

GAO

Report to the Chairman, Special
Committee on Aging, U.S. Senate

April 2002

MAMMOGRAPHY

Capacity Generally Exists to Deliver Services



G A O

Accountability * Integrity * Reliability

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Abbreviations

ARRT	American Registry of Radiologic Technologists
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
FDA	Food and Drug Administration
MQSA	Mammography Quality Standards Act
NCI	National Cancer Institute
OMB	Office of Management and Budget
SCHIP	State Children's Health Insurance Program



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United States General Accounting Office
Washington, DC 20548

April 19, 2002

The Honorable John Breaux
Chairman, Special Committee on Aging
United States Senate

Dear Mr. Chairman:

Breast cancer is the second leading cause of cancer deaths among American women. In 2001, an estimated 192,200 new cases of breast cancer were diagnosed and an estimated 40,200 women died from the disease. The probability of survival increases significantly, however, when breast cancer is discovered in its early stages. Currently, the most effective technique for early detection of breast cancer is screening mammography,¹ an X-ray procedure that can detect small tumors and breast abnormalities up to 2 years before they can be detected by touch. Various groups such as the National Cancer Institute (NCI), the American Cancer Society, and the U.S. Preventive Services Task Force recommend regular mammograms for women age 40 and older—the age group considered at greatest risk.² Although controversy has recently arisen about the scientific evidence supporting these recommendations, all of these groups still maintain that the evidence supports benefits of mammography, and on February 21, 2002, the secretary of health and human services reiterated the government's recommendations.

Increased emphasis on providing mammography services for all women age 40 and above has raised some concerns about whether the nation's capacity to provide these services is keeping pace with demand. Based on the Bureau of the Census' population projections, the number of women age 40 and older who need mammography services will increase by more than 1 million each year. Concerned about recent media reports of long waiting times for appointments at some locations and closures of

¹Screening mammography refers to routine mammograms recommended for women without symptoms of problems. In contrast, diagnostic mammography refers to follow-up mammograms performed on women who had signs, such as skin changes or abnormal screening mammograms that indicate a need for additional evaluation.

²The 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 like mammography.

mammography facilities due to financial difficulty in others, you asked us to examine several capacity issues in more detail. Specifically, you asked us to

- determine if the nation’s capacity to provide mammography services is adequate to meet the growing need for these services, and
- identify geographic areas where the capacity to perform mammography services has decreased and assess the effect of these decreases on access to services.

To assess the adequacy of the nation’s capacity, we compared the most recent trend data on use of mammography services with the most recent data on trends in facilities, equipment, and personnel available to deliver these services. We generated data on utilization of services—that is, the number of mammograms provided—from the Behavioral Risk Factor Surveillance System, a data system administered by the Centers for Disease Control and Prevention (CDC). The most recent data available in the system were for 2000. Within this database, we compared 1998 and 2000 screening rates for women age 40 and above and used these rates to estimate changes in the number of women receiving mammography services during these 2 years. To measure changes in the number of facilities, machines, and radiologic technologists, we used the latest data available from the Food and Drug Administration (FDA), the agency with regulatory authority over mammography facilities. We compared data on characteristics of facilities operating on October 1, 1998, with those operating 3 years later on October 1, 2001. We analyzed these capacity changes at the national, state, and county levels. Because data were not available to measure the effect of changes in capacity on mammography utilization rates at the county level, we selected 61 metropolitan and rural geographic locations where FDA data or other reports showed a sizable decrease in capacity and interviewed state and local officials to obtain information on local conditions. In addition, we interviewed officials in several professional organizations, such as the American College of Radiology and the American Cancer Society, along with officials of FDA, CDC, NCI, and the Centers for Medicare and Medicaid Services (CMS). Details of our scope and methodology are presented in appendix I.

