DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 1, 1998

Dear Mammography Quality Advocate:

Because of your expressed interest in mammography, the Food and Drug Administration (FDA) is sending you the enclosed document, ***Mammography Facility Performance for Calendar Year 1997,*** which was mandated by Congress in the Mammography Quality Standards Act (MQSA) of 1992. The purpose of the report is to assist health professionals and consumers in evaluating the performance of mammography facilities. In the future, we will continue to send you annual reports as they are published. We encourage you to make this information available to your constituents, especially physicians and the general public, and to announce the report's availability in your organization's publication.

The report includes the following:

- background information;
- a list of mammography facilities against which adverse actions were taken in 1997; and
- directions for obtaining a list of FDA-certified facilities by locale.

You may also find this report, along with other MQSA-related documents, on the MQSA Internet home page, located at http://www.fda.gov/cdrh/dmqrp.html. You will then be presented with a list of documents to view. To read documents labeled "PDF Format," you'll need the Acrobat Reader. To access Acrobat, click on "PDF Reader" in the introduction of the Mammography Quality and Radiation Programs home page, and then click on "Instructions."

If you have any questions regarding this report, send them to Pat Hoage, 1350 Piccard Drive, Rockville, Maryland 20850, or by fax at 301-594-3306.

Sincerely yours,

John L. McCrohan

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MAMMOGRAPHY FACILITY PERFORMANCE FOR CALENDAR YEAR 1997

Quality mammography saves lives. Mammography is a low-dose x-ray of the breast to detect small tumors and breast abnormalities. It provides the best means of early detection of breast cancer, the second leading cause of cancer deaths among American women. Studies indicate that widespread use of mammography could reduce deaths from this disease by one-third. The National Cancer Institute recommends that women in their 40s or older get screening mammograms on a regular basis, every one to two years.

The enactment of the Mammography Quality Standards Act of 1992 (MQSA) by Congress marked the first time that mammography facilities were required by the federal government to meet uniform, baseline mammography requirements aimed at strengthening mammography quality. Working in partnership with other federal, State, and private organizations, the Food and Drug Administration (FDA) has implemented these requirements. A major focus of the MQSA program is to monitor the performance of each facility in meeting standards for personnel, equipment, quality control, and recordkeeping. Each facility must be accredited by an FDA-approved accreditation body, be FDA certified, and undergo a yearly inspection.

As required by MQSA, the FDA is providing this third annual report for calendar year 1997. The report includes information that is useful in evaluating the performance of mammography facilities. MQSA specifically requires the report to include a listing of facilities that had adverse actions taken against them under the statute. In addition, as required by the Act, this report includes a list of facilities against which States have taken adverse actions. In an effort to assist in the interpretation of the data compiled below, the report also provides background information on MQSA, quality mammography standards of performance, and directions for acquiring a list of FDA-certified facilities.

MQSA Standards Yielded Immediate Improvements in Mammography Quality

The General Accounting Office (GAO), Congress' oversight body, summarized early results of MQSA by reporting:

> Early indications are that MQSA has had a positive effect on the quality of mammography services....these standards are having more than a symbolic effect, because in order to become fully certified, many facilities have had to improve their practices.[1]

[1] Mammography Services: Initial Impact of New Federal Law Has Been Positive (GAO/HEHS-96-17, Oct. 27, 1995).

In addition, the GAO report concluded that, although a small number of facilities have voluntarily ceased mammography services rather than correct problems, early indications show no significant adverse impact on women's access to mammography services.

In a 1997 report, GAO concluded that—

> . . . First, overall, MQSA has had a positive impact on the quality of mammography services and no effect on access to them. In looking at the currently measurable areas, such as the accreditation and inspection results, the quality of X-ray images, and the extent of facility closures, the evidence is strong that the quality of services has been improved and that access has not been adversely affected. We believe it is reasonable to attribute a large part of the quality improvements to (1) MQSA processes that enforced accreditation standards that were not previously followed by many facilities and (2) FDA's annual inspection process, which provides a valuable, systematic means of helping ensure that these higher standards are maintained.[2]

First Calendar-Year Inspection Results

Results from the first year of annual MQSA inspections conducted in 1995 showed that the vast majority of the fully certified facilities inspected made great efforts to comply with the new standards. Problems found during inspections were categorized into three groups, with Level 1 being the most serious and Level 3 being minor. The data showed that of the fully certified facilities inspected in 1995:

- Thirty-two percent of the facilities inspected performed quality mammography without any violations being noted.

