine the effects of the loss or absence of mammography machines on access to services, including access for medically underserved women, we used FDA data to select a stratified random sample of 9 urban counties and 9 rural counties, within 16 states, that lost more than 25 percent of their mammography machines from October 1, 2001, to October 1, 2004; we randomly selected the counties to avoid bias in their selection.[13] We interviewed officials familiar with these counties to obtain their views on the effect of machine losses and facility closures. These officials generally included county health department personnel in the affected counties, state radiation control personnel under contract to FDA to conduct annual on-site MQSA compliance inspections of mammography facilities, and quality improvement organization (QIO) officials under contract to CMS to monitor and improve screening rates for Medicare beneficiaries.[14] To assess the effects of the absence of machines on access to services, we used FDA data on the number and locations of machines nationwide as of October 1, 2004, and identified counties that had no machines. In our interviews with state radiation control program personnel and QIO officials from the 16 states containing the 18 counties in our random sample, we also asked about access in their states beyond the sampled counties, including access for medically underserved women. To obtain additional information on the effects of facility closures on access for medically underserved women, we interviewed state officials who direct CDC's National Breast and Cervical Cancer Early Detection Program in selected states and officials of several community health centers that receive funding through the federal Consolidated Health Centers program.

[13]The sample of 18 counties is too small to project the results of our work to the entire group of counties that lost more than 25 percent of their mammography machines during this period.

[14]In addition to monitoring and trying to improve mammography screening rates for Medicare beneficiaries, QIO officials responsible for each U.S. state and territory and the District of Columbia work, under CMS's direction, with consumers, physicians, hospitals, and other health care providers to improve service delivery and help ensure that patients receive quality care, with particular attention to underserved populations.

To examine the measures state bodies have taken to avoid conflicts of interest and FDA's oversight of state bodies' performance in this area, we reviewed MQSA and MQSA regulations issued by FDA, FDA and state documents, state ethics laws, state agency personnel policies, state bodies' procedures, FDA evaluation protocols, and FDA reports on the performance of state bodies. In addition, we interviewed officials from FDA; ACR; accreditation bodies in Arkansas, Iowa, and Texas; and certification bodies in Illinois and Iowa. We also interviewed FDA officials about their oversight role and approach. California and South Carolina are not included in our review because the California accreditation body withdrew its participation in the MQSA program before our review began and South Carolina's certification program began operating after our review began.

To assess the reliability of the FDA, ACR, and state body data on mammography facility closures and mammography capacity, we talked with knowledgeable officials of these organizations about data quality control procedures and reviewed relevant documentation. We also electronically tested the FDA data to identify problems with accuracy and completeness. To assess the reliability of the NHIS data on the numbers of women age 40 and older who received a screening or diagnostic mammogram in 2000 and 2003 and the population estimate data from the Census Bureau, we reviewed the existing documentation on methodology and data collection procedures. We determined that the data were sufficiently reliable for the purposes of this report.

Appendix II provides additional information on our scope and methodology. We conducted our work from November 2004 through July 2006 in accordance with generally accepted government auditing standards.

Results in Brief

Closures of certified mammography facilities outpaced openings during a recent 3-year period, and financial considerations were most often cited as the reason for facility closures. FDA data show that from October 1, 2001, to October 1, 2004, the number of certified mammography facilities nationwide decreased from 9,306 to 8,768. During this period, 1,290 certified mammography facilities closed, while 752 facilities began providing services, resulting in a net decrease of 538 facilities, or 6 percent. Mammography facility officials most often reported to ACR that they closed for financial reasons, and officials of state accreditation bodies in Arkansas, Iowa, and Texas told us that closures in their states were generally due to financial concerns. Experts we interviewed said that

financial considerations and difficulties recruiting and retaining staff have contributed to closures.

Although key elements that make up mammography capacity have decreased and use of mammography services has increased, we found that current nationwide capacity is adequate. From October 1, 2001, to October 1, 2004, in addition to the 6 percent decrease in mammography facilities, the number of machines decreased by 4 percent; the number of radiologic technologists who perform mammography decreased by 3 percent; and the number of physicians who interpret mammograms, who are usually radiologists, decreased by 5 percent. While the nation lost capacity, the estimated number of women age 40 and older who received a screening mammogram within the previous year increased, largely because of the increase in the number of women eligible for screening. From 2000 to 2003, the estimated number of women age 40 and older who received a screening mammogram increased nationwide by 14 percent, from about 29 million to about 33 million. Over the same period, the estimated number of women age 40 and older who received a diagnostic mammogram decreased from about 3 million to about 2 million. Based on our calculation that the estimated number of mammograms performed by U.S. machines in 2003 was substantially lower than the number that could have been performed, we found that current capacity is adequate. Most experts we interviewed told us that current overall capacity is likely adequate, but all of the experts expressed concern that the numbers of radiologic technologists and radiologists entering the mammography field might not be sufficient to serve the increasing population of women age 40 and over. This potential development could result in access problems in the future.

The loss or absence of mammography machines in certain locations may have resulted in access problems for women, including problems for those who are medically underserved. FDA data show that from October 1, 2001, to October 1, 2004, the number of counties having mammography machines remained relatively constant at about 72 percent, but the number of machines decreased in certain counties. Of 413 U.S. counties that had a net loss of at least one mammography machine during that period, 117 counties lost more than 25 percent of their machines. As of October 2004, 865 counties—containing 3.4 percent of the U.S. population—had no machines. The majority of officials we interviewed about access in their states, including access in 18 counties that had lost over 25 percent of their mammography machines, told us that machine losses had not resulted in access problems because women were able to obtain services at other facilities. However, some officials told us that the

loss or absence of machines in certain counties has resulted in access problems consisting of considerable wait times or lengthy travel distances to obtain services. For example, a West Virginia official working with CDC's early detection program for low-income women estimated that after the closure of a facility in one county, program participants' wait time for diagnostic mammography averaged 8 weeks and was as long as 3 months. A Virginia official estimated that after one county lost its only mammography facility, the absence of a facility resulted in some women needing to travel 60 miles to obtain services, in comparison with 20 to 25 miles before the facility closed. Lengthy travel distances may especially pose a barrier to access for underserved women who face transportation difficulties or who would bear a significant burden if they had to take extra time away from work or family responsibilities. Access problems for these women are of particular concern because women who lack health insurance or have low incomes have lower-than-average screening mammography rates.

State bodies that accredit or certify mammography facilities have varying measures to help ensure that individuals conducting work for these bodies—including state employees and contractual and volunteer image reviewers—avoid conflicts of interest. These measures include state ethics laws, state agency personnel policies, and procedures state bodies use to carry out their duties. As required by regulation, FDA has reviewed and approved the measures used by the state accreditation and certification bodies to avoid conflicts of interest and has conducted annual performance evaluations of state bodies to assess whether they are complying with MQSA regulations. An FDA official told us that agency officials have asked questions about conflicts of interest during their evaluations and that they have not found any conflicts. FDA's written protocols for performance evaluations have not always included specific questions on the subject of conflicts of interest, but FDA recently revised its written protocol for evaluating certification bodies to increase attention to this subject.

In commenting on a draft of this report, FDA provided additional details and clarification regarding its activities for certifying mammography facilities and overseeing state accreditation and certification bodies. We incorporated FDA's comments as appropriate.

Background

The purpose of screening mammography is to detect breast cancer before there are apparent symptoms. Screening mammography usually consists of two X-ray views of each breast. A physician need not be on site to

interpret a screening mammogram immediately, but may read a group of mammograms at a later time. Diagnostic mammograms are used to evaluate patients with abnormalities detected on a screening mammogram or during a physical examination. Diagnostic mammography takes longer than screening mammography, because an interpreting physician generally examines the mammograms while the patient is waiting and the procedure may require additional breast views, such as magnification views of suspicious breast tissue, to provide more information about a lesion.

Because detecting breast cancer as early as possible improves the likelihood that treatment will be successful, access to high-quality mammography services is essential for improving a woman's chance of survival. The federal government plays a role in both ensuring quality and promoting access. FDA has responsibility for ensuring the quality of mammography services. Other federal agencies have initiatives intended to help improve access to mammography services.

FDA Oversight of Mammography

Under MQSA, FDA has several responsibilities to ensure the quality of mammography. FDA is responsible for establishing quality standards for mammography equipment, personnel, and practices. In 1993, FDA issued interim regulations establishing such standards,[15] and in 1997, FDA issued final regulations establishing quality standards.[16] Most of these quality standards went into effect in 1999. However, certain quality standards for mammography equipment, which were more stringent than the previous standards, went into effect in 2002. The agency is also responsible for ensuring that all mammography facilities are accredited by an FDA-approved accreditation body[17] and have obtained a certificate permitting them to provide mammography services from FDA or an FDA-approved certification body.[18] FDA is also responsible for ensuring that all

[15]58 Fed. Reg. 67565-72 (Dec. 21, 1993). Interim regulations issued on the same day included standards for accreditation bodies. See 58 Fed. Reg. 67558-65.

[16]62 Fed. Reg. 55852-994 (Oct. 28, 1997) (codified at 21 C.F.R. Part 900).

[17]Under MQSA, mammography facilities operated by the Department of Veterans Affairs are excluded from FDA's review, but they are accredited by ACR and are required by the Veterans' Health Care Eligibility Reform Act to meet standards equivalent to those in MQSA. Pub. L. No. 104-262, § 321(a)(1), 110 Stat. 3177, 3195 (codified at 38 U.S.C. § 7319).

[18]FDA's final MQSA regulations also included standards for accreditation bodies that took effect in 1999. In 2002, FDA issued regulations containing standards for certification bodies. See 67 Fed. Reg. 5446-69 (Feb. 6, 2002).

mammography equipment is evaluated at least annually by a qualified medical physicist and that all mammography facilities receive an annual MQSA compliance inspection from an FDA-approved inspector. In addition to carrying out these activities, FDA maintains the Mammography Program Reporting and Information System database, a nationwide database on mammography facilities that incorporates data from the accreditation and certification processes and inspections of facilities. Finally, FDA is responsible for performing annual evaluations of the accreditation and certification bodies.

Quality Standards for Mammography Personnel

In addition to setting comprehensive quality standards for the operation of mammography equipment, FDA regulations specify detailed qualifications and continuing training requirements for mammography personnel, such as radiologic technologists who perform the examinations and physicians who interpret the images. Radiologic technologists are required to be either licensed by a state[19] or certified by an appropriate board, such as the American Registry of Radiologic Technologists, in general radiography.[20] They must also meet additional training, continuing education, and experience requirements related to mammography. FDA also specifies that all interpreting physicians be licensed in a state; be certified in the specialty by an appropriate board, such as the American Board of Radiology;[21] and meet certain medical training, continuing education, and experience requirements related to mammography.

Accreditation and Certification of Facilities

To legally perform mammography, a facility must be accredited by an FDA-approved body and certified by FDA or an FDA-approved body. FDA categorizes facilities applying for accreditation into three groups: new applicants; reinstating applicants, such as a previously certified facility whose certificate was suspended or revoked; and reaccrediting applicants that have been accredited and certified for 3 years and are seeking to

[19]As of January 2006, 41 states had licensing requirements for radiologic technologists.

[20]The American Registry of Radiologic Technologists is the nation's credentialing organization for radiologic technologists. It administers an examination for certification, maintains a registry of currently certified general radiologic technologists, and administers a subspecialty examination and certification program for mammography technologists. Although technologists who perform mammography do not have to be certified in the mammography subspecialty, the majority of the technologists who perform mammography, including those who are licensed by states, have such certification.

[21]Physicians who interpret mammograms can also meet FDA's requirements if they have had a minimum of 3 months of documented specialized training in the interpretation of mammograms.