Results in Brief

Nationwide data indicate that the nation’s overall capacity to provide mammography services is generally adequate to meet the growing demand for these services. Between 1998 and 2000, both the population of women age 40 and older and the extent to which they were screened increased, resulting in a 15 percent increase in the total number of mammograms

provided to this group. The most recent data show that between October 1998 and October 2001, the total number of machines and radiologic technologists available to perform mammography services had increased 11 percent and 21 percent respectively, even though the total number of certified facilities for providing mammography services decreased about 5 percent. While the average number of mammograms performed per machine increased slightly, the number was still considerably below estimates of full capacity. However, the availability of radiologic technologists to operate mammography machines and interpreting physicians to read mammograms may be a concern in the future. For example, the number of first-time candidates who sit for the examinations to qualify as a radiologic technologist or an interpreting physician has dropped considerably each year during the last 4 years, which has raised concerns about the future availability of personnel.

Although mammography services are generally available, women have problems obtaining timely mammography services in some locations. Most of the availability problems are in certain metropolitan areas, although the greatest losses in capacity have come in rural counties. In all, 121 counties, most of them rural, have experienced a drop of more than 25 percent in the number of mammography machines in the last 3 years. State and local officials from 37 of these counties whom we interviewed reported that the decrease generally had not had a measurable adverse effect on the availability of mammography services. By contrast, in 18 metropolitan counties that lost a smaller percentage of their total capacity, officials in one half of the counties reported a variety of service disruptions. For example, an average waiting time of up to 3 months was reported in three counties surrounding the Baltimore metropolitan area, compared to less than 1 month in areas that reported no problems. State and local officials in the Baltimore area said that shortages of technologists and financial difficulties had caused many facilities to consolidate or close resulting in a net decrease in capacity, while the demand for services continued to increase. Officials from 6 other urban areas we contacted, such as Houston and Los Angeles, reported that local factors, such as having large patient loads at public health facilities that serve low income women, can cause substantially long waiting times at these facilities while no delays existed at other facilities. In almost all cases, however, officials reporting problems said that women whose clinical exam or initial mammogram indicated a need for a follow-up mammogram generally were able to get appointments within 1 to 3 weeks. We provided FDA with a draft of the report for review and comment. FDA responded that it found the report to be accurate.

Background

Research studies, including eight large randomized clinical trials with 11-20 years of followup, indicated that widespread use of mammography could reduce breast cancer mortality. The benefit of mammography has recently been challenged by two Danish researchers and an NCI advisory panel made up of independent experts; they cite serious flaws in six of the eight clinical trials that showed benefits. However, subsequent to the Danish report and the NCI panel's statement, both NCI and the U.S. Preventive Services Task Force reiterated their recommendations for regular mammography screening. While acknowledging the methodological limitations in these trials, the U.S. Preventive Services Task Force concluded that the flaws in these studies were unlikely to negate the reasonable consistent and significant mortality reductions observed in these trials.

The effectiveness of mammography as a cancer detection technique is directly tied to the quality of mammography procedures. Concerned about the quality of mammography procedures provided by the nation's mammography facilities, the Congress enacted the Mammography Quality Standards Act (MQSA) of 1992,³ which imposed standards effective October 1, 1994.

FDA has major oversight responsibilities, including establishing quality standards for mammography equipment and personnel and certifying and inspecting each facility to ensure it provides quality services.⁴ For mammography personnel, such as radiologic technologists and interpreting physicians, FDA specifies detailed qualifications and continuing training requirements. Mammography technologists are required to be licensed by a state or certified by the American Registry of Radiologic Technologists in general radiography, and meet additional mammography-specific training and continuing education and experience

³Pub. L. No. 102-539, 106 Stat.3547 (codified at 42 U.S.C.§ 263b (1994)).

⁴These responsibilities include (1) establishing quality standards for mammography equipment, personnel, and practices, (2) ensuring that all mammography facilities are accredited by an FDA-approved accrediting body and obtain a certificate from FDA in order to legally provide mammography services, and (3) ensuring that all mammography facilities are evaluated annually by a qualified medical physicist and inspected annually by FDA-approved inspectors.

requirements.⁵ Similarly, FDA specifies that all interpreting physicians be licensed in a state and certified in the specialty by an appropriate board, such as the American Board of Radiology, and meet certain mammography-specific medical training, as well as continuing education and experience requirements.