- Fewer than 3 percent (165 facilities) had serious problems.

Fourth Calendar-Year Results Show Continued Improvement in Compliance

By September 18, 1998, a total of 6,432 fully certified facilities have had their 1998 annual inspection. As compared to the first calendar year of inspections, this calendar year's inspections for the 6,432 fully certified facilities inspected to date show that:

- Sixty percent of the facilities inspected performed quality mammography without any violations being noted.

- The number of serious findings dropped from 2.3 percent in 1995 to less than 1 percent.

[2] Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes (GAO/HEHS-98-11, Oct. 21, 1997, p. 19).

Facilities Against Which Adverse Actions Were Taken in Calendar Year 1997

Medicare/Medicaid Actions

- The Florida Medicaid Fraud Control Unit reported to the Department of Health and Human Services State Medicaid Oversight and Policy Staff that Dr. James W. Pickett III of Sanford, FL, was convicted and incarcerated for 11 counts of Medicare fraud, 22 of Medicaid fraud, and 1 count of CHAMPUS (Civilian Health and Medical Program for the Uniformed Services) fraud.

Accreditation Body Actions

- On March 5, 1997, the State of California Accrediting Body revoked the accreditation of Heritage Medical Center (FDA #196311) of Auburn, CA, because the facility site was abandoned and the owner, James Pond, could not be contacted. The patient files and mammography machine were left in the abandoned premises.

- The American College of Radiology and the Accreditation Bodies of the States of Arkansas and Iowa reported no accreditation revocations.

State Actions

MQSA does not preclude a State or U.S. territory from having stricter mammography requirements. In States that have additional requirements, facilities are required to comply with both State and MQSA regulations to operate lawfully.

A number of actions reported to FDA by the States and U.S. territories for this report were taken by those States pursuant to their own legislation. The Agency has included in this listing those State cases that reflect conditions comparable to those that could be the subject of adverse actions under MQSA.

The actions reported by the States begin on page 4.

ARIZONA

- Arizona Institute of Medical Surgery
  3636 Stockton Hill Road
  Kingman, AZ 86401
  Facility ID # 191718

  Adverse action: Fines/penalties; remedial or corrective actions plan(s) required by State authorities.

  Reason for action: Fine/penalty assessed for no mAs meter; no mAs meter constituted a continuing citation from a 2/19/97 action.

  Corrective action: $1,500 civil penalty fine paid; mAs meter installed.

  Date of inspection/adverse action: 12/11/97

  Date of corrective action/reinstatement: 1/11/98

  Status of facility: Performing mammography.

- Med Tech Mammography
  144080 Country Club
  Mesa, AZ 85210
  Facility ID # 167015

  Adverse action: Fines/penalties; remedial or corrective actions plan(s) required by State authorities.

  Reason for action: Fines/penalties for repeat violations. Equipment testing, phantom; LP (line pairs/mm) < 13; Health Physicist recommendations not corrected; image receptor overshoot.

  Corrective action: Fines/penalties still pending; new unit ordered.

  Date of inspection/adverse action: 9/16/97

  Date of corrective action/reinstatement: Still pending.

  Status of facility: Performing mammography.

CALIFORNIA

- Mobile Mammography Service
  6314 Houston Ave
  Hanford, CA 93230
  Facility ID # 190991

  Adverse action: Facility license suspension.

  Reason for action: Equipment certification or registration; lack of MQSA certification; lack of State authorization; medical audit program; medical records and reporting; personnel qualifications; quality control program.

  Corrective action: Emergency cease and desist order issued 8/27/97 because the facility continued operating after being told to stop on 6/24/97 (Clinical Image Review (CIR) failure) due to Level 1 violations on inspection. Office hearing was held 10/22/97.

  Date of inspection/adverse action: 6/24/97

  Date of corrective action/reinstatement: Facility license suspension process not completed as of 12/31/97—facility had not responded to 10/22/97 letter by 12/31/97.

  Status of facility: Not performing mammography.

- Universal Medical Group
  2015 W. Olympic Boulevard
  Los Angeles, CA 90006
  Facility ID # 214205

  Adverse action: Facility license suspension (permanent); fines/penalties; remedial or corrective actions plan(s) required by State authorities; prosecution and conviction under State laws.