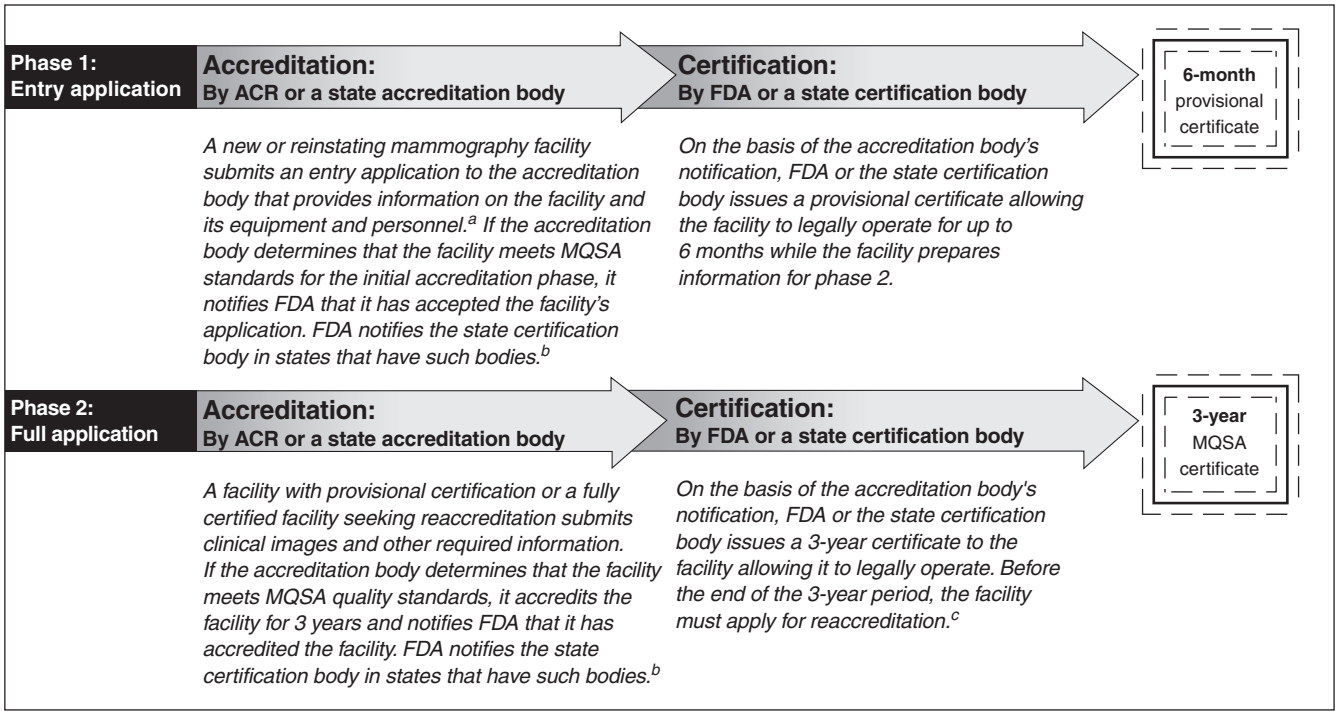
renew their accreditation. To become accredited, a new mammography facility must undergo a two-phase application review process conducted by an FDA-approved accreditation body. (See fig. 1.) First, the facility must pay an application fee and submit to the accreditation body an entry application that provides such information as equipment performance specifications, the qualifications of its personnel, and the results of the facility medical physicist's equipment tests.[22] A facility seeking accreditation reinstatement follows the same process as the new applicant, but must also submit to the accreditation body a corrective action plan that describes the action the facility has taken to correct problems that prevented it from achieving or maintaining certification. If the accreditation body determines that a new or reinstating facility meets the MQSA standards for the initial accreditation phase, it notifies FDA; for states with an FDA-approved state certification body, FDA in turn notifies the state certification body.[23] FDA or the state certification body then issues a provisional certificate that allows the facility to operate legally for up to 6 months.[24]

[22]Although all accreditation bodies follow MQSA standards for accrediting mammography facilities, the accreditation processes established by each accreditation body vary slightly, such as with respect to when facilities must submit certain information for review and when to submit the accreditation application fee. For example, Iowa's application fee is required as part of the second phase of the accreditation process.

[23]ACR notifies both FDA and, when applicable, the state certification body.

[24]A facility that does not complete the accreditation process within the 6-month provisional period must either cease performing mammography or apply for a onetime 90-day extension of the provisional certificate. MQSA requires that to receive the extension, the facility must show that access to mammography in the geographic area served by the facility would be significantly reduced if the facility did not receive the extension. 42 U.S.C. § 263b(c)(2).

Figure 1: Overview of the Mammography Facility Accreditation and Certification Processes



Source: GAO analysis of MQSA, MQSA regulations, and documents and information provided by FDA and the accreditation and certification bodies.

Notes: As of June 2006, the states with accreditation bodies were Arkansas, Iowa, and Texas. The states with certification bodies were Illinois, Iowa, and South Carolina. (Because South Carolina's certification program began operating after our review began, it was not included in our review.) State accreditation and certification bodies may review only facilities within their own state. Facilities in a state with an accreditation body have the option of seeking accreditation from either that body or ACR. However, facilities in a state with a certification body may receive certification only from their state body, not from FDA. The accreditation processes established by ACR and the states differ slightly, such as on the points at which facilities must submit certain information to accreditation bodies for review.

[a]A reinstating facility must also submit to the accreditation body a corrective action plan that describes the action the facility has taken to correct problems that prevented it from achieving or maintaining certification.

[b]ACR notifies both FDA and, when applicable, the state certification body.

[c]A mammography facility seeking to renew its 3-year accreditation and certification is not required to obtain a provisional certificate if it completes the reaccreditation process prior to the expiration of the existing MQSA certificate.

Second, to achieve full accreditation, the facility must submit to the accreditation body phantom and clinical images,[25] quality control tests, and other information required by MQSA. If the accreditation body determines that the facility meets MQSA standards applicable to the images and all other submitted information, it accredits the facility and each of the facility's approved mammography machines for 3 years. The accreditation body notifies FDA of each mammography machine's approval; for states with certification bodies, FDA in turn notifies the state certification body.[26] On the basis of the accreditation body's notification, FDA or the state certification body issues a 3-year MQSA certificate to the facility, which allows it to legally perform mammography up to the certificate expiration date.[27] Accreditation bodies notify facilities they have accredited about 6 to 8 months prior to expiration of their 3-year certification period that they must apply for reaccreditation. Facilities applying for reaccreditation are not required to obtain a provisional certificate if they submit all the information required for full accreditation before their certificate expires and if the facility meets FDA standards. After approval by its accreditation body, a facility receives a new 3-year MQSA certificate from FDA or the state certification body.

Each accreditation body is required to make annual on-site visits to a sample of facilities that it accredited.[28] The on-site visits include reviewing

[25]A phantom image is a radiographic (X-ray) image of a phantom, which is a plastic block used to simulate radiographic characteristics of breast tissue. FDA-approved phantoms simulate a 4.2-centimeter-thick compressed breast consisting of 50 percent glandular and 50 percent fatty tissue, and contain16 test objects that simulate aspects of breast disease and cancer. The phantom is used to assess the ability of the facility's imaging equipment to detect breast disease and cancer. Under Arkansas's and Iowa's procedures, facilities must submit the phantom images as part of the initial application package.

[26]ACR notifies both FDA and, when applicable, the state certification body.

[27]The facility must display its MQSA certificate to operate legally. 42 U.S.C. § 263b(b)(1)(A)(iii).

[28]MQSA regulations require that each accreditation body annually visit at least 5 percent of the facilities it accredits and that at least half of the facilities be selected randomly. The other facilities are selected based on problems identified in various ways, such as through state or FDA compliance inspections, previous history of noncompliance, and serious consumer complaints. The accreditation body must visit at least 5 facilities each year, but is not required to visit more than 50 unless problems that had been identified indicate a need to visit more than 50 facilities. See 21 C.F.R. § 900.4(f)(1).

samples of randomly selected clinical images to assess image quality,[29] verifying the information that facilities provided in the accreditation application,[30] and reviewing documentation showing that facilities sent reports on mammography results to patients and physicians. In addition, on-site visits have an educational element; for example, members of the accreditation body team may suggest ways to improve clinical image quality.

The annual MQSA compliance inspections conducted by FDA and the state certification bodies differ in focus and scope from the on-site accreditation visits, although both the inspections and the on-site accreditation visits are intended to monitor and assess facility compliance with MQSA standards.[31] In addition to verifying information submitted during the accreditation process, FDA and the state compliance inspectors—including those under contract to FDA and those working for the state certification bodies—conduct several other reviews. These include performing equipment tests and in-depth reviews of personnel qualifications and reviewing quality control and quality assurance records.[32] For example, inspectors review quality control records for each film processor[33] and X-ray machine used for mammography. FDA and state certification bodies are responsible for monitoring and enforcing the correction of facility problems discovered during MQSA compliance

[29]The random sample of clinical images that each accreditation body reviews annually must include images from at least 3 percent of the facilities the body accredited. See 21 C.F.R. § 900.4(f) (2).

[30]Accreditation body staff verify, among other things, that the facility personnel and equipment identified in the application are the ones used to perform mammography services and that the facility has in place a consumer complaint system and a medical audit system, which is a system for reviewing and tracking outcomes of positive mammograms—those identified as having abnormalities—and correlating them with biopsy results. See 21 C.F.R. § 900.4(f)(1)(ii) for a description of the minimum review requirements accreditation body site visits must meet.

[31]FDA and certification bodies must perform annual inspections to ensure compliance with all the quality standards found in 21 C.F.R. § 900.12.

[32]The purpose of reviewing quality control records is to ensure that the equipment quality control tests performed by radiologic technologists are routinely done at the required frequencies, that test records are in order, and that corrective actions are taken when warranted. The purpose of reviewing quality assurance records is to ensure that the facility develops and maintains policies and procedures to monitor the performance of facility personnel and equipment.

[33]The film processor is the device that develops the film to produce a mammographic image.

inspections. If a facility fails to correct a problem, FDA and state certification bodies may take enforcement actions, including suspending or revoking a facility's certification.

National Database on Mammography Facilities

FDA maintains a national database—the Mammography Program Reporting and Information System database—that incorporates data from the accreditation and certification processes and from annual compliance inspections of facilities. The database contains facility identification information, as well as information on the number of machines and personnel at a facility, the medical physicist who evaluated equipment at the facility, the estimated number of mammograms performed, and whether the facility is active or no longer certified.

Oversight of Accreditation and Certification Bodies

Under MQSA, FDA can approve a state agency or a private nonprofit organization to accredit facilities and a state agency to certify facilities if the agency or organization meets MQSA standards. MQSA regulations require that each accreditation body adopt standards for mammography facilities that are substantially the same as the quality standards established by FDA to ensure the safety and accuracy of mammography; each certification body must establish standards that are at least as stringent as FDA's standards. MQSA regulations do not allow individuals who review facilities' phantom or clinical images for the accreditation body or perform accreditation site visits to maintain a financial relationship with or have any other conflict of interest or bias in favor of or against the facility.[34] This requirement applies not only to individuals who review phantom or clinical images, but also to state agency managers, consultants, administrative personnel, and any other individuals working for the accreditation body. MQSA regulations also require that FDA conduct annual performance evaluations of accreditation bodies' and certification bodies' compliance with MQSA standards. MQSA requires that FDA annually submit to congressional oversight committees a written report on the performance of the accreditation bodies.[35]

[34]21 C.F.R. § 900.4(a)(4) and 21 C.F.R. § 900.22(a) (2005).

[35]42 U.S.C. § 263b(e)(6) requires the annual report to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce.