FDA collects detailed information about each facility when a facility is initially certified. FDA has established a database that incorporates data from the certification process and from its annual inspection program. Besides facility identification information, the database contains information on the number of machines, personnel, and whether the facility is active or no longer certified.

Medicare, the federal government's health insurance program for people age 65 and above, is the nation's largest purchaser of health services. Beginning in 1991, Medicare provided coverage of annual mammography screening for women beneficiaries. Medicare is administered by CMS. As a part of its health care improvement program, since 1999, CMS and a set of contractors, called peer review organizations, have been involved in monitoring and improving the quality of care, including increasing mammography screening rates among women Medicare beneficiaries.

National Capacity for Mammography Services Is Generally Adequate

The nation's overall capacity to meet the growing demand for mammography services is generally adequate. Between 1998 and 2000, the use of services, as measured by the number of mammograms provided to women age 40 and older, increased nearly 15 percent. The most recent data on capacity show that the total number of machines and radiologic technologists available to perform mammography services increased 11 percent and 21 percent respectively from October 1998 to October 2001. During this same period, the total number of mammography facilities decreased about 5 percent, indicating that facilities were consolidating or becoming somewhat larger. The average number of mammograms

⁵The American Registry of Radiologic Technologists (ARRT) 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 began a subspecialty examination and certification program for mammography technologists in 1991. FDA does not require all technologists who perform mammography to be certified by ARRT in the mammography subspecialty. However, the majority of the technologists who perform mammography have such certification because almost all employers and states that license mammography technologists have such a qualification requirement, according to the executive director of ARRT.

performed per machine increased slightly but was considerably below estimates of full capacity. The one potentially negative development is in personnel, where the number of new entrants into the field—as measured by the number of persons who sit for mammography technologist or diagnostic radiology examinations for the first time—has dropped each year since 1997.

Utilization of Mammography Services Continues to Grow

The use of mammography as a tool for detecting early cancer continues to increase. Data from CDC's Behavioral Risk Factor Surveillance System indicate a continuing increase in national mammography screening rates. The proportion of women age 40 and over who had received a mammogram within the past year increased from 58 percent in 1998 to about 64 percent in 2000. These screening rate increases, coupled with the growth of this population,⁶ have resulted in significant increases in the number of mammograms provided each year. Based on CDC's data on screening rates and Bureau of Census population data, we estimate that the total number of mammograms received by women 40 and above nationwide has increased nearly 15 percent, from about 35 million in 1998 to more than 40 million in 2000.

These increases in mammography utilization extended across nearly every state. Using the screening rates and the Bureau of Census population data, we computed the number of mammograms received by women age 40 and above on a state-by-state basis. Between 1998 and 2000, screening rates for women in this age group increased in all but one state (i.e., Oklahoma) and the District of Columbia, and 39 states had an increase of more than 10 percent in the total number of women age 40 and above who had received a mammogram within the past year.

Capacity to Provide Mammography Services Has Also Increased

The nation's capacity to provide mammography services, as measured by the numbers of machines and radiologic technologists available to perform mammography services, has also increased. FDA's data show that between October 1998 and October 2001, the total number of mammography machines and radiologic technologists available nationwide to perform mammography services increased 11 percent and 21 percent respectively (see table 1). While FDA's data showed that the total number of certified facilities has decreased about 5 percent between 1998 and 2001, the

⁶In this period, the population of women age 40 and older increased about 5 percent.

average number of machines per facility increased from 1.22 in 1998 to 1.42 in 2001. Overall, the 5 percent decrease in facilities has been offset by the 16 percent increase in the number of machines per facility and the increase in personnel.

Table 1: Changes in Total Numbers of Facilities, Machines, and Radiologic Technologists, October 1, 1998, and October 1, 2001

	1998	2001	Percent change
Machines	12,076	13,384	11
Technologists	37,219	44,857	21
Facilities	9,884	9,393	-5

Note: Excludes facilities in Puerto Rico and other U.S. territories and federal facilities operated by the Department of Defense and the Department of Veterans Affairs.

Source: FDA database on mammography facilities.