  Reason for action: Equipment certification or registration; lack of State authorization; personnel qualifications; quality control program.

  Corrective action: Emergency cease and desist order given on 2/27/97. Clinic owner fined $15,000 and radiologist fined $10,000 for civil penalties and cost recovery. Patient notification was conducted; clinic owner paid for repeat mammograms for all 120 patients. Clinic owner and radiologist both convicted of three criminal misdemeanor charges (violation of State mammography laws) on 11/5/97 and served time in jail.

  Date of inspection/adverse action: 2/27/97

  Date of corrective action/reinstatement: Not applicable.

  Status of facility: Not performing mammography.

FLORIDA

- Continucare
  4201 Palm Avenue
  Hialeah, FL 33012
  Facility ID # 211573

  Adverse action: Facility license suspension.

  Reason for action: Lack of MQSA certification.

  Corrective action: Provisional reinstatement; failed reaccreditation.

  Date of inspection/adverse action: 10/21/97

  Date of corrective action/reinstatement: 11/18/97

  Status of facility: Not performing mammography.

NEVADA

- Joseph A. Debellis, M.D., Ltd.,
  Diagnostic Center of Medicine
  8801 W. Sahara
  Las Vegas, NV 89117
  Facility ID # 211508

  Adverse action: Fines/penalties.

  Reason for action: Lack of State authorization (facility was operating with expired Nevada certificate).

  Corrective action: Facility obtained new State certification. Patient notification was directed, either to the patient or the referring physician.

  Date of inspection/adverse action: 6/27/97

  Date of corrective action/reinstatement: 7/23/97

  Status of facility: Performing mammography.

- The Elko Clinic
  762 14th Street
  Elko, NV 89801
  Facility ID # 111682

  Adverse action: Fines/penalties.

  Reason for action: Quality control program.

  Corrective action: Prior to the 10/15/97 State inspection, facility had hired new mammographer and new chief technologist. The new staff had initiated procedures to correct previous quality control issues.

  Date of inspection/adverse action: 10/15/97

  Date of corrective action/reinstatement: 10/15/97
  Fines/penalties still pending

  Status of facility: Performing mammography.

NEW YORK CITY

- Empire Medical Building Associates of Rockaway, Inc.
  88-20 Rockaway Beach Boulevard
  Rockaway Beach, NY 11693
  Facility ID # 198424

  Adverse action: Restrictions or similar sanctions.

  Reason for action: Equipment testing, phantom.

  Corrective action: Stop order.

  Date of inspection/adverse action: 12/4/97

  Date of corrective action/reinstatement: Not Applicable.

  Status of facility: Not performing mammography.

TEXAS

- Colorado-Fayette Medical Center
  400 Youens Drive
  Weimar, TX 78962
  Facility ID # 179556

  Adverse action: Other State action: emergency cease and desist order.

  Reason for action: An inspection by Texas Department of Health (TDH) representatives determined that phantom images had failed to meet State requirements between August 26, 1997, and December 23, 1997, and mammography examinations were performed during this time period.

  Corrective action: The facility submitted phantom images and medical physicist report to the TDH. The TDH's review of these documents determined that the facility was now in compliance with State requirements.

  Date of inspection/adverse action: 12/23/97 (Posted in the *Texas Register* on 1/23/98.)

  Date of corrective action/reinstatement: 1/16/98

  Status of facility: Performing mammography.

- Dolly Vinsant Memorial Hospital
  400 E. Highway 77
  San Benito, TX 78586
  Facility ID # 206748

  Adverse action: Other State action: emergency cease and desist order.

  Reason for action: An inspection by Texas Department of Health (TDH) representatives determined that the facility was performing mammography without current State certification for this location; failed to have only qualified operators of mammographic equipment perform mammography; and failed to use only qualified physicians for the interpretation of mammographic images.

  Corrective action: Extensive actions were taken by the facility to implement an adequate quality assurance program and the facility attended an Enforcement Conference.

  Patient notification was conducted under State Law.

  The TDH will perform unannounced inspections at a reduced interval.

  Date of inspection/adverse action: 10/2/97 (Posted in the *Texas Register* on 12/16/97.)

  Date of corrective action/reinstatement: 2/3/98

  Status of facility: Performing mammography.

- East San Antonio Imaging Center
  1954 East Houston, Suite 105
  San Antonio, TX 78202
  Facility ID # 165548

  Adverse action: Other State action: Enforcement Conference.