Initiatives to Help Improve Access to Mammography

The federal government supports two initiatives to help improve access to mammography services. The Breast and Cervical Cancer Mortality Prevention Act of 1990[36] established CDC's National Breast and Cervical Cancer Early Detection Program. Under this program, CDC makes grants to states to provide mammography services to medically underserved women, especially those with low incomes and without health insurance coverage.[37] From 2001 through 2003, over 50 percent of the women served by the program were from minority groups. The second initiative relates to coverage for screening mammography under Medicare, the federal government's health insurance program for people age 65 and older and certain disabled people. CMS, which administers Medicare, has contracted with QIOs in each state to assist it in monitoring and improving the quality of health care, including improving mammography screening rates among Medicare beneficiaries. QIOs seek to improve mammography screening rates by working with physician offices and other health care providers to establish improved systems for referring patients for mammography and collaborating with state and local coalitions and other organizations on promotion efforts, such as the distribution of educational materials on mammography and outreach to encourage Medicare beneficiaries to obtain screening.

In addition to these initiatives, the federal Consolidated Health Centers program, administered by HHS's Health Resources and Services Administration (HRSA), increases access to health care services, including screening mammography, for women in medically underserved areas.[38] In 2004, 71 percent of health center patients had a family income at or below the federal poverty level, and 40 percent were uninsured. In addition,

[36]Pub. L. No. 101-354, 104 Stat. 409 (codified at 42 U.S.C. §§ 300k through n).

[37]The program operates in every state, the District of Columbia, 4 U.S. territories, and 13 American Indian and Alaska Native organizations.

[38]Criteria for designating a medically underserved area or population include the ratio of primary medical care physicians per 1,000 population, infant mortality rate, percentage of the population with incomes below the federal poverty level, and percentage of the population age 65 or older. In 2005, the federal poverty level for a family of four was an annual income of $19,350 in the 48 contiguous states and the District of Columbia.

63 percent of patients were members of racial or ethnic minority populations, and 29 percent spoke a primary language other than English.[39]

Facility Closures Outpaced Openings, with Financial Considerations Most Often Cited as Reason for Closure

From October 2001 to October 2004, certified mammography facility closures outpaced openings, and financial considerations were most often cited as the reason for facility closures. According to FDA data, the number of certified mammography facilities nationwide decreased by 6 percent, from 9,306 to 8,768, from October 1, 2001, to October 1, 2004.[40] During this period, 1,290 certified mammography facilities closed, while 752 facilities received 6-month provisional certificates to begin providing services, resulting in a net decrease of 538 facilities, including a net decrease of 87 mobile mammography facilities, which may serve multiple locations.[41] Forty states lost facilities during this period, including 10 states that each lost more than 20 facilities.[42] These 10 states accounted for over half of the 538 net decrease. (See app. III for information by state.)

The most commonly cited reasons for facility closures were related to financial considerations. We relied on data from ACR for information on what facility officials reported as the reasons for closure[43] because FDA's Mammography Program Reporting and Information System database does not include such data. For certified mammography facilities that had been accredited by ACR and that closed from October 1, 2001, to October 1, 2004, facility officials most often reported financial

[39]Information on health center patients is based on data from HRSA's Uniform Data System. The percentages related to income level and race/ethnicity exclude patients whose status HRSA reported as unknown. The income level of 19 percent of patients was reported as unknown, and the race/ethnicity of 6 percent was reported as unknown.

[40]Facilities in U.S. territories, federal facilities operated by the Department of Defense, facilities at prisons and correctional institutions, and facilities that had not achieved provisional or accreditation status were excluded from the analysis.

[41]A mobile mammography facility performs mammography using a vehicle equipped with a mammography X-ray machine and travels from one location to another. In some cases, one or more of these mobile facilities are dedicated to a fixed facility, such as a hospital, outpatient clinic, or radiology practice.

[42]The 10 states that lost more than 20 facilities are California, Florida, Georgia, Illinois, New Jersey, New York, Ohio, Pennsylvania, Texas, and Virginia.

[43]In April 2001, ACR began tracking the number of closures of facilities that it accredited and the reasons for closure that were reported by facility officials.

considerations as the reason for closure.[44] Specifically, for 35 percent of the closures, facility officials told ACR that the primary reason was financial. (See table 1.) In addition, even when they did not cite financial considerations specifically, their reasons were often related to finances. For 25 percent of the closures, facility officials reported that they moved their facility to a sister site, and an ACR official said that many of the facilities consolidated their mammography activities in an effort to conserve financial resources. Facility officials also frequently reported equipment and staffing problems as reasons for closure, and an ACR official told us that these problems were sometimes financial in nature. In addition, officials of state accreditation bodies told us that closures in their states from 2001 to 2004 were generally related to financial concerns. For example, a Texas accreditation body official said she believed that the majority of closures accredited by the state body were due to bankruptcy, low business volume, or low reimbursement rates for services. FDA and mammography experts also identified financial considerations as having contributed to facility closures.

[44]ACR learns of facility closures from a variety of sources, including facility personnel, FDA, state certifiers, state inspectors, local cancer societies, and patients. When ACR is notified that a facility has closed, ACR contacts the facility by telephone to confirm the closure and sends a facility closure memorandum. A facility closure memorandum asks for general information about the closure and the reason for closure. ACR officially lists the facility as closed in its records after the memorandum has been signed by the facility's lead radiologist, chief executive officer, or president. If the memorandum is not returned to ACR within 10 business days after it has been sent, ACR closes the facility in its database.

Table 1: Reasons for Closures of ACR-Accredited Mammography Facilities in the United States, October 1, 2001, to October 1, 2004

Reason for closure[a]	Number of closures[b]	Percentage of total
Financial decision	424	35
Relocation of facility to sister site	305	25
Other/equipment problems[c]	136	11
Staffing problems	124	10
Bankruptcy	25	2
Other/mobile facility merged with another site	28	2
Other/changes in ownership	23	2
Unknown	80	7
Other/miscellaneous	66	6
Total	**1,211**	**100**

Source: GAO analysis of ACR data on the number of ACR-accredited mammography facilities that closed and reasons for closure.

[a]ACR asks facility officials to provide a closure memorandum in which they are asked to check a reason for closure from among five categories: unit moved to a sister site, bankruptcy, financial, staffing problems, and other. Facility officials who checked other were asked to specify the reason, and these reasons included equipment problems, mobile facility merged with another site, and changes in ownership. According to ACR, officials from 34 facilities reported two reasons for closure. In these instances, ACR recorded the predominant response provided during conversations with facility personnel prior to closure.

[b]According to ACR, 1,211 ACR-accredited facilities closed during this period. This number differs from the number of closures reported by FDA during this period because although most closed facilities in the two databases are the same, there are differences between the databases. For example, FDA's data include facility closures reported by state accreditation bodies, while ACR's do not. We relied on ACR data for reported reasons for facility closures because FDA's database does not include such information.

[c]An ACR official told us that equipment problems were most likely either a facility's inability to meet the more stringent FDA quality assurance regulations for equipment that went into effect in 2002 or equipment failures that facilities decided were too costly to repair.

Experts also told us that difficulties in recruiting and retaining staff have contributed to closures. Officials of the American Society of Radiologic Technologists said that some radiologic technologists think the repetitive nature of mammography procedures—especially screening mammography—makes mammography seem like an unattractive, assembly-line operation and that radiologic technologists who perform mammography are paid less, in general, than those in other imaging specialties. Experts also reported that some radiologists consider the mammography field unappealing because it is stressful, "low tech," and lower paying and less respected than other imaging specialties; involves

repetitious work because of the need to read large volumes of screening mammograms; and has a high rate of malpractice litigation.

Although Key Capacity Elements Have Decreased and Use of Mammography Services Has Increased, Current Nationwide Capacity Is Adequate

Although key elements that make up mammography capacity have decreased and the use of mammography services has increased—largely because of the increase in the population of women age 40 and older—we found that current nationwide capacity is adequate. Key capacity elements—the numbers of facilities, machines, radiologic technologists, and interpreting physicians—declined from 2001 to 2004. In contrast, from 2000 to 2003, the estimated number of women age 40 and older who received a screening mammogram within the previous year increased. Nevertheless, we determined that the estimated number of screening mammograms that women age 40 and older received was substantially lower than the number that could have been performed in 2003, and there was also sufficient capacity for the number of diagnostic mammograms women in that age group received. Although experts believe the nation's current overall capacity to provide mammography services is adequate, they are concerned that the numbers of radiologic technologists and radiologists entering the mammography field might not be sufficient to serve the increasing population that will need mammography services.

Key Elements That Make Up Capacity to Provide Mammography Services Have Decreased

Key elements that make up mammography capacity decreased from October 1, 2001, to October 1, 2004. In addition to the number of facilities decreasing by 6 percent, the number of mammography machines decreased by 4 percent, the number of radiologic technologists decreased by 3 percent, and the number of physicians who interpret mammograms decreased by 5 percent.[45] (See table 2.) During the period, the average number of machines per facility remained about the same—1.50 in 2001 and 1.53 in 2004—and the average number of radiologic technologists per machine remained about the same—2.24 and 2.28, respectively.

[45]Many of the names in FDA's database within each year are duplicates because many of these individuals work at multiple facilities and their names are counted at each facility they serve. After correcting errors in the spelling of names and other data entry mistakes, we calculated the unduplicated numbers of radiologic technologists and interpreting physicians. We determined that the unduplicated numbers of radiologic technologists in FDA's Mammography Program Reporting and Information System database were 31,402 in 2001 and 30,503 in 2004. We determined that the unduplicated numbers of interpreting physicians in the database were 19,675 in 2001 and 18,690 in 2004. (See app. II.)

Table 2: Changes in Numbers of Mammography Facilities, Machines, Radiologic Technologists, and Interpreting Physicians from October 1, 2001, to October 1, 2004

	2001	2004	Percentage change
Facilities	9,306	8,768	-6
Machines	13,995	13,400	-4
Radiologic technologists who perform mammography	31,402	30,503	-3
Physicians who interpret mammograms	19,675	18,690	-5

Source: GAO analysis of FDA's Mammography Program Reporting and Information System database on mammography capacity elements.

Number of Women Who Received Screening Mammograms Increased as Population of Women Age 40 and Older Grew

Reflecting the steady increase in the population of women age 40 and older,[46] the estimated number of women in this age group who received a screening mammogram within the previous year has increased and is likely to continue to grow over the next several years. Based on NHIS survey data, the estimated number of women age 40 and older who received a screening mammogram within the previous year increased nationwide by 14 percent from 2000 to 2003, from about 29 million to about 33 million.[47] This increase resulted from the population growth in this age group coupled with a slight increase—from 50 percent in 2000 to 51 percent in 2003—in the estimated proportion of women in this age group who received a screening mammogram within the previous year.[48] The number of women age 40 and older who receive a screening mammogram is likely to continue to grow over the next several years

[46]The population of women age 40 and older increased by about 6 percent from 2000 to 2003.

[47]Based on NHIS survey data, screening mammograms accounted for 91 percent of the number of women age 40 and older who received a mammogram in 2000 and 94 percent in 2003.

[48]In the 2003 NHIS survey, uninsured women age 40 and older and poor women age 40 and older reported lower screening rates than other women in that age group. Twenty-six percent of uninsured women age 40 and older reported having a screening mammogram within the previous year, in comparison with 57 percent of women in the same age group who had private insurance or were enrolled in the U.S. military's medical health benefits program. Similarly, 36 percent of poor women age 40 and older reported having a screening mammogram within the previous year, in comparison with 52 percent of women with middle incomes and 60 percent of women with high incomes. The following are the 2003 NHIS screening rates for this age group by ethnicity: White—52 percent; African American—51 percent; Hispanic—48 percent; Asian—44 percent; and Native American—35 percent.

because the number of women age 40 and older is projected to increase from about 68 million in 2003 to about 74 million in 2010 and about 78 million in 2015, according to the Census Bureau.