Utilization Does Not Appear To Be Straining Capacity

The current average number of mammograms actually being performed per machine appears to be well below estimates of how many mammograms could be performed, if equipment is operating at full capacity. While there is no uniform standard on the number of mammograms that a mammography machine can do in a day, FDA officials estimated that one machine and one full-time technologist can potentially perform between 16 and 20 mammograms in an 8-hour work day, or between 4,000 to 5,000 mammograms a year (assuming 5 days a week and 50 weeks a year).⁷ Using CDC's data on mammography screening rates, Bureau of Census data on the population of women age 40 and older, and FDA's data on the number of machines, we computed the average number of mammograms performed per machine. At the national level, the average number of mammograms per machine was 2,759 in 1998. While this average number of mammograms per machine had increased to 2,840 in 2001, it was still well under 4,000, the lower end range of

⁷FDA officials estimated that it normally takes between 20 to 30 minutes of machine and technologist's time to perform a mammogram. Also, data from a 1992 survey conducted by NCI showed that at that time mammography facilities reported that they could perform 20 mammograms a day if they were to operate at full capacity. FDA data indicated that most facilities had only one machine. At 20 a day, the yearly total mammograms per facility or machine would be around 5,000, assuming 5 days a week and 50 weeks a year (allowing 2 weeks for holidays and vacations).

estimated full capacity.⁸ At the state level, the average number of mammograms per machine in 2001 ranged from a low of 1,790 in Alaska to a high of 3,720 in Maryland.

While the number of radiologic technologists has increased in the past in general proportion with the increase in mammography utilization, certain trends bear monitoring. According to an American Hospital Association survey, the job vacancy rate for radiologic technologists was 18 percent in 2001, and 63 percent of hospitals reported that they had more difficulty recruiting radiologic technologists than the previous year. Data from ARRT show the rate of increase for certified mammography technologists through 2000 has slowed down substantially in recent years. Similarly, the number of new entrants to the field, as represented by the number of first-time examinees for the mammography certificate, declined substantially each year from 1996 through 2000 (see table 2).

Table 2: Total Numbers of Registrants and First-Time Examinees for Mammography Technologists, 1996-2000

Year	Registrants ^a		First-time examinees	
	Number	Percent change from previous year	Number	Percent change from previous year
1996	35,943	N/A	5,001	N/A
1997	39,128	8.9	3,674	-26.5
1998	41,536	6.2	2,969	-19.2
1999	42,699	2.8	1,799	-39.4
2000	43,718	2.4	1,214	-32.5

^aThe number of registrants each year does not necessarily correspond with that of first-time examinees because the number of registrants is influenced by the number of existing registrants who decide to renew their certificate, the number of past registrants who are reinstated each year, and the number of first-time examinees who passed the examination.

Source: American Registry of Radiologic Technologists.

⁸If mammography screening rates have continued to rise since 2000, the last year for which utilization data were available, these estimates may slightly understate the number of mammograms per machine.

In addition, while comprehensive data are not available on the total number of radiologists available to interpret mammograms,⁹ the limited data available also indicate that the availability of radiologists may bear watching. For example, data from the employment placement service of the American College of Radiology show an increasing ratio of job listings per job seeker for radiologists –from 1.3 in 1998 to 3.8 in 2000. Also, data from the American Board of Radiology show that the number of first-time candidates who sit for diagnostic radiology examination has declined each year from 1997 through 2001 (see table 3).¹⁰

Table 3: Number of First-Time Examinees for Diagnostic Radiology Examination, 1997 to 2001

Year	Number of examinees	Percent change from previous year
1997	947	N/A
1998	916	-3
1999	894	-2
2000	863	-3
2001	787	-9

Source: The American Board of Radiology.

Capacity Has Decreased in Some Locations, Causing Scattered Problems

Because of local factors such as a shortage of personnel or closure of certain facilities, waiting times for routine mammograms could be several months in certain locations. Nationwide, 241 counties had a net loss of mammography machines between October 1998 and October 2001, with 121 of them losing more than 25 percent. Our follow-up at 55 rural and metropolitan counties where reductions occurred indicated that lengthy appointment waiting times for mammography services were primarily in metropolitan locations.

