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SCREENING MAMMOGRAPHY:

Quality Standards Are Needed In A Developing Market

Statement of
Janet L. Shikles, Director
Health Financing and Policy Issues
Human Resources Division

Before the
Subcommittee on Aging
Committee on Labor and Human Resources
United States Senate

SUMMARY OF GAO TESTIMONY BY JANET L. SHIKLES
ON NEED FOR QUALITY STANDARDS FOR SCREENING MAMMOGRAPHY

GAO reported in SCREENING MAMMOGRAPHY: Low-Cost Services Do Not Compromise Quality (GAO/HRD-90-32, January 1990) that many of the screening mammography providers it surveyed lacked the quality assurance programs needed to ensure that women receive safe and accurate mammograms. Members of Congress were concerned that a new Medicare screening mammography benefit with a limit on provider charges might lead to the creation of "mammography mills" providing substandard care. However, GAO found that high volume was associated with greater compliance with quality standards, and that price was not indicative of the extent of quality control. GAO identified a need for strong federal standards to assure the quality of screening mammography. Specifically, GAO found that:

-- Many of the 1,485 mammography providers surveyed in four states lacked adequate quality assurance programs.

-- Those providers reporting the highest rates of compliance with many quality standards were those performing the highest volume of mammography. However, GAO found no consistent relationship between what providers charged for screening mammograms and their compliance with quality standards.

-- The association between higher volume and greater quality control is important because high volume screening can permit economies of scale that lower fees. Providing screening in regulated, high-volume settings can help assure the availability of safe and accurate screening mammography at a cost consistent with the Medicare fee limit.

-- Primary care physicians and multispecialty clinics were the screening mammography settings that consistently reported the lowest rates of compliance with quality assurance standards.

-- At the time of our review, federal and state oversight of mammography services was limited by the absence of legally binding quality standards. State inspections revealed problems in image quality and dose that underscore the need for federal quality standards.

-- HCFA's 1991 regulations for Medicare-funded screening mammography closely parallel professional quality standards designed to ensure safe and reliable screening services. Women not covered by Medicare who are recommended for regular screening mammography may obtain services at facilities that do not meet HCFA's quality standards.

GAO in its testimony suggested that the Congress may wish to consider options to encourage states to regulate screening mammography more stringently.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss GAO's report, SCREENING MAMMOGRAPHY: Low-Cost Services Do Not Compromise Quality (GAO/HRD-90-32, January 1990). The Congress directed us to review the quality of screening mammography[1] in different types of settings, such as physicians' offices and hospitals.[2] Members of Congress were concerned that a new Medicare benefit for screening mammography might lead to the creation of "mammography mills" providing substandard services, and that the limit on what facilities could charge for Medicare-funded screening might make it difficult for women to obtain safe and accurate mammograms.

In the four states we surveyed, many screening mammography providers lacked adequate quality assurance programs. However, high volume was associated with higher quality in our survey--the facilities that reported the highest rates of compliance with many quality standards were those providing the highest volume of mammography services. We found no consistent relationship between what providers charged for screening mammograms and their compliance with quality standards. Several low-charge facilities met professional standards designed to ensure a quality screening program.

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[1]A radiographic test to detect breast cancer in apparently healthy women.

[2]Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360), Sec. 204.

We also identified a need for strong federal standards to assure the quality of screening mammography. We found at the time of our review that federal and state oversight of mammography services was limited by the absence of legally binding quality standards. In creating the new Medicare screening benefit, the Congress required the Secretary of Health and Human Services to establish standards for mammography providers serving the Medicare population. However, the National Cancer Institute recommends regular screening for millions of women not eligible for Medicare, and these women are not necessarily protected by federal quality standards.

BACKGROUND

The American Cancer Society estimates that over 44,000 women will die of breast cancer during 1991 and that 175,000 new cases will be diagnosed. Breast cancer incidence has increased dramatically; approximately one in nine American women will develop breast cancer during her life.

The best method we currently have to reduce the number of breast cancer deaths is early detection, and the most effective way to detect breast cancer at the earliest stages is mammography, an X-ray of the breast. The value of mammography for breast cancer screening is that it can detect cancers that are too small for a

doctor or the woman herself to feel through physical examination, and these early stage cancers can be 90 to almost 100 percent curable. When detection occurs at a later stage, treatment is both more debilitating and much less effective.

Mammography is performed for two different purposes, screening and diagnosis. Screening mammography is an examination of a woman without breast symptoms, and is done simply to detect breast cancer before a lesion can be felt by her or her physician. Diagnostic mammography is an examination of a woman who already has a symptom, such as a lump, that suggests she may have breast cancer. It is performed to provide as much information as possible about a suspected lesion.

The process of performing the mammogram is the same in both cases. A diagnostic procedure, however, may require additional breast views and other tests. Because of its more limited purpose, screening mammography can take advantage of certain economies not possible during diagnostic mammography. For example, a radiologist need not be present to immediately interpret a screening mammogram. Instead, the day's films can be read all at one time, allowing greater efficiency in the costly use of a radiologist's time.

The Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) created a new Medicare benefit for screening mammography that went

into effect January 1, 1991.[3] Previously Medicare covered only diagnostic mammography. To help contain costs, the act generally limits the fee providers may charge for a screening mammogram to $55.[4] Some members of Congress expressed concern that the charge limit could compromise the quality of Medicare-funded screening mammography. To help assure that quality services would be provided, the Congress required the Secretary of Health and Human Services (HHS) to establish quality standards for facilities providing screening mammography to Medicare beneficiaries.

To obtain information about screening mammography practices in a variety of settings, we conducted a mail survey of 1,485 providers in California, Florida, Idaho, and Michigan. These were all the facilities identified as having mammography equipment by those states' radiological health departments. Our questionnaire[5] requested information about equipment, personnel, quality assurance activities, reporting and record-keeping, volume, and charges. The

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[3]The Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) created such a benefit to go into effect in January 1990. However, on November 22, 1989, the Congress repealed most provisions of the act, including the mammography benefit.

[4]The limit will be updated annually by the percentage increase in the Medicare Economic Index.

[5]Questionnaire items were based on the standards and recommendations developed by the American College of Radiology (ACR) for use in its screening mammography accreditation program, the requirements of the Medicare Catastrophic Coverage Act (which were retained in the 1990 Omnibus Budget Reconciliation Act), and factors identified by other experts as associated with quality in screening mammography. The questionnaire was reviewed by officials from ACR and the National Cancer Institute.

response rate was 82 percent overall, and, for each state, at least 80 percent.

When analyzing the questionnaire responses, we used the following categories of settings where mammography services are provided: primary care physician, radiology private practice, hospital, hospital breast clinic, breast clinic, health maintenance organization (HMO), multispecialty clinic, mobile van, and other. To gather information about topics not addressed in the questionnaire--such as training and experience of personnel and the physical environment of facilities--we conducted site visits at 15 providers participating in the survey. We also reviewed government regulation and oversight of mammography services in the four states we studied.

MANY PROVIDERS DID NOT MEET STANDARDS FOR QUALITY ASSURANCE PROGRAMS

Most of the features considered necessary for quality screening mammography contribute to the goal of obtaining good image quality with minimal risk to the patient. Because a mammogram is among the radiographic images most difficult to read, it must have optimal clarity. If image quality is poor or the interpretation faulty, the interpreter may fail to identify a malignancy. This could delay treatment and result in an avoidable death or mastectomy. Problems with images or interpretation also

can lead to unnecessary testing and biopsies if normal tissue is misread as abnormal.

We found widespread compliance with certain quality standards, such as using dedicated mammography equipment (equipment specifically designed for mammography)[6] and employing certified or licensed technologists to perform the mammograms[7]. But many facilities did not comply with professional standards for quality assurance programs, such as annual inspection by a radiological physicist[8]. A comprehensive quality assurance program is essential to evaluate both equipment and staff performance, and includes procedures such as checking the performance of the film processor and using a phantom to evaluate image quality[9]. The lack of such a program can result in problems with image quality and radiation dose.

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[6]To obtain the best mammographic image with the smallest dose of radiation, it is essential to use dedicated mammography equipment. Its features enable the operator to obtain high-quality images with much lower radiation exposure than is possible with general X-ray equipment.

[7]The person taking the mammogram plays an essential role in providing quality mammography, as proper positioning of the patient and adjustment of the equipment are vital to producing a good image.

[8]The radiological physicist performs a series of tests on the mammography equipment to ensure that it is safe and functioning properly.

[9]Phantoms simulate breast tissue when exposed. Objects that simulate growths that could be cancerous are embedded in the phantom. When the phantom is exposed with a facility's mammography equipment, the visibility and clarity of these objects provides feedback on the quality of image the system is producing.

The importance of ongoing quality feedback for mammography providers is illustrated by the results of the American College of Radiology (ACR) Mammography Accreditation Program. About 30 percent of providers applying for accreditation fail on the first attempt. ACR officials have observed that since the accreditation program is voluntary and applicants probably think they meet ACR standards, the failure rate suggests that improvement is needed even at facilities that believe they are providing good mammography.[10]

In our survey, primary care physicians and multispecialty clinics consistently reported the lowest levels of compliance with quality assurance standards. For example, only 43 percent of primary care physicians reported that a radiological physicist inspected their mammography equipment at least once a year, compared to 85 percent of hospital breast clinics and 91 percent of mobile vans. While over half the HMOs and hospitals said they checked their film processor on a daily basis, only 10 percent of primary care physicians did so.

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[10]McLelland, et al., "The American College of Radiology Mammography Accreditation Program," American Journal of Radiology, 157:473-479, September 1991.

HIGH-VOLUME PROVIDERS MORE OFTEN ADHERED TO QUALITY STANDARDS

We found a strong relationship between the volume of mammography performed and the rate of compliance with many quality standards. For example, 87 percent of facilities performing over 100 mammograms per week reported having annual inspections by a physicist, while 58 percent of those doing fewer than 25 weekly mammograms said they had such inspections. Half of the high-volume providers did a daily check of their film processor, compared to 24 percent of the low-volume providers.