Data from NHIS indicate that the proportion of women age 40 and older who received a diagnostic mammogram within the previous year decreased from 5 percent in 2000 to 3 percent in 2003. The estimated number of women age 40 and older who received a diagnostic mammogram within the previous year declined from about 3 million women in 2000 to about 2 million in 2003.

Current Nationwide Mammography Capacity Is Adequate

National mammography capacity data we reviewed indicate that the nation's current capacity to provide mammography services is adequate. Our estimates of current capacity found that the number of mammograms performed by U.S. machines was substantially lower than the number that could be performed. Since screening mammograms accounted for 94 percent of the mammograms provided in 2003, we began our capacity calculations by focusing on screening mammograms. The majority of experts we interviewed estimated that it normally takes 15 to 20 minutes of machine and radiologic technologist time to perform a screening mammogram.[49] Using the upper range of this estimate, we estimated that a machine and one radiologic technologist could perform 3 mammograms per hour, or 24 mammograms in an 8-hour day. This rate would yield a potential capacity of 6,000 mammograms per machine per year.[50] Using FDA data on the number of machines in 2003 (13,510), we calculated that in 2003 about 81 million screening mammograms could have been performed by U.S. machines.[51] Data from the 2003 NHIS indicate that nationwide an estimated 33 million women age 40 and older received a screening mammogram and that an estimated 2 million women in that age group received a diagnostic mammogram. Most experts we interviewed estimated that it takes 30 to 60 minutes of machine and radiologic technologist time to perform a diagnostic mammogram. The excess

[49]Of the eight experts we consulted, five experts estimated a time of 15 to 20 minutes. Two other experts and an FDA official estimated a time of 10 to 15 minutes. One expert did not provide an estimate.

[50]This yearly total is based on the assumption that a machine was in operation 5 days per week and 50 weeks per year.

[51]We did not determine whether there were a sufficient number of radiologic technologists available to perform mammograms for the estimated level of machine capacity.

capacity that we found for performing screening mammograms in 2003 would have been more than adequate for performing the estimated 2 million diagnostic mammograms that were performed that year.[52] These capacity estimates are rough estimates, but the difference between estimated machine capacity and estimated use is sufficiently large to indicate that there is unused capacity nationwide. It is difficult to measure capacity precisely because several variables can affect capacity at the individual facility level, such as the efficiency of facilities' operations.[53]

Most of the experts we interviewed told us that current overall capacity is likely adequate, but all of the experts expressed concern that the numbers of radiologic technologists and radiologists entering the mammography field might not be adequate to serve the increasing population of women age 40 and older. For example, one expert questioned whether the mammography workforce would be sufficient to meet the demand for services in 10 years, in light of the increasing number of women in this age group. Another expert commented that for the past few years, facilities have been experiencing problems recruiting mammography personnel. Data from the American Registry of Radiologic Technologists show that the number of individuals who took the mammography technologist examination to become certified for the first time declined slightly from 1,214 in 2000 to 1,112 in 2005.

The number of available radiologists might also lead to future access problems, according to an official of the American Board of Radiology. Although the number of first-time candidates who sat for diagnostic radiology examinations increased from 816 in 2001 to 1,057 in 2005, the official expressed concern about whether the current flow of candidates would be sufficient to meet the expected growth in the population who will need imaging procedures. In addition, experts told us that there were many unfilled job openings for radiologic technologists who perform

[52]The excess capacity also would have been adequate to provide the estimated 3 million mammograms received that year by women age 30 to 39.

[53]Factors that can affect capacity include a facility's balance between screening and diagnostic mammograms and its approach to scheduling those services. For example, some facilities achieve greater efficiency by scheduling screening and diagnostic mammograms at different times. Facilities also differ in the way they manage their personnel and schedules. At some facilities, radiologic technologists who perform mammograms help patients complete forms and prepare for the examination, reducing the number of mammograms they can perform, while at other facilities assistants perform this work. Some facilities have evening and weekend hours, increasing their capacity.

mammography services and for radiologists who interpret mammograms. In a 2004 survey of community-based mammography facilities in three states, 44 percent reported experiencing a shortage of radiologists and 46 percent reported having some level of difficulty in maintaining adequate numbers of qualified technologists.[54]

Loss or Absence of Mammography Machines May Have Resulted in Access Problems in Certain Locations

The loss or absence of mammography machines in certain locations may have resulted in access problems consisting of lengthy travel distances or considerable wait times to obtain mammography services, including problems for women who are medically underserved. FDA data show that from October 1, 2001, to October 1, 2004, the number of counties with machines remained relatively constant, but the number of machines decreased in certain counties. During the 3-year period, 117 counties lost more than 25 percent of their machines. As of October 1, 2004, there were 865 counties that had no machines. While the majority of officials we interviewed told us that the loss of machines in counties in their states had not resulted in access problems, some officials told us that the loss or absence of machines in certain counties had resulted in lengthy travel distances to obtain services or had resulted in significant wait times for services.

[54]Carl D'Orsi, et al., "Current Realities of Delivering Mammography Services in the Community: Do Challenges with Staffing and Scheduling Exist?" *Radiology*, vol. 235, no. 2 (2005): 391-395.

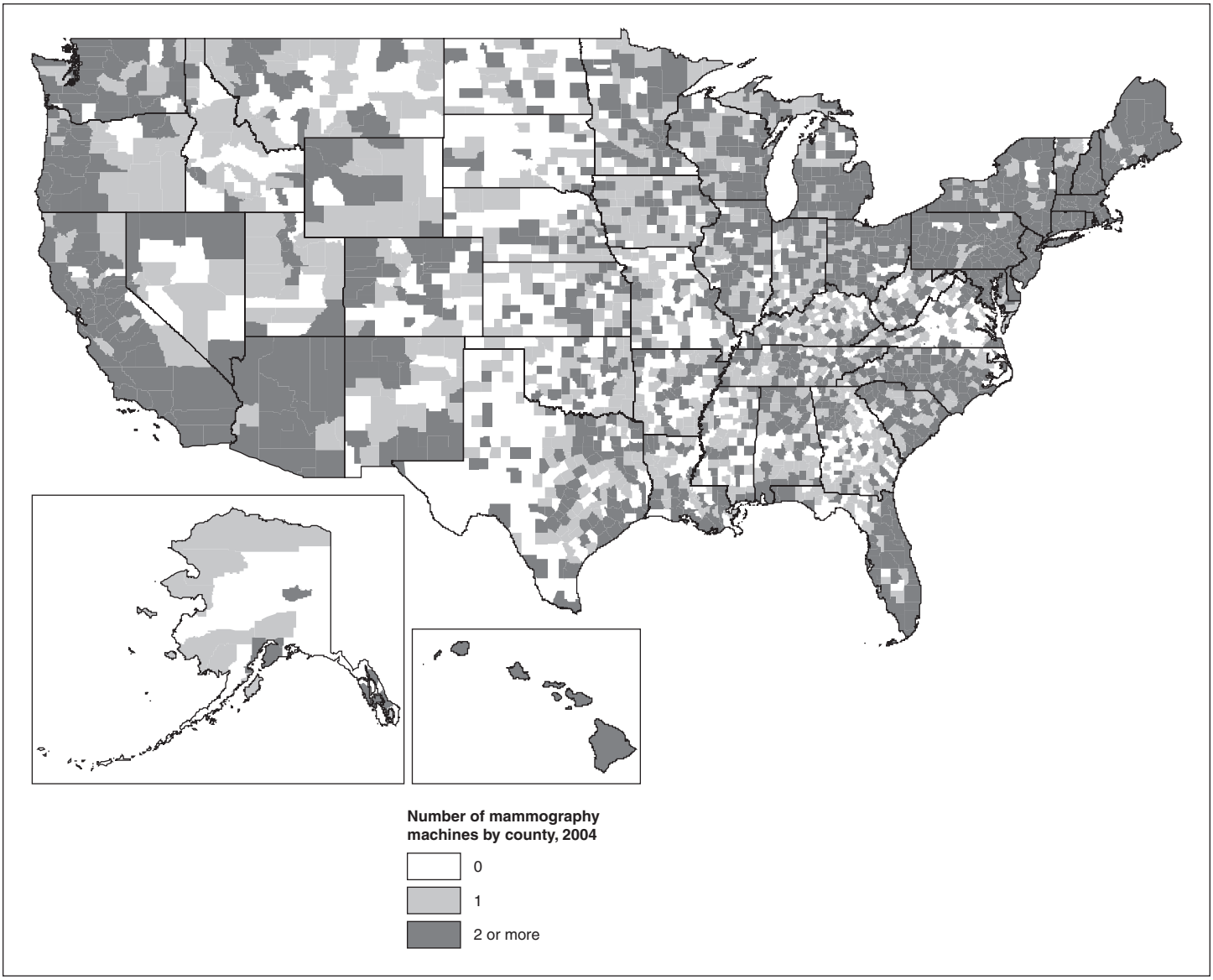
Number of Counties with Machines Remained Relatively Constant, but Number of Machines Decreased in Certain Counties

While nationwide the proportion of counties that had at least one mammography machine remained relatively constant from 2001 to 2004 at about 72 percent, in some counties the number of machines decreased during that period. FDA data show that the number of counties that had at least one machine rose slightly from October 1, 2001, to October 1, 2004—from 2,259 to 2,276.[55] As of October 1, 2004, 865 counties had no mammography machines; these counties tended to be concentrated in certain midwestern, southern, and western states and contained 3.4 percent of the U.S. population.[56] (See fig. 2.) Some of these counties, however, may have been served by mobile mammography machines; as of October 1, 2004, there were 266 mammography machines in 222 mobile facilities nationwide.

[55]There are 3,141 counties, including the District of Columbia.

[56]U.S. Census Bureau, Population Estimates Program, *County Population Estimates and Estimated Components of Change: April 1, 2000 to July 1, 2004* (Washington, D.C.: April 2005) http://www.census.gov/popest/counties (downloaded March 6, 2006).

Figure 2: Number of Mammography Machines by County, October 1, 2004



Source: GAO analysis of FDA's Mammography Program Reporting and Information System database on the number and locations of mammography machines.

Notes: Federal facilities operated by the Department of Defense, facilities at prisons and correctional institutions, and facilities that had not achieved provisional or accreditation status were excluded from our analysis of FDA's Mammography Program Reporting and Information System database. The numbers of mammography machines shown include mobile mammography facilities that were located in one county but may also have provided services to other counties, including counties that had no machines.

Nationwide, 413 counties that had at least one machine at some point during the 3-year period had experienced a net loss of mammography machines as of October 1, 2004. Of these counties, 117—containing 2.6 percent of the total 2004 U.S. population—lost more than 25 percent of their machines.[57] Our analysis of the available supply of mammography machines in counties that are adjacent to these 117 counties found that 75 are not adjacent to any county that gained machines during this period, and 47 of these 75 counties are adjacent to at least one other county that lost machines.[58]

Loss or Absence of Mammography Machines in Certain Locations May Have Resulted in Considerable Travel Distances or Wait Times to Obtain Services

Although national mammography capacity appears to be adequate in general, in certain locations the loss or absence of machines may have resulted in access problems consisting of lengthy travel distances or significant wait times. The majority of officials we interviewed about the effects of the loss or absence of machines told us that machine losses had not resulted in access problems because women were able to obtain mammography services at other facilities.[59] However, several of the officials told us that the loss or absence of machines had affected access for some women.

In certain locations, the loss or absence of mammography machines resulted in women—including women who are medically underserved—needing to travel lengthy distances for mammography services. For 6 of the 18 counties we randomly selected for review that lost more than

[57]In 82 (70 percent) of the 117 counties that lost more than 25 percent of their machines, the population increased from 2001 to 2004, with increases ranging from less than 1 percent to 21 percent.