⁹The only data source that contains information on radiologists practicing mammography is the FDA database. However, we were unable to use the database to determine the total number of radiologists available to read mammograms. Although the database has names of radiologists practicing at each facility, it does not uniquely identify each radiologist and radiologists often read mammograms at multiple facilities.

¹⁰Radiologists must pass a diagnostic radiology examination to become board certified and qualified to interpret mammograms. However, those who pass the examination may also choose to practice in other fields of radiology other than mammography.

Small Proportion of Counties Nationwide Lost Capacity

Our county-by-county analysis of data on equipment shows that overall, 241 counties had a net loss in the number of mammography machines between October 1998 and October 2001.¹¹ Of these counties, 121 lost more than 25 percent of their machines. This number represents counties spread throughout the nation. These counties together contained less than 1.9 percent of the total U.S. population in the 2000 census.

We conducted an analysis to determine what had occurred in those counties close to the 121 counties that lost more than 25 percent of their machines. In general, the adjacent counties showed an increase in the number of machines, with nearly all of the 121 counties being within 50 miles of a county that gained machines.¹² Thus, residents in most of the counties that lost services appear to be able to draw on increased resources nearby.

Counties with Largest Losses Are Mostly Rural; Most Reported No Significant Problems

Because data are not available to measure the effect of capacity loss on the mammography utilization rates at the county level, we randomly selected 37 of the 121 counties that lost more than 25 percent of their machines for in-depth analysis at the local level. These 37 counties are located in 19 states (see appendix I for a list of these 37 counties). Over three quarters of these counties are in nonmetropolitan areas.¹³ Eighteen of the counties we selected had one facility and 11 had no facility at all in 2001. We interviewed state and local officials familiar with conditions in these counties, asking them to assess the impact of the loss of facilities.

¹¹There are 3,141 counties (including the District of Columbia) nationwide; 241 counties lost machines, 730 counties gained machines, and 1,334 counties had no change in machines (the remaining 836 counties had no machines in either 1998 or 2001).

¹²We measured the distance between the central points of the counties that lost machines with the central points of the nearby counties that gained machines.

¹³This determination is based on the 1993 rural-metropolitan continuum codes published by the Economic Research Service of the U.S. Department of Agriculture. These codes classify counties by metropolitan and nonmetropolitan categories based on an Office of Management and Budget (OMB) standard and the 1990 Census of population. OMB defines nonmetropolitan counties as those outside the boundaries of metropolitan areas and have no cities with as many as 50,000 residents. New codes based on the 2000 Census are not expected to be available until 2003.

With two exceptions, officials generally reported no significant problems.¹⁴ They said existing facilities in the county or neighboring counties were able to provide needed services, and the longest appointment waiting time reported for routine screening mammograms was 1 month or less, which they considered to be reasonable. In most counties where women had to travel to neighboring counties for services, the travel distance was less than 40 miles, which officials considered common in rural areas. Several officials also said that some counties were served by mobile facilities that travel to their areas.

Largest Service Dislocation Appears to Be Occurring in Some Metropolitan Areas

In metropolitan counties, the picture was more mixed than for rural counties. To examine the extent of problems in metropolitan areas, we selected 18 additional counties (including the District of Columbia¹⁵) from a list of counties that lost the largest number of machines. All of these counties are classified as metropolitan counties¹⁶ (see appendix I for a list of these counties). As we did for the rural counties, we contacted state and local officials and asked them to assess the impact of the loss of machines on women's access to services. These officials reported wide variations in availability of services. While no problems were reported in nine counties, officials in the other nine counties reported a variety of problems. The nine counties with problems are concentrated in five metropolitan areas—Baltimore, Boston, the District of Columbia, and San Antonio and Wichita Falls, Texas. For example, officials in three counties surrounding the Baltimore metropolitan area reported an average waiting time of up to

¹⁴An official from Chaves County, New Mexico, said that due to the loss of one large provider, women in the county depended primarily on a county hospital for services and the appointment waiting time for screening mammograms was about 3 months. Women deciding not to wait must travel 70 miles or more to facilities in neighboring counties. However, the official said women whose clinical exams or initial mammograms indicated a need for follow-up diagnostic mammograms generally were able to get appointments with the county hospital within a week. In addition, in one Oklahoma County, an official reported long waiting times for American Indian women at tribal facilities, although no problem was reported in that county for the general population.