  Reason for action: Inspection by Texas Department of Health representatives determined that this facility failed to have only qualified operators of mammographic equipment perform mammography; the supervising physician failed to adequately oversee the quality assurance program; and the facility failed to cease performing mammograms after it was notified by the accrediting body that it was no longer accredited and after its Texas certification had expired.

  Corrective action: Extensive actions were taken by the facility to implement an adequate quality assurance program. The facility representatives attended Enforcement Conference and submitted adequate written documentation for all violations. After the conference, additional documentation was submitted regarding the technologist's qualifications and these documents indicated that the technologist was qualified when performing mammography during the period of time in question.

  Date of inspection/adverse action: 2/18/97

  Date of corrective action/reinstatement: Certification expired, renewal denied.

  Status of facility: Not performing mammography

- Mercy Regional Medical Center
  1620 McClelland
  Laredo, TX 78040
  Facility ID # 210849

  Adverse action: Other State action: emergency cease and desist order.

  Reason for action: An inspection by Texas Department of Health representatives determined that the facility was performing mammography without current State certification for this location.

  Corrective action: The facility submitted a completed accreditation application package for the unit at this location to the American College of Radiology and the site was added on the State certification.

  Date of inspection/adverse action: 11/14/97 (Posted in the *Texas Register* on 12/16/97.)

  Date of corrective action/reinstatement: 12/10/97

  Status of facility: Performing mammography.

- Spohn Bee County Hospital
  1500 E. Houston
  Beeville, TX 78102
  Facility ID # 198069

  Adverse action: Fines/penalties.

  Reason for action: Inspection by Texas Department of Health (TDH) representatives determined that the facility's supervising physician was not performing the duties required by State regulation, even after other enforcement actions had been taken against the facility for this same violation of State regulation in 1996.

  Corrective action: The facility attended a Settlement Conference on September 26, 1997, and entered into an Agreed Order on November 25, 1997, which included a penalty of $10,000, promotion of breast cancer awareness in the community for a period of 1 year, and a commitment that the supervising physician would not be employed by, or otherwise used by, the facility for at least 18 months.

  Patient notification was conducted under State Law.

  The TDH will perform unannounced inspections at a reduced interval.

  Date of inspection/adverse action: 6/17/97

  Date of corrective action/reinstatement: 11/25/97

  Status of facility: Performing mammography.

- Westlaco Radiology Center, Inc.
  913 S. Airport Drive
  Westlaco, TX 78596
  Facility ID # 170050

  Adverse action: Other State action: Enforcement Conference.

  Reason for action: An inspection by Texas Department of Health (TDH) representatives determined that this facility failed to document image quality evaluation with phantom specific to mammographic imaging; the supervising physician was not performing the duties of this position as required by the State; failed to perform quarterly audits; failed to cease clinical image processing when the processor analysis control tests limits were exceeded; failed to cease performing mammography after its certification had expired; failed to perform repeat analysis; and numerous other violations.

  Corrective action: Extensive actions were taken by the facility to implement an adequate quality assurance program. The facility attended the Enforcement Conference, and State certification was issued.

  The TDH will perform unannounced inspections at a reduced interval.

  Date of inspection/adverse action: 7/11/97

  Date of corrective action/reinstatement: 8/8/97

  Status of facility: Performing mammography.

How to Find an FDA-Certified Facility

Cancer Information Service. To operate legally, a mammography facility must have and prominently display an FDA certificate. This certificate shows that the facility is meeting baseline quality standards under MQSA. Consumers and health professionals can locate FDA-certified facilities in their geographical area by calling the Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). Information specialists at this number have been trained to answer questions about mammography and breast cancer. Written information on mammography is also available on request.

Internet. The MQSA Internet home page (http://www.fda.gov/cdrh/dmqrp.html) provides a listing of all FDA-certified mammography facilities by selected State (or U.S. territory) and ZIP code.

National Technical Information Service. For a computer diskette containing a complete list of all FDA-certified facilities, contact:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The list is available for a fee on 3 1/2" DOS diskettes in ASCII format.

- To order a single disk, call 1-703-487-4650. The NTIS order number is SUB-5386/Code D01.

- To order a 1-year subscription of the list, updated quarterly, call 1-703-487-4630. The NTIS order number is SUB-5386.