[58]In 51 (68 percent) of the 75 counties, the population increased from 2001 to 2004, with increases ranging from less than 1 percent to 17 percent.

[59]State, local, and QIO officials discussing 11 of the 18 counties in our study that lost more than 25 percent of their machines told us that the loss of machines had not affected access to mammography services. We do not have information on 1 of the 18 counties because for that county only one QIO official responded and she had no knowledge of machine losses in the county. Officials who work with CDC's early detection program in four of eight states we reviewed said that facility closures had no effect on access to mammography services for underserved women in their program. In addition, 9 of the 10 community health center officials we interviewed reported that facility closures in their counties did not create access problems for their patients.

25 percent of their machines,[60] one local or QIO official told us that facility closures and machine losses in those counties had resulted in women traveling longer distances than previously.[61] For example, a Mississippi QIO official estimated that after one facility closure left Newton County with one facility that provided only screening mammography, some women had to travel about 30 miles for screening and about 50 miles for diagnostic mammography. He said that women depended on working family members for transportation, and that according to mammography facility staff, fewer women were obtaining mammograms. Similarly, in four states,[62] officials working with CDC's early detection program for medically underserved women told us that seven facility closures, involving the loss of seven machines, had affected program participants' travel distances. For example, a Virginia official estimated that after Dickenson County lost its mammography facility and associated machine, program participants who previously traveled from 20 to 25 miles for services had to travel about 60 miles to obtain services. A West Virginia official working with the CDC program noted that program participants in Jackson County had to travel a longer distance to obtain mammography services because of a facility closure and faced problems of increased travel cost and time away from families and jobs.

State and QIO officials also told us about certain locations in their states other than the 18 counties we randomly sampled where the absence of machines resulted in lengthy travel to obtain mammography services. For example, as of October 1, 2004, 12 of Alabama's 67 counties had no mammography machines. An Alabama QIO official identified 10 counties that to her knowledge had never had a mammography facility and were not being served by mobile mammography facilities; each of the counties was designated by HRSA as a medically underserved area. She estimated that women living in the 10 counties had to travel distances ranging from

[60]The six counties are Navajo County, Arizona; Warren County, Iowa; Butler County, Kansas; Newton County, Mississippi; Wayne County, New York; and Dickenson County, Virginia.

[61]For each of the six counties, one of the three officials we interviewed reported that women had experienced longer travel distances. The other officials who responded to our request for information stated either that women's access to mammography services had not been adversely affected or that they did not have knowledge of the effects of facility closures and machine losses from 2001 to 2004.

[62]The states are Idaho, New York, Virginia, and West Virginia.

30 to 60 miles to obtain mammography services. In Missouri,[63] 50 of the state's 115 counties had no machines as of October 1, 2004. A Missouri QIO official told us that two mobile mammography facilities provided services once or twice a year to the northeast and southeast corners of the state, which have neighboring counties without mammography facilities. However, if a mobile facility could not provide for films to be read on site, she estimated that women requiring repeat films and additional studies because their mammograms indicated a possible breast problem would have to travel about 250 miles to the provider's central location—about a 5-hour trip in each direction.

The loss or absence of machines in certain counties may also have caused women—including those who are medically underserved—to experience significant wait times for mammography services. Although there is no specific medical standard for the maximum amount of time a woman should have to wait for mammography services, most experts we interviewed said that it was best if the wait time for screening mammography did not exceed 30 days and if the wait time for diagnostic mammography did not exceed 2 days. State officials working with CDC's early detection program and a QIO official told us of situations where the loss or absence of machines in certain locations might have resulted in wait times that exceeded wait times the experts said were appropriate. For example, New York officials working with CDC's early detection program estimated that after the closure of two facilities involving the loss of two machines in Brooklyn, the screening wait time for participants who had used those facilities was about 2 months; at the busiest time of the year, the wait time was 3 to 4 months. The West Virginia program official estimated that after the facility closure in Jackson County, participants' wait time for diagnostic mammography averaged 8 weeks, and could be as much as 3 months.[64] A North Dakota QIO official told us that women in parts of the state face significant wait times for mammography services. Sixty percent of North Dakota's counties had no machines as of October 1, 2004, and the official said that a limited number of providers served large geographic locations in the largely rural state. For example, she told us that one provider's mobile facility served almost the entire northwest

[63]Missouri counties were not part of our random sample of counties. We spoke with a Missouri QIO official because of her expertise in access to mammography.

[64]The New York and West Virginia officials did not provide estimates of the number of days women had to wait for mammography services prior to the facility closures.

quarter of the state and was available to some communities once every 4 months and to others only once a year.

State Bodies Have Varying Measures to Avoid Conflicts of Interest, and FDA's Evaluations Have Not Found Conflict-of-Interest Problems

State accreditation and certification bodies have varying measures to help ensure that individuals conducting work for these bodies, including state employees and contractual and volunteer image reviewers, avoid conflicts of interest. FDA has approved the measures used by the state bodies to avoid conflicts of interest and has conducted annual performance evaluations of state bodies to assess whether they are complying with MQSA regulations. An FDA official told us that agency officials have asked questions about conflicts of interest during their evaluations and that they have not found any conflicts. FDA's written protocols for performance evaluations have not always included specific questions on the subject of conflicts of interest, but FDA recently revised its written protocol for evaluating certification bodies to increase attention to this subject.

State Accreditation and Certification Bodies Have Varying Measures to Avoid Conflicts of Interest

State mammography accreditation and certification bodies have varying measures to help ensure that state employees avoid conflicts of interest, such as those caused by a financial interest, outside employment, or a family tie. These measures also apply to physicians who work for accreditation bodies on a contract or volunteer basis as clinical image reviewers and who also conduct image reviews for their main business practice. The measures are a combination of state ethics laws, state agency personnel policies, and procedures state bodies use to carry out their duties. FDA has approved each state's combination of measures. (See table 3.)

Table 3: State Accreditation and Certification Bodies' Measures to Avoid Conflicts of Interest

	State accreditation bodies			State certification bodies	
Measures	**Arkansas**	**Iowa[a]**	**Texas[b]**	**Illinois**	**Iowa[a]**
State laws or personnel policies					
Code of ethics	•	•	•[c]	•	•
Financial disclosure statement required of state body employees	•[d]			•[e]	
Required ethics training			•	•	
Procedures					
Use a list of facilities where reviewers have a financial or other relationship in determining assignment of clinical images to reviewers	•	•	•[b]	N/A	N/A
Conduct "blind reviews" of mammography images by concealing facility identity[f]	•	•		N/A	N/A
For each clinical image and phantom image review, use two or more individuals working independently[g]	•	•	•[b]	N/A	N/A

Source: GAO analysis of state laws and policies and of documents and information provided by FDA, Arkansas, Illinois, Iowa, and Texas officials.

Legend: • = a measure is in place; N/A = not applicable.

Note: South Carolina's certification body is not included in our review because its certification program began operating after our review began.

[a]Iowa is the only state that has authority to accredit and certify mammography facilities.

[b]Texas contracts with ACR to review phantom and clinical mammography images. ACR has policies to avoid conflicts of interest, including a requirement that its reviewers sign a statement that provides information about financial or other relationships that may constitute a conflict of interest.

[c]Texas law requires that all state employees file a written statement acknowledging receipt of the state's standard of conduct laws.

[d]Arkansas ethics laws require that state agency heads, department directors, and division directors file a financial disclosure statement. In addition, all Arkansas state employees are required to file a statement disclosing any income source other than their regular salary from which they received over $500.

[e]Illinois ethics laws require a statement of economic interest from state employees who function as the head of a department, supervise 20 or more employees, or have authority to approve certifications or licenses.

[f]Personnel from the accreditation body cover the name of the facility that appears in the mammography film to conceal the facility's identity prior to submitting the image for clinical review.

[g]State accreditation bodies use private-sector physicians working under contract or as volunteers to review clinical images. State accreditation bodies use their own qualified staff to review phantom images, except the accreditation body in Texas, which uses ACR's reviewers.

Accreditation Bodies

Employees and others, such as contractual reviewers, who provide services for the three state accreditation bodies are subject to state ethics laws and policies that generally prohibit them from having a conflict of interest.[65] These laws and policies vary in scope across the three states, and each state has penalties associated with violating its laws.[66] For example, with regard to financial disclosure, Arkansas requires all state employees to file a statement disclosing any income source other than their regular salary from which they received over $500.[67] In contrast, Iowa requires only certain individuals, such as elected officials and higher level agency officials, to file financial disclosure forms[68] and in general does not require this of employees carrying out accreditation responsibilities. While Texas also requires only certain individuals, such as elected officials and higher level agency officials, to file financial disclosure forms,[69] the Texas accreditation body contracts with ACR for its phantom and clinical image reviews, and ACR's reviewers are subject to ACR's requirement to disclose financial and other relationships with businesses or clients involving mammography and to report related compensation over $200.[70] The Texas accreditation body is the only one that requires its employees to attend ethics training when they are hired. In addition, Texas law requires its employees to acknowledge that they have received copies of the state employee standards of conduct.[71]

In addition to state laws and policies, the state accreditation bodies have various procedures to help ensure that phantom and clinical image reviewers avoid conflicts of interest. For example, all three state

[65]Ark. Code Ann. § 21-8-304 (2005); Iowa Code Ann. § 68B2.A (2005); Tex. Gov't Code Ann. §§ 572.001 and 572.051 (2005).

[66]Ark. Code Ann. § 21-8-302 (2005); Iowa Code Ann. § 68B.25 (2005); Tex. Gov't Code Ann. §§ 572.007, 572.033, and 572.0034 (2005).

[67]Ark. Code Ann. § 21-8-203 (2005).

[68]Iowa Code Ann. § 68B.35 (2005).

[69]Tex. Gov't Code Ann. § 572.021 (2005).

[70]ACR's image reviewers are not ACR employees but experts in their fields who volunteer their services to ACR and receive modest reimbursement. Texas's contract includes reviews associated with new mammography facilities or equipment, accreditation renewal, random on-site reviews, and additional mammography reviews. Additional mammography reviews are performed outside the normal accreditation or reaccreditation process when there are concerns about mammography quality at a facility.

[71]Tex. Gov't Code Ann. § 2113.014 (2005).

accreditation bodies assign at least two individuals to independently review clinical and phantom images. (See table 3.) In addition, in all three states, reviewers are required to submit a list of facilities where they have a financial interest, perform services, or have other associations, and accreditation officials refer to these lists when assigning clinical images to reviewers. Arkansas's clinical image reviewers are not permitted to review images from facilities located within 50 miles of their primary practice locations. Moreover, because clinical image reviewers in Arkansas and Iowa may be familiar with mammography facilities in their states, accreditation bodies in these states use blind reviews of clinical images. That is, state employees mask the names of facilities before presenting images to reviewers. In Iowa, furthermore, state employees proctor the clinical image reviews to ensure that the facility's identity is not revealed during the process. In ACR's review of Texas facilities' phantom and clinical images, reviewers from Texas or the surrounding states cannot conduct the reviews. ACR procedures do not include blind reviews; instead, ACR requires that reviewers sign a form disclosing any financial or other relationship that could constitute a conflict of interest.[72] ACR legal staff review all potential conflicts of interest annually, according to an ACR official, and if an actual conflict of interest exists, the reviewer may be removed or allowed to perform only limited types of reviews. In addition, reviewers who are familiar with a facility must immediately report any conflict of interest to the appropriate ACR official and recuse themselves. In assigning images to reviewers, ACR uses computer software that automatically blocks reviewers from reviewing images from facilities in states where they live or practice or in other states they have identified where they may have a conflict of interest.