¹⁵Based on the National Institute of Standards and Technology (with the secretary of commerce's approval), the District of Columbia is considered to be equivalent to a county for legal and statistical purposes.

¹⁶Based on the 1993 rural-metropolitan continuum codes published by the Economic Research Service of the U.S. Department of Agriculture, 10 of these counties are coded as central or fringe counties with populations of 1 million or more and 8 counties are coded as smaller metropolitan areas with 6 having populations of 250,000 to 1 million and 2 with populations of fewer than 250,000.

3 months for screening mammograms and 2 to 3 weeks for follow-up diagnostic mammograms. Similarly, a survey conducted by Massachusetts officials in April 2001 found that, in the Boston metropolitan area, appointment waiting time for screening mammograms ranged from 1 to 20 weeks, depending on facilities. In the District of Columbia, officials reported that the only facility available in one part of the city had up to an 8-week backlog of appointments, while the rest of the city generally did not have significant problems.

In addition to contacting these 18 counties, we also contacted state and local officials to inquire about six other urban areas—Buffalo, Chicago, Houston, Los Angeles, New York, and Tallahassee—where no significant number of machines was lost but problems were cited by state and local officials or media reports. Officials familiar with situations in these cities reported that most of the problems were limited to certain facilities. For example, an official in Buffalo said that one well-known facility there had a 3-month waiting list for appointments while others could accommodate appointments within 2 weeks. In Chicago, Houston, and Los Angeles, long waiting time problems were concentrated in public health facilities that served low income populations. In New York and Tallahassee, long waiting times of 5 to 6 months were reported in 2000, but our recent interviews with officials found no significant problem. In almost all cases where some problems were reported, officials said that women who needed a diagnostic mammogram generally were able to get appointments within 1 to 3 weeks.

Several factors have contributed to the waiting time problems in the nine metropolitan counties and the six urban areas that we identified. Among the reasons provided by state and local officials were the following:

- Demand for services grew while capacity declined. In the Baltimore area, for example, officials said that a shortage of technologists and financial difficulty caused many facilities to consolidate or shut down, resulting in a net decrease in capacity, while the demand for services continued to grow.
- High demand for services at some facilities. In cities such as Buffalo, Boston, Houston, and Los Angeles, where variation was more on a facility-by-facility basis, officials provided various reasons for the high demand at some facilities. For example, such factors as facilities' reputations, physicians' referral patterns, and large patient workload from public assistance programs cause some facilities to have a large backlog of appointments. Some women may experience waiting time problems because they are restricted by insurance coverage as to where they can go for services.

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- Inability to meet FDA's quality requirements. Several officials told us that many small facilities with old machines had shut down because they could not meet FDA quality requirements. For example, an official from Los Angeles said that one provider had shut down three mobile units during the last 2 years because of quality problems.
 - Temporary interruptions in availability. The waiting time problems may also be caused by the closure of one or more large facilities—a temporary problem that often resolves itself when new facilities open or existing facilities expand in the area. For example, lengthy waiting problems in Tallahassee in 2000 were largely generated by the closure of one large mammography facility but a local public assistance program official told us in March 2002 that women in her program could get appointments within 2 weeks as the result of a recent opening of one new facility.

In addition to these factors, state and local officials also frequently raised concerns about the adequacy of the Medicare reimbursement rate, particularly in the high cost metropolitan areas. However, during the course of our work, CMS implemented a statutory change to the method for determining the Medicare reimbursement rate for screening mammography.¹⁷ The new method includes geographic adjustments for cost differences among areas and resulted in significant rate increases for high cost areas.¹⁸

Concluding Observations

In general, the increase in mammography equipment and personnel has been sufficient to meet the steady increase in demand for mammography services. However, while the general buildup of personnel has been in line with the growth in the use of services, the last few years show a substantial decline in the number of new entrants to the fields, which

¹⁷Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No.106-554. App. F, § 104(a), 114 Stat. 2763, 2763-469.