Higher charges, however, did not necessarily buy higher quality. We found no consistent relationship between charge and adherence to quality standards. For several standards, we found no correlation between price and degree of compliance with professional standards. For other standards, there was a relationship, but in some cases providers charging the lowest fees had the highest rate of compliance with a quality standard, while in other cases those with the highest fees had the highest rate of compliance.

Our site visits also tended to dispel the concern that quality would be compromised at facilities charging lower fees for screening mammography. This concern was related to the limit the Congress placed on the fee providers may charge for Medicare-funded

screening mammograms, currently around $55. We visited three facilities that reported complying with many important quality standards and that charged $50 or less for screening mammograms. They employed trained, experienced radiologists; used certified technologists; and had extensive quality assurance programs. All reported volume levels of at least 200 mammograms per week.[11]

The association between high volume and adherence to quality standards is significant, because high volume is a critical factor in reducing the price of screening mammography. One important way high volume contributes to quality is that it gives radiologists sufficient work to increase the proficiency of their interpretations. They are then less likely to miss a sign of cancer in a mammogram or cause a woman to undergo an unnecessary procedure by identifying normal breast tissue as abnormal. Providing screening in regulated, high-volume settings can help assure the availability of safe and reliable screening mammography at a cost consistent with the Medicare fee limit.

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[11]One facility used a significant amount of volunteer labor to lower operating costs, but the other two did not.

FEDERAL AND STATE REGULATION OF SCREENING MAMMOGRAPHY LIMITED

At the time of our review, only the states had responsibility for regulating both mammography equipment and services.[12] Of the states we reviewed, only Michigan had a law requiring the use of dedicated mammography equipment and the setting of image quality and radiation dose standards. The lack of such standards in the other three states limited their ability to regulate screening mammography services. Because state requirements were limited, when state inspectors identified image quality problems they could not require mammography providers to correct them. Idaho had no minimum qualifications for the operators of mammography equipment, and the states we visited had varied requirements for persons interpreting mammograms.

In January 1991, the Health Care Financing Administration (HCFA) implemented interim final regulations setting quality standards for providers of Medicare-funded screening mammography services. These standards parallel those used by ACR and other professional organizations with expertise in screening mammography. They mandate the use of dedicated equipment; set certification,

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[12]The Food and Drug Administration (FDA) has responsibility for regulating the manufacture and assembly of mammography equipment. Its standards apply only to the manufacturer and assembler of the equipment, not to the facility using it. FDA has no standards for mammographic image quality or the radiation dose received by the patient. It considers dose a practice-of-medicine issue not within its purview.

experience and continuing education requirements for technologists performing mammograms and physicians interpreting them; establish reporting and record-keeping requirements; and mandate comprehensive quality assurance programs. The agency expects to issue final regulations early in 1992.

CONCLUSIONS AND MATTERS FOR CONSIDERATION

HCFA quality standards should help assure that providers deliver safe and accurate screening mammography services to the Medicare population. However, the National Cancer Institute and other medical organizations recommend that women begin regular screening at the age of 40, and that women have annual screening mammograms starting at age 50. Over 16 million American women not covered by Medicare are candidates for annual screening, and it is recommended that over 14 million additional women be screened every one to two years.

As a practical matter, most mammography providers will want to receive HCFA certification and therefore most women who are not Medicare beneficiaries will obtain their screening mammograms at facilities that meet HCFA's quality standards. However, women not covered by Medicare could obtain mammograms from providers that are not certified by HCFA and that do not comply with federal quality standards. These women would be protected only by state

regulations, which in some states are too limited to ensure the provision of safe and reliable screening services.

Because some mammography providers may choose not to be certified for Medicare and because the states, as a rule, do not stringently regulate these providers, the Committee may want to encourage states to adopt regulatory programs. A number of options are available and I will mention several of them. One option is to extend Medicare's screening mammography standards to Medicaid and condition federal sharing in a state's Medicaid mammography costs on the state's having a regulatory program at least as stringent as Medicare's. A federal Medicaid requirement like this would give the states a financial incentive to better regulate screening mammography. Also, federal sharing in the costs of state survey and certification activities would be available under Medicaid.

Another option would be to condition states' participation in the Preventive Health and Health Services Block Grant program[13] on having mammography standards. A rationale for using this block grant to encourage regulation is that screening mammography is an important preventive service for women.

Alternatively, the Committee could consider a more direct federal role. For example, a regulatory program similar to that for Medicare supplemental (Medigap) insurance could be established.

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[13]P.L. 97-35 (42 U.S.C. Sec. 300w, et seq.).

Under the Medigap regulatory program, federal law establishes minimum standards that must be met before policies can be sold.[14] Enforcement of the federal Medigap requirements is delegated to the states as long as their regulatory programs are at least as stringent as the federal standards. Similarly, the federal government could establish minimum quality standards for screening mammography and delegate enforcement to states with regulatory programs meeting these standards.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions.

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[14]The federal standards incorporate by reference the model Medigap regulatory program developed by the National Association of Insurance Commissioners (42 U.S.C. Sec. 1395ss).

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