Certification Bodies

The two state certification bodies apply state ethics laws and personnel policies that prohibit state employees from having a financial interest or other interest, including one based on family ties or outside employment, that conflicts with their duties. The same state ethics laws that govern Iowa's accreditation body activities apply to its certification body activities. Illinois ethics law requires that state employees who function as the head of a department, supervise 20 or more employees, or have authority to approve certifications or licenses file a financial disclosure

[72]An ACR official told us that ACR does not use blind reviews because of the regulatory requirement to verify that each clinical image contains the name and location of the facility that produced it. In Arkansas and Iowa, accreditation body employees first verify that an image contains the appropriate identifying information and then conceal this information before giving the image to the reviewer.

statement annually.[73] Illinois officials told us that employees of the Illinois certification body with decision-making responsibilities—including the coordinator of MQSA certification functions—submit a financial disclosure statement. However, in general, Illinois employees who inspect mammography facilities are not required to file such statements.[74] Illinois ethics law also requires that all state employees annually complete ethics training,[75] which in the past has covered topics such as acceptance of gifts and conflicts of interest.

FDA Approved State Bodies' Measures to Avoid Conflicts of Interest, and Its Evaluations of State Bodies Have Not Found Problems

As part of the state accreditation and certification body application processes, FDA approved the measures each state body submitted as its approach for avoiding conflicts of interest. These measures consisted of the state ethics laws, state agency personnel policies, and procedures the state body would use to carry out its duties. (See table 3.) FDA officials told us that in determining whether these measures were adequate to ensure independence, they based their decisions on the conflict-of-interest standards in MQSA regulations. MQSA regulatory standards on conflicts of interest are broadly written; they do not provide specific guidance to states on what measures they should take to avoid conflicts.

Using written protocols, FDA has conducted annual performance evaluations of state accreditation and certification bodies to assess whether these bodies are complying with MQSA regulations. Evaluations of state accreditation bodies have covered, among other things, state bodies' procedures for reviewing phantom and clinical images and for resolving consumer complaints about mammography facilities. These procedures are a part of the accreditation bodies' efforts to avoid conflicts of interest. In addition, FDA staff have independently reviewed samples of phantom and clinical images previously reviewed by the accreditation body to monitor the quality of the accreditation body's work.[76] FDA officials told us that their staff have also reviewed several randomly

[73]5 Ill. Comp. Stat. Ann. § 420/4A-101(f)(1-8) (2005).

[74]FDA officials told us that MQSA compliance inspectors employed by FDA are required to file financial disclosure statements, but state inspectors working under contract with FDA are not required to do so.

[75]5 Ill. Comp. Stat. Ann. § 430/5-10 (2005).

[76]Two FDA interpreting physicians independently review samples of clinical images, and two FDA expert staff independently review samples of phantom images.

selected facility files, including files on any complaints received by the accreditation bodies since the previous FDA evaluation, and accreditation body staffing qualifications. FDA has submitted to the Congress its required annual written evaluation reports on the performance of accreditation bodies. FDA's annual evaluations of state certification bodies have included reviews of each body's policies and procedures for certification, inspection, appeals, consumer complaints, and certification revocation and suspension. In addition, FDA officials told us that FDA auditors have annually evaluated the performance of FDA inspectors and state inspectors by accompanying them on facility compliance inspections. Prior to going on these inspections, the auditors review inspection records completed by the inspectors they will be accompanying. FDA prepares an annual written evaluation report on the performance of state certification bodies; it is not required to submit these reports to the Congress. An FDA official told us that these annual evaluations allow FDA to oversee state accreditation and certification bodies' performance regarding avoiding conflicts of interest.

An FDA official told us that during the on-site visits that have been part of FDA annual evaluations and during FDA's quarterly meetings with state body officials, FDA officials have asked whether any conflict-of-interest problems have arisen.[77] According to this official, state body officials have never reported to FDA during a quarterly meeting that they had experienced a conflict-of-interest problem. During on-site visits, FDA officials have inquired about state bodies' overall policies and procedures. State bodies' staff have generally described their policies and procedures for avoiding conflicts of interest and orally assured FDA that they are following these measures. FDA relies on the states to oversee the implementation of state ethics laws and policies. However, FDA requires state bodies to immediately report any situation that might adversely affect the public's health, including complaints about conflicts of interest involving state bodies' personnel. The FDA official also said that no state body has ever reported a problem or concern related to a conflict of interest involving a reviewer or inspector and that FDA has never found a conflict-of-interest problem in its evaluations of state bodies' performance.

[77]Until recently, the annual evaluations included on-site visits to state bodies, but in 2005 FDA decided to visit state bodies every other year, alternating visits to accreditation and certification bodies. For example, FDA planned to visit accreditation bodies in 2005 and certification bodies in 2006. The biennial schedule is due to budget constraints and state bodies' consistent performance in implementing policies and procedures, according to FDA officials.

Officials of HHS's Office of the Inspector General, similar state agencies responsible for overseeing state bodies that we reviewed, and the Department of Justice told us that they have not undertaken any investigations related to conflicts of interest or complaints of fraud or abuse involving state agencies that accredit or certify mammography facilities.

While FDA officials told us that they have asked questions related to conflicts of interest during on-site visits, until recently the agency's written protocols for conducting annual evaluations of state bodies' performance have not explicitly addressed state bodies' implementation of conflict-of-interest policies and procedures or the application of state ethics laws. In addition, FDA's annual reports to the Congress on the performance of the accreditation bodies have not discussed the subject of conflicts of interest, and its annual evaluation reports on certification bodies have not consistently included this topic.

In June 2005, FDA revised its written protocol for evaluating certification bodies to include a review of certain aspects of state bodies' performance related to conflicts of interest. The revised protocol requires FDA to (1) review any changes that the certification bodies made to their conflict-of-interest policies and procedures since FDA's last annual evaluation, (2) review any complaints related to conflicts of interest involving state personnel or MQSA inspectors and the resolution of the complaints, and (3) cover the topic of conflict of interest in the annual reports it prepares on the performance of certification bodies. FDA has not revised its protocol for conducting annual evaluations of accreditation bodies to include specific questions about conflicts of interest, and FDA officials told us they currently have no plans to revise it.

Concluding Observations

Current nationwide capacity for mammography services is adequate, despite recent decreases in the facility and human resources that affect capacity and an increase in the number of women eligible for screening mammography. However, women may have difficulty gaining access to mammography services in certain locations, particularly where the loss or absence of machines has resulted in lengthy travel distances or significant wait times. Lengthy travel distances may especially pose a barrier to access for underserved women who lack means of transportation, must incur increased travel costs, or must take extra time away from work or family responsibilities. Access problems for these women are of particular concern because they have lower-than-average mammography screening rates. Furthermore, while current overall capacity is adequate, if the

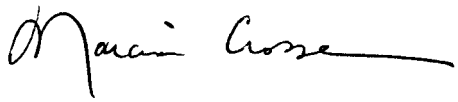
numbers of radiologic technologists and radiologists entering the mammography field are insufficient to serve the growing population of women eligible for regular screening, access problems could occur in the future.

Agency Comments

We provided a draft of this report to FDA for comment. FDA's comments are reprinted in Appendix IV. In its comments, FDA provided additional details and clarification regarding its activities in certifying mammography facilities and overseeing state accreditation and certification bodies; FDA also provided technical comments. We incorporated FDA's comments as appropriate.

As arranged with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff members have any questions, please contact me at (202) 512-7119 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made contributions to this report are listed in appendix V.



Marcia Crosse
Director, Health Care

Appendix I: The Food and Drug Administration's Mammography Facility Inspection Demonstration Program

As authorized under the Mammography Quality Standards Reauthorization Act of 1998 (MQSRA), the Food and Drug Administration (FDA) conducted an inspection demonstration program (IDP) to evaluate the feasibility and impact of conducting mammography facility compliance inspections less frequently than annually.[1] FDA's goal for the IDP was to determine whether the inspection frequency of mammography facilities that had been found to be in compliance with the Mammography Quality Standards Act of 1992 (MQSA) standards could be reduced from yearly to once every 2 years without a decrease in compliance rates. FDA carried out the IDP from November 2001 through August 2004.[2] This appendix summarizes the methodology and results of the IDP.

Methodology

MQSRA required that facilities selected for the IDP be "substantially free of incidents of noncompliance" and that the number of facilities selected be sufficient to provide a statistically significant sample of facilities.[3] FDA selected facilities for the IDP from states that indicated a willingness to participate in the program and met certain criteria.[4] For example, FDA excluded states that had laws, regulations, or policies requiring annual inspections, and considered states that could accept changes to their existing inspection contract with FDA to reflect the reduction in the number of facilities that they would inspect during the IDP.[5] To minimize the financial impact that a reduced inspection schedule would have on

[1]The Mammography Quality Standards Act of 1992 (MQSA) requires the annual inspection of mammography facilities to ensure compliance with the act's requirements. See 42 U.S.C. § 263b(g). Members of the mammography industry had questioned the need to annually inspect facilities that had been found to be in compliance with the FDA MQSA regulations. MQSRA retained the annual inspection requirement, but included a provision that allowed FDA to carry out the inspection demonstration program. See Pub. L. No. 105-248, § 8, 112 Stat. 1864, 1865-66 (codified at 42 U.S.C. § 263b(g)(6)).

[2]FDA issued a report describing the results of the IDP in January 2005.

[3]MQSRA did not stipulate an implementation deadline, program duration, or inspection interval, but stated that the program could not be implemented before April 1, 2001.

[4]To develop criteria for selecting states and facilities to participate in the program, FDA officials from the Division of Mammography Quality and Radiation Programs worked with various groups, including the Conference of Radiation Control Program Directors, a professional organization whose members include directors of state radiation control programs; the National Mammography Quality Assurance Advisory Committee; and officials from other FDA units.

[5]FDA contracts with most states to conduct the annual compliance inspections for which FDA is responsible in its role as a certifying body. Its contracts specify, among other things, the number and cost of inspections to be conducted.

states that depend on income from their FDA inspection contracts to fund inspectors' salaries, FDA officials placed a 10 percent limit on the number of facilities from each state that could participate in the IDP. On the basis of these criteria, FDA selected 11 states, the District of Columbia, Puerto Rico, and New York City to participate in the IDP. The states were Arkansas, Florida, Mississippi, New York, Ohio, Oklahoma, Pennsylvania, South Dakota, Washington, Wisconsin, and Wyoming.

FDA established that to be eligible to participate in the IDP, a facility had to be free of MQSA violations during the two most recent annual inspections and have undergone at least two annual inspections under the final MQSA regulations that took effect in April 28, 1999. Among other things, a facility also had to maintain full accreditation and certification throughout the program and expect to provide services through the duration of the IDP. Using random selection, FDA divided the eligible facilities in the 14 jurisdictions into a study group and a control group. The study group consisted of 146 facilities. The control group had 132 facilities in the first year of the program and 126 of those facilities in the second year.[6]

FDA officials told us that they were not able to achieve a statistically valid sample that would allow the results to be projected nationwide, primarily because a number of states were not willing to participate in the demonstration program or had state laws that required annual inspections. An FDA official said that FDA implemented the demonstration program even though the results could not be projected nationwide because agency officials believed that the results of the program would be useful to the Congress.