¹⁸Prior to January 2002, the method for determining the Medicare reimbursement rate for screening mammography each year resulted in a uniform rate nationwide; this payment rate was \$69.23 in 2001. The recent statutory change required CMS to include screening mammography in its Medicare physician fee schedule. Under this fee schedule, the annual payment amount for each service is based on a formula that includes geographic adjustments for cost differences among areas. Under CMS's updated fee schedule that became effective January 2002, the Medicare reimbursement rates for screening mammography increased significantly for high cost areas. For example, New York (Manhattan) received a 51 percent increase (from \$69.23 to \$105.08) and Los Angeles received a 30 percent increase (from \$69.23 to \$90.48). Lower cost areas received less, for example, the rate in Arkansas increased less than 2 percent (from \$69.23 to \$70.33).

could result in a reversal in this trend. If this reversal occurs, more personnel shortage problems could arise in the future.

Some instances of long waiting times for services are occurring. Consolidation of facilities and increases in demand can create a strain on service availability in specific communities. However, appointment delays are primarily for screening mammograms rather than for follow-up diagnostic mammograms. These conditions, which can be temporary, may be exacerbated by local physicians' referral patterns, patients' insurance coverage, or local shortages in available personnel.


Agency Comments

We provided FDA with a draft of the report for review and comment. FDA responded that it found the report to be accurate and it had no other general comments. In addition, FDA provided technical comments, which we incorporated as appropriate. Appendix II contains FDA's written response.

As arranged with your offices, unless you release its contents earlier, we plan no further distribution of this report until 10 days after its issue date. At that time, we will send copies to the secretary of health and human services, the commissioner of FDA, the director of NCI, the director of CDC, the administrator of CMS, appropriate congressional committees, and other interested parties.

If you or your staff have any questions about this report, please contact me at (202) 512-7250. Other contacts and major contributors are included in appendix III.

Sincerely yours,



Janet Heinrich
Director, Health Care—Public Health Issues

Appendix I: Scope and Methodology

To compare recent trends in the use of mammography services with changes in facilities, equipment, and personnel available to deliver these services, we did the following.

- We used data from CDC's Behavioral Risk Factor Surveillance System for calendar years 1998 and 2000 (the most recent year available) to estimate mammography screening rates for women age 40 and older on a state-by-state basis. To estimate the number of mammograms provided to these women in 1998 and 2000, we then multiplied these screening rates by the population of women age 40 and over, using Census' population estimates for 1998 and the 2000 Census population.
- We used FDA's national database on mammography facilities to assess the change in the total numbers of certified facilities, machines, and radiological technologists at national, state, and county levels. We compared the characteristics of facilities operating on October 1, 1998, with those operating 3 years later on October 1, 2001. FDA estimated an error rate of less than 1 percent for the data on mammography facilities. We excluded facilities in Puerto Rico, other U.S. territories, and federal facilities operated by the Department of Defense and the Department of Veteran Affairs from the analysis.

To identify geographical areas where the capacity to perform mammography services had decreased, and to assess the effect of these decreases on access to services, we used FDA's national database to identify counties that lost mammography machines and focused on those that lost more than 25 percent of their machines from October 1, 1998, to October 1, 2001. To determine if machines became more available in areas close to these counties, we analyzed what had happened to the number of machines in nearby counties. Because data were not available to measure the effect of changes in capacity on mammography utilization rates at the county level, we carried out follow-up interviews with state and local officials in a random sample of 37 counties that lost more than 25 percent of their machines (see table 4).

Table 4: Counties Randomly Selected From Those That Lost Over 25 Percent of Their Mammography Machines for Follow-up Contact, October 1, 1998, to October 1, 2001

State	County	State	County
Alabama	Franklin Talladega	New Mexico	Chaves
Arkansas	Arkansas Dallas Hempstead Mississippi	North Carolina	Granville
Florida	Suwannee Walton	North Dakota	Cavalier
Illinois	Jersey	Ohio	Darke Scioto
Indiana	Daviess Jasper Putnam	Oklahoma	Adair Choctaw Kay Mcclain
Kentucky	Breathitt Logan Jackson	Tennessee	Greene Tipton Wilson
Louisiana	Caldwell	Texas	Starr
Mississippi	Madison Scott	Virginia	Roanoke Sussex
Missouri	Cooper Jefferson	Washington	Franklin
Nebraska	Cass		

Source: FDA database on mammography facilities.

Because over three quarters of these counties are in nonmetropolitan areas, we selected an additional 18 counties (including the District of Columbia) from a list of counties that lost the largest number of machines (though not enough to reduce the number by more than 25 percent). All of these 18 counties are in metropolitan areas. We also made additional inquiries about six other urban areas—Buffalo, Chicago, Houston, Los Angeles, New York, and Tallahassee—where problems had been cited by state and local officials or media reports. Table 5 lists the 18 counties and their metropolitan areas.

Table 5: Counties Judgmentally Selected From Those That Lost the Largest Number of Mammography Machines for Follow-up Contact and the Metropolitan Areas of These Counties, October 1, 1998, to October 1, 2001

State	County	Metro area
Florida	Orange	Orlando
Maryland	Anne Arundel	Baltimore
	Baltimore	Baltimore
	Baltimore city ^a	Baltimore
	Prince George's	District of Columbia
Massachusetts	Norfolk	Boston
	Suffolk	Boston
Ohio	Mahoning	Youngstown
	Montgomery	Dayton
	Stark	Canton
	Summit	Akron
Texas	Bexar	San Antonio
	Grayson	Sherman-Denison
	Jefferson	Beaumont-Port Arthur
	Wichita	Wichita Falls
Virginia	Arlington	Arlington (Northern VA)
	Richmond City	Richmond
District of Columbia	District of Columbia ^a	District of Columbia

^aOn the basis of the National Institute of Standards and Technology (with the secretary of commerce's approval), Baltimore City, which is independent from Baltimore County, and the District of Columbia are considered to be equivalent to counties for legal and statistical purposes.

Source: FDA database on mammography facilities.

Because no systematic data were available on waiting times and travel distances for mammography services, we relied on observations of state and local officials about the situations at each location. For each selected location, both rural and metropolitan, we interviewed officials familiar with the availability of mammography services in these areas to obtain their views on whether women in their areas were experiencing problems with long waiting times for appointments and/or long travel distance to obtain services. These officials generally included

- state radiation control personnel contracted by FDA to conduct annual onsite inspections of mammography facilities;
- state and local public health officials involved in CDC's Breast and Cervical Cancer Early Detection Program, which contracts with mammography facilities in each state to provide screening and diagnostic mammograms to underserved women; and
- in some locations, officials of Medicare peer review organizations contracted by CMS to monitor and improve the quality of care, including

increasing statewide mammography screening rates for Medicare beneficiaries.

While most of these officials have not conducted any formal studies to gather this type of information, some have conducted informal surveys about waiting times and others were able to provide estimates of waiting times and travel distances through their involvement and frequent contacts with mammography facilities.

In addition, we interviewed representatives from several professional organizations, such as the American College of Radiology, the American Cancer Society, and ARRT, along with officials of FDA, CDC, NCI, and CMS. We performed our work from June 2001 through March 2002 in accordance with generally accepted government auditing standards.

Appendix II: Comments from the Food and Drug Administration



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 12, 2002

Ms. Janet Heinrich
Director, Health Care-Public Health Issues
United States General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Heinrich:

Thank you for the opportunity to review GAO's draft report, MAMMOGRAPHY: Capacity Generally Exists to Deliver Services (GAO-02-532). We find this report to be accurate and well written. We have no general comments to submit to you on this report. FDA has already provided technical comments directly to your staff.

We appreciate your staff's attention to this important topic and the opportunity to work with them in developing this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Lester M. Crawford".

Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner

Appendix III: GAO Contacts and Staff Acknowledgments

GAO Contacts

Frank Pasquier, (206) 287-4861
Sophia Ku, (206) 287-4888

Acknowledgments

In addition to those named above, Jennifer Cohen and Stan Stenersen made key contributions to this report.

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