Results

Overall, the inspections of the study group facilities, which occurred after a 2-year interval, found that facilities did not maintain the violation-free compliance level that they had previously. Of the 146 study group facilities, 58 percent were in full compliance with MQSA, while 42 percent

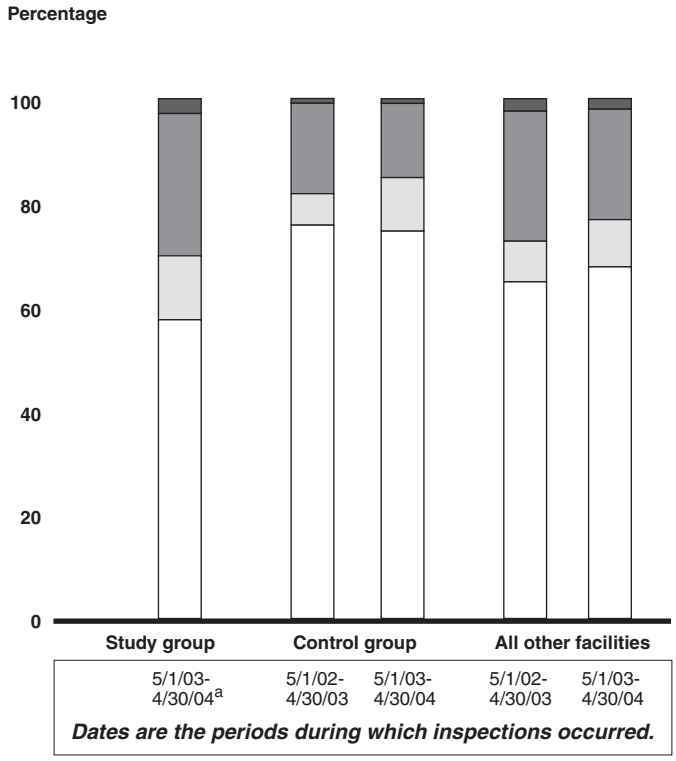
[6]The lower number of control group facilities available for inspection in the second year of the IDP was due primarily to facility closures.

were cited for violations.[7] (See fig. 3.) Moreover, the study group facilities had a lower compliance rate than facilities inspected annually, either as part of the IDP's control group or outside of the demonstration program. The facilities in the study group had a higher percentage of violations across all three violation levels than facilities that had annual inspections. Most of the study group's level 1, or most serious, violations were related to missing records of the quality control tests, such as those required for the mammography film processor.[8] Level 2 violations—the most prevalent category of violation for all groups—were almost twice as high in the study group (27 percent) as in the control group (14 percent).

[7]FDA classifies facility noncompliance with MQSA standards into three violation levels, ranging from level 1, the most severe with the most detrimental effect on quality, to level 3, the least severe, where the violations are generally minor deviations from standards. Some facilities had multiple violations within each level or across two or more levels. In determining the percentage of facilities cited at each violation level, FDA placed each facility in the violation level representing its most serious violation.

[8]The processor is the device that develops the film to produce a mammographic image. MQSA regulations require that film processors used to develop mammograms be adjusted and maintained to meet certain technical development specifications. A processor performance test must be performed each day before any clinical films are processed. See 21 C.F.R. § 900.12(e).

Figure 3: Percentages of Mammography Facilities with MQSA Violations, by Level of Violation, during FDA's IDP



	Study group 5/1/03-4/30/04[a]	Control group 5/1/02-4/30/03	Control group 5/1/03-4/30/04	All other facilities 5/1/02-4/30/03	All other facilities 5/1/03-4/30/04
Level 1 violations	3%	1%	1%	2%	2%
Level 2 violations	27%	17%	14%	25%	21%
Level 3 violations	12%	6%	10%	9%	9%
Compliance/no violations	58%	76%	75%	63%	68%

Source: FDA.

Notes: Level 1 violations are the most serious, and level 3 the least serious. Some facilities had multiple violations within each level or across two or more levels, but for this analysis FDA placed the facility in the level representing its most serious violation. Percentages for a given period may not sum to 100 because of rounding.

[a]Facilities in the study group did not receive inspections during the period of May 1, 2002, through April 30, 2003.

Because the study group had a decrease in compliance, FDA officials decided not to expand the demonstration program and returned all mammography facilities to the annual inspection schedule. In commenting on the IDP results, an FDA official responsible for the program noted that the IDP did not provide evidence that facilities could maintain their violation-free status without annual compliance inspections.

Appendix II: Scope and Methodology

To identify the number of certified mammography facilities that closed nationwide in recent years, we obtained and analyzed data from FDA's Center for Devices and Radiological Health Mammography Program Reporting and Information System database on the number of certified mammography facilities that closed and those that received 6-month provisional certificates to begin providing services from October 1, 2001, to October 1, 2004. To examine information on the factors that contributed to mammography facility closures in recent years, we used three sources. We obtained data from the American College of Radiology (ACR) on mammography facilities accredited by ACR that closed from October 1, 2001, to October 1, 2004, and the reasons for closures reported by officials of facilities accredited by ACR. We reviewed data and interviewed officials of state accreditation bodies in Arkansas, Iowa, and Texas about closures of facilities accredited by these states from 2001 through 2004. We also interviewed eight radiologists who are experts in mammography about factors that contribute to mammography facility closures.

To examine changes in the nation's capacity for and use of mammography services in recent years and the adequacy of current capacity, we analyzed data from FDA's Mammography Program Reporting and Information System database on the total numbers of certified facilities, machines, radiologic technologists who perform mammography, and physicians who interpret mammograms as of October 1, 2001, and October 1, 2004. We excluded facilities in U.S. territories. We also excluded federal facilities operated by the Department of Defense, and facilities at prisons and correctional institutions because they are not generally accessible to the public. We also excluded facilities that had not achieved provisional or accreditation status that were in FDA's Mammography Program Reporting and Information System database because they had not been certified by FDA or a state certification body as of October 1, 2001, and October 1, 2004. FDA's database contains many duplicate names of radiologic technologists and interpreting physicians because many of these individuals work at multiple facilities and their names are counted at each facility they serve. To remove the duplicates, we analyzed data files from FDA that contained the names and addresses of radiologic technologists and interpreting physicians who worked at mammography facilities as of October 1, 2001, and October 1, 2004,[1] and used an iterative process to edit

[1]FDA's Mammography Program Reporting and Information database reported for October 1, 2001, and October 1, 2004, respectively, 43,596 and 42,602 radiologic technologists and 62,559 and 59,718 interpreting physicians.

the data fields containing the technologists' and physicians' first and last names. The first step was to "clean" the fields of extraneous commas, spaces, punctuation, and other values. The next step was to correct obvious and common spelling errors, such as Michael spelled Micheal. The last step was to visually check for additional misspellings, using the address information on the FDA file to confirm that an entry was indeed a duplicate with a misspelled first or last technologist or physician name. The duplicates were removed from the edited file, and the analysis continued using the edited file of unduplicated names of radiologic technologists and interpreting physicians. To examine changes in the nationwide use of mammography services, we analyzed data from the 2000 and 2003 National Health Interview Survey (NHIS),[2] administered by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics, to estimate the number of women age 40 and older who received a screening or diagnostic mammogram within the previous year. NHIS data on the use of mammography services are based on data that are self-reported by respondents. NHIS asked women age 30 and older about the length of time since their last mammogram and about the reason for the mammogram. NHIS surveys conducted in 2000 and 2003 provided the most recent trend data available at the time we conducted our analysis. Using the 2000 and 2003 NHIS data, we compared screening rates and diagnostic rates for women age 40 and older and estimates of the number of women receiving screening and diagnostic mammograms nationwide within the previous year. To determine the adequacy of current capacity, we obtained estimates from mammography experts of the amount of time it takes to perform a screening mammogram, and we used those estimates and FDA data on the number of machines available in 2003 to calculate the number of screening mammograms that potentially could have been performed in 2003. We compared our estimate of 81 million screening mammograms that could have been performed by U.S. machines to the estimated number of women age 40 and older who received a screening mammogram within the previous year, based on data from the 2003 NHIS. We also obtained estimates from mammography experts of the amount of time it takes to perform a diagnostic mammogram and data on the estimated number of women age 40 and older who received a diagnostic mammogram in 2003.[3] To examine changes in the population of women

[2]In 2000 and 2003, NHIS asked women age 30 and older about the length of time since their last mammogram and the reason for the last mammogram.

[3]According to NHIS data, about 92 percent of the women who received a mammogram in 2003 were 40 and older.

age 40 and over, we used Census Bureau population data for 2003 and projections for 2010 and 2015. In addition, we interviewed a number of individuals about issues related to mammography facility closures, mammography capacity, and access to mammography services. These individuals included officials from FDA, CDC, the National Cancer Institute, and the Centers for Medicare & Medicaid Services; representatives from several professional organizations, such as the American Board of Radiology, the American Cancer Society, ACR, and the American Society of Radiologic Technologists; and eight radiologists who are experts in mammography.

We took three steps to assess the effects of the loss or absence of mammography machines on access to services, including access for medically underserved women. First, we used data from FDA's Mammography Program Reporting and Information System database to randomly select 18 counties in 16 states that lost more than 25 percent of their machines and interviewed officials about the effects of the loss of machines in these counties. Second, using data from FDA's database, we identified counties with no machines and interviewed officials knowledgeable about access, including access for medically underserved women, in locations beyond the 18 counties we reviewed. Third, we interviewed officials working with CDC's National Breast and Cervical Cancer Early Detection Program and officials from community health centers that are funded through the Health Resources and Services Administration's (HRSA) Consolidated Health Centers program regarding the effect of facility closures on access for medically underserved women.

Specifically, for our first step of assessing the effects of machine loss on access to services, we used data from FDA's database to identify counties that lost mammography machines and focused on those that lost more than 25 percent of their machines from October 1, 2001, to October 1, 2004. We selected for our review a stratified random sample of 9 urban counties and 9 rural counties, within 16 states, of the 117 counties nationwide that lost more than 25 percent of their mammography machines. (See table 4.) We randomly selected the counties to avoid bias in their selection. However, the sample of 18 counties is too small to project the results of our work to the entire group of counties that lost more than 25 percent of their mammography machines during this period.

Table 4: Counties Randomly Selected for Review from Those That Lost over 25 Percent of Their Mammography Machines from October 1, 2001, to October 1, 2004

Rural counties		Urban counties	
County	**State**	**County**	**State**
Navajo	Arizona	Houston	Alabama
Drew	Arkansas	Saint Johns	Florida
Putnam	Florida	Coweta	Georgia
Shiawassee	Michigan	Warren	Iowa
Newton	Mississippi	Butler	Kansas
Lewis and Clarke	Montana	Wayne	New York
Fulton	New York	Morton	North Dakota
Duplin	North Carolina	Pottawatomie	Oklahoma
Dickenson	Virginia	Lubbock	Texas

Source: GAO analysis, based on FDA's Mammography Program Reporting and Information System database.

The determination of the 18 counties as urban or rural is based on the 2003 Rural-Urban Continuum Codes published by the Department of Agriculture, which classifies all U.S. counties into nine categories. The Department of Agriculture groups nonmetropolitan counties into six rural categories by size of the urban population and nearness to a metropolitan area; it groups metropolitan counties into three urban categories based on the size of the metropolitan area in which the county is located.

For the 18 counties selected, we interviewed officials familiar with access to mammography services in these counties and asked them about their views on the effects of the loss of machines and facilities on access in these counties. These officials generally included county health department officials who coordinate health programs; state radiation control personnel under contract to FDA to conduct annual on-site inspections of mammography facilities; and quality improvement organization (QIO) officials under contract to CMS to monitor and improve the quality of care, including increasing statewide mammography screening rates for Medicare beneficiaries. We also interviewed two QIO officials—one from Missouri and one from Washington—about access in areas of their states. The 18 counties we selected did not include any in Missouri or Washington, but these two officials were among three QIO officials we attempted to contact who were recommended by a CMS official as being knowledgeable about mammography access issues in their states.

For our second step of assessing the effects of the absence of machines on access to services, we used FDA data on the number and locations of mammography machines nationwide as of October 1, 2004, to identify counties that had no machines. In interviews with state radiation control program personnel and QIO officials in 11 states that had counties with no machines, we obtained their views on the effects of the absence of mammography machines on access in their state, including access for medically underserved women. We also discussed Missouri counties that had no mammography machines with the Missouri QIO official.

For our third step, to provide additional information on the effects of facility closures on access for medically underserved women, we interviewed state officials who direct CDC's National Breast and Cervical Cancer Early Detection Program and officials of community health centers. To identify facilities that closed and where program participants had been receiving services, we worked with CDC officials to request from state directors of CDC's early detection program the names and addresses of mammography facilities that provided mammography services to program participants from 2001 through 2004. In all, officials of 37 states and the District of Columbia provided complete or partial lists of facilities. We matched the facility lists provided by the state directors with facility closures from October 1, 2001, to October 1, 2004, in FDA's database. This analysis resulted in a total of 164 closed facilities. We identified the counties and states where these facilities were located and selected for review 9 rural and 9 urban counties where a total of 24 closed facilities were located. (See table 5.) We selected 4 of the 9 urban counties because they are central counties of metropolitan areas with populations of 250,000 to 1 million or more—Fulton County, Georgia; Cook County, Illinois; Wayne County, Michigan; and Kings County, New York—and we selected 3 counties because they were located in American Indian Health Service areas. In total, we interviewed officials in 8 states that work with CDC's early detection program about the effect of the facility closures in the 18 counties.

Table 5: Selected Counties with Closures of Facilities That Had Provided Mammography Services to Participants in CDC's National Breast and Cervical Cancer Early Detection Program, 2001 through 2004

County	State	Rural/urban county designation
Logan	Arkansas	Rural
Sharp		Rural
Fulton	Georgia	Urban
Wilkes		Rural
Gem	Idaho	Rural
Shoshone		Rural
Cook	Illinois	Urban
Peoria		Urban
Berrien	Michigan	Urban
Wayne		Urban
Kings	New York	Urban
Oneida		Urban
Saint Lawrence		Rural
Tioga		Urban
Dickenson	Virginia	Rural
Washington		Urban
Hardy	West Virginia	Rural
Jackson		Rural

Source: GAO analysis, based on state National Breast and Cervical Cancer Early Detection Program lists of facilities that provided mammography services to National Breast and Cervical Cancer Early Detection Program clients and information on facility closures from FDA's Mammography Program Reporting and Information System database.

With the assistance of HRSA, we obtained a list of facility closures that were located in the same counties as community health centers. HRSA identified the closures from data it requested from FDA on our behalf on mammography facilities that were certified as of October 2003 but were closed as of October 2004. HRSA then matched the addresses of the closures with its list of community health centers funded in 2004. This yielded a list of 34 closed mammography facilities that were in the same counties as community health centers. We selected 10 counties and interviewed a community health center official in each county (six officials from urban centers and four from rural centers)[4] regarding the

[4]The urban/rural designation is self-reported by health centers in their grant application to HRSA. HRSA instructs health centers to classify themselves as urban or rural based on where the majority of their patients reside. For example, if a health center is located in an urban area, but more than 50 percent of its patients reside in rural areas, the center should classify itself as rural.

effect of closures on their patients' access to mammography services. (See table 6.)

Table 6: Selected Counties with Mammography Facility Closures and Community Health Centers, October 2003 to October 2004

County	State	Community health center rural/urban designation
Anchorage	Alaska	Rural
Tulare	California	Rural
Leon	Florida	Rural
Delaware	Indiana	Urban
Orleans	Louisiana	Urban
Baltimore	Maryland	Urban
Onondaga	New York	Urban
Harris	Texas	Urban
King	Washington	Urban
Washburn	Wisconsin	Rural

Source: GAO analysis of FDA data on mammography facilities that closed from October 2003 to October 2004 and HRSA data on community health centers that were funded during fiscal year 2004.

In each of our interviews with officials on access to mammography services, we asked the official to provide estimates of the numbers of days women had to wait to obtain screening mammography and diagnostic mammography in counties that had a loss or absence of machines. In counties where officials reported access problems, we asked them to provide estimates of the distances women had to travel to mammography facilities both before and after the loss of machines, and when state and QIO officials identified counties with an absence of machines, we asked them to provide estimates of the travel distance to mammography services. While most officials had not conducted formal studies to gather information on wait times and travel distances, they generally provided information based on informal surveys they had conducted of facilities in their counties or nearby counties or on their involvement and frequent contacts with mammography facilities.

To examine the measures state bodies have taken to avoid conflicts of interest and FDA's oversight of state bodies' performance in this area, we reviewed MQSA and MQSA regulations that govern state bodies' functions, FDA documents, state ethics laws, and state bodies' policies and procedures. In addition, we interviewed officials from FDA's Center for Devices and Radiological Health; accreditation bodies in Arkansas, Iowa,

and Texas; certification bodies in Illinois and Iowa; and ACR.[5] We reviewed state and FDA documents containing ethics laws and policies and procedures, including information on conflict-of-interest policies that state bodies are required to submit to FDA as part of the initial application process. We also reviewed FDA's inspection procedures, which states are required to use to conduct inspections. The California and South Carolina state agencies are not included in our review because the California state agency withdrew its application to continue to operate as an FDA-approved accreditation body before our review began, and South Carolina's certification program began operating after our review began.

In examining FDA's oversight of state bodies, we reviewed FDA's annual evaluation reports on the performance of each state accreditation and certification body for calendar years 2003 and 2004 and FDA's annual reports to the Congress covering the performance of all accreditation bodies for calendar years 2000 through 2004—the most recent available at the time of our review. In addition, we reviewed the protocols that FDA officials use to conduct their evaluations of state bodies' performance and the timetables for FDA evaluations.

During our interviews with FDA officials, we discussed the criteria they use to determine whether states have any conflict-of-interest problems that could affect their impartiality in carrying out accreditation, certification, and inspection functions and actions FDA takes to oversee state bodies. We did not review state and federal documents, such as financial disclosure statements, employment records, or any other documents typically used in making assessments about potential or actual conflicts of interest. In addition, we did not make on-site visits to state accreditation and certification bodies or observe MQSA inspections.

To describe the methodology and results of FDA's IDP, we reviewed FDA documents and interviewed officials from FDA's Center for Devices and Radiological Health. We also examined whether the sample of facilities that FDA included in the IDP met the criterion of being free of violations for 2 consecutive years prior to IDP implementation by reviewing reports

[5]The state accreditation bodies are the Arkansas Department of Health and Human Services's Division of Health Radiation Section; Iowa Department of Public Health's Bureau of Radiological Health; and Texas Department of State Health Services' Radiation Control Program. The state certification bodies are the Illinois Emergency Management Agency's Bureau of Radiation Safety and Iowa Department of Public Health's Bureau of Radiological Health.

of MQSA inspections conducted during 2000, 2001, and January through April 2002. We reviewed reports on a sample of 49 mammography facilities, with 25 randomly selected from the universe of study control group facilities and 24 from the control group.[6]

To assess the reliability of the FDA, ACR, and state body data on mammography facility closures and mammography capacity, we talked with knowledgeable officials of these organizations about data quality control procedures and reviewed relevant documentation. We also electronically tested the FDA data to identify problems with accuracy and completeness. To assess the reliability of the NHIS data on the numbers of women age 40 and older who received a screening or diagnostic mammogram in 2000 and 2003 and the population estimate data from the Census Bureau, we reviewed the existing documentation on methodology and data collection procedures. We determined that the data were sufficiently reliable for the purposes of this report.

We conducted our work from November 2004 through July 2006 in accordance with generally accepted government auditing standards.

[6]Our sample included 25 facilities randomly selected from the study group total of 146 facilities and 24 facilities randomly selected from the control group total of 258 facilities. FDA selected facilities for the IDP in November 2001 and May 2002.

Appendix III: Changes in the Number of Certified Mammography Facilities by State, October 1, 2001, to October 1, 2004

State	Number of facilities in 2001	Number of facilities in 2004	Net change in number of facilities
Alabama	157	140	-17
Alaska	32	30	-2
Arizona	148	151	+3
Arkansas	111	102	-9
California	768	736	-32
Colorado	111	106	-5
Connecticut	154	143	-11
Delaware	24	30	+6
District of Columbia	21	19	-2
Florida	487	460	-27
Georgia	261	240	-21
Hawaii	41	40	-1
Idaho	47	44	-3
Illinois	418	384	-34
Indiana	229	219	-10
Iowa	151	147	-4
Kansas	134	122	-12
Kentucky	172	164	-8
Louisiana	166	160	-6
Maine	62	61	-1
Maryland	148	135	-13
Massachusetts	194	177	-17
Michigan	334	316	-18
Minnesota	212	202	-10
Mississippi	104	104	0
Missouri	182	172	-10
Montana	48	48	0
Nebraska	92	92	0
Nevada	61	70	+9
New Hampshire	49	46	-3
New Jersey	278	250	-28
New Mexico	48	49	+1
New York	701	631	-70
North Carolina	249	234	-15

State	Number of facilities in 2001	Number of facilities in 2004	Net change in number of facilities
North Dakota	42	43	+1
Ohio	440	417	-23
Oklahoma	102	100	-2
Oregon	99	99	0
Pennsylvania	440	402	-38
Rhode Island	43	38	-5
South Carolina	123	116	-7
South Dakota	48	46	-2
Tennessee	207	199	-8
Texas	563	529	-34
Utah	46	47	+1
Vermont	19	17	-2
Virginia	204	183	-21
Washington	175	158	-17
West Virginia	84	75	-9
Wisconsin	250	250	0
Wyoming	27	25	-2
Total	**9,306**	**8,768**	**-538**

Source: GAO analysis of FDA's Mammography Program Reporting and Information System database on mammography facilities.

Appendix IV: Comments from the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 30, 2006

Marcia Crosse
Director, Health Care
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Crosse:

Please find enclosed the Food and Drug Administration's general comments in response to the General Accountability Office's correspondence entitled, *"MAMMOGRAPHY: Current Nationwide Capacity is Adequate, but Access Problems May Exist in Certain Locations (GAO-06-724)."*

We appreciate the opportunity to review and comment on this draft correspondence before it is published, as well as the opportunity to work with your staff in its development.

Sincerely,

Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs

Enclosure

GENERAL COMMENTS TO THE DRAFT REPORT ENTITLED, "MAMMOGRAPHY: CURRENT NATIONWIDE CAPACITY IS ADEQUATE, BUT ACCESS PROBLEMS MAY EXIST IN CERTAIN LOCATIONS, (GAO-06-724)"

1. On page 3,

   - First paragraph, lines 16 and 17, which states, "For most states where FDA certifies the facilities, it contracts with state inspectors to perform MQSA compliance inspections." FDA suggests adding a reference 8a after the above-mentioned sentence and making the following sentence footnote 8a, "FDA also contracts with certain non-state entities, i.e., the City of New York and the Commonwealth of Puerto Rico."

   - Change footnote 8 to footnote 8b and revise the footnote reading, "As of January 2006, FDA did not have contracts with Nebraska, New Hampshire, and New Mexico, according to FDA officials. FDA inspectors are responsible for conducting inspections in these states and in federal facilities." to read, "As of June 2006, FDA did not have contracts with Nebraska, New Hampshire, and Washington, D.C. FDA inspectors are responsible for conducting inspections in Nebraska, New Hampshire, Washington, D.C., and in federal facilities."

2. On page 9, first full paragraph, revise the sentence at lines 5-8 to read, "As required by regulation, the measures used by the state accreditation and certification bodies to avoid conflicts of interest must be submitted for FDA's review and approval. FDA has conducted annual performance evaluations of state bodies to assess whether they are complying with MQSA regulations."

3. On page 14, footnote 26, after the phrase, "...facilities it accredits" add the words in parentheses, "(but no more than 50 facilities must be visited)."

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7119 or crossem@gao.gov

Acknowledgments

In addition to the contact named above, Helene Toiv, Assistant Director; Darryl Joyce; Roseanne Price; Mary Reich; Carmen Rivera-Lowitt; and Suzanne Worth made key contributions to this report.

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are $2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548