DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

October 1, 1999

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 1998***, which was mandated by Congress in the Mammography 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 1998
- Directions for obtaining a list of FDA-certified facilities by location

You may also find this report, along with other MQSA-related documents, on the FDA mammography website, http://www.fda/gov/cdrh/mammography. Click on "Facilities" and then select "Performance" from the list of choices on the left. To read documents labeled "PDF," you'll need the Adobe Acrobat Reader. If you have not already downloaded this Reader, go to the bottom of the page under "MQSA" and follow the instructions.

If you have any questions regarding this report, send them to Evelyn Wandell by mail to 1350 Piccard Drive (HFZ-240), Rockville, Maryland 10850, or by fax to 301-594-3306.

Sincerely yours,

John L. McCrohan, M.S.
Director
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MAMMOGRAPHY FACILITY PERFORMANCE FOR CALENDAR YEAR 1998

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 MQSA certified, and undergo a yearly inspection.

To meet the congressional mandate that all mammography facilities be certified by October 1, 1994, FDA published interim regulations. On October 28, 1997, FDA published in the *Federal Register* the final mammography regulations that became effective on April 28, 1999.

On October 9, 1998, the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998 was signed into law extending MQSA to 2002. Although MQSRA continued the provisions of the original Act largely unchanged, there were some important additions. As of April 28, 1999, all facilities are required to provide all patients with a written lay-language summary of their mammography report. In addition, MQSRA stipulates that, when requested by patients or their representatives, facilities must provide original – not copies of – mammography films for both temporary and permanent transfer.

As required by MQSA, FDA is providing this report for calendar year 1998. MQSA specifically requires the report to include a list 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 standards of performance, and directions for acquiring a list of MQSA-certified facilities.

MQSA Standards Yielded Immediate Improvements in Mammography Quality

The General Accounting Office (GAO), Congress' oversight body, conducted three staged reports on the effectiveness of the program. In the final report, dated October 21, 1997, the 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.[1]

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.

Fifth Calendar-Year Results Show Continued Improvement in Compliance

By July 5, 1999, a total of 4,687 of the 9,911 fully-certified facilities had been inspected since January 1, 1999. As compared to the first calendar year, inspections of these 4,687 fully-certified facilities show that:

- Sixty-one percent of the facilities inspected performed quality mammography without any violations being noted.
- The number of serious findings dropped from less than 3 percent in 1995 to less than 1 percent.

Facilities Against Which Adverse Actions Were Taken in Calendar Year 1998

<u>Medicare/Medicaid Actions</u>

No medicare or medicaid actions were reported as being taken against facilities 1998.

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

Accreditation Body Actions

The State of California revoked the accreditation of one facility in 1998.

- PRD Radiology Diagnostics, Incorporated of Hemet, CA. When facility mail was returned to the Accreditation Body, an inspector was dispatched to the facility and found it abandoned. The owners cannot be located.

The American College of Radiology (ACR) and the States of Arkansas and Iowa reported no revocations for any facilities in 1998.

FDA Actions

- Community Medical Imaging, Inc. (CMI)
  143 W. 95th Street
  Chicago, IL 60628
  Facility ID # 214007

  Adverse Action: Civil money penalties

  Reason for action: Uncertified operation

  Corrective Action: Facility agreed to pay $30,000. The facility and the president of the facility agreed to remove themselves from the mammography field for five years. In addition, under the settlement, CMI, of Chicago, and its president, will jointly pay $25,000. The facility's supervisory radiologist will pay $5,000.

  Date of inspection/adverse action: 08/21/96

  Date of corrective action/reinstatement: 08/98

  Status of facility: No longer performing mammography

Other FDA Actions

- Adverse Action: Criminal prosecution of an individual

  Reason for action: Clinical image discrepancy and falsification of records for reaccreditation

  Charge: Providing false information to the government

  Result: On 09/18/98, a mammography technologist pled guilty to fraud and was sentenced to two years probation and a $1,000 fine.

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 for this report were taken by the States and U.S. territories under their own legislation. The Agency has included in this listing only 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 5

CALIFORNIA

- Mammographia Denny S. Anspach MD
  920 29th Street
  Sacramento, CA 95816
  Facility ID # 161570

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Personnel qualifications

  Corrective action: Technologist applied for and was issued a certificate

  Date of inspection/adverse action: 7/7/98

  Date of corrective action/reinstatement: 7/17/98

  Status of facility: Performing mammography

- Tower Roxsan Radiology
  465 North Roxbury Drive, Suite 101
  Beverly Hills, CA 90210
  Facility ID # 154146

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Equipment testing, radiation dose: dose exceeded state dose requirement of 200 mRads. Did not exceed 300 mRads

  Corrective action: Radiation dose corrected

  Date of inspection/adverse action: 3/12/98

  Date of corrective action/reinstatement: 3/17/98

  Status of facility: Not performing mammography

- Facey Medical – Canyon Country
  17909 Soledad Canyon Road
  Canyon Country, CA 91351
  Facility ID # 91351

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Equipment testing, radiation dose

  Corrective action: Radiation dose corrected

  Date of inspection/adverse action: 4/8/98

  Date of corrective action/reinstatement: 4/9/98

  Status of facility: Performing mammography

- South Figueroa Radiology
  5260 South Figueroa Street, Suite 106
  Los Angeles, CA 90037
  Facility ID # 197392

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Quality control (QC) program

  Corrective action: Physicist evaluation done

  Date of inspection/adverse action: 9/22/98

  Date of corrective action/reinstatement: 9/24/98

  Status of facility: Not performing mammography

- Lakewood Regional Medical Center
  3700 East South Street
  Lakewood, CA 90713
  Facility ID # 110288

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Lack of State certification

  Corrective action: Applied for and received State certificate

  Date of inspection/adverse action: 9/8/98

  Date of corrective action/reinstatement: 9/18/98

  Status of facility: Performing mammography

- Clinica Medica General – Huntington Park
  6347 Pacific Boulevard
  Huntington Park, CA 90255
  Facility ID # 196154

  Adverse action: Facility license suspension (temporary or permanent)
  Other State action: office hearing (9/10/98)

  Reason for action: Personnel qualifications: physician's State license had expired.
  No QA program.

  Corrective action: Facility acquired and provided all required documentation

  Date of inspection/adverse action: 8/31/98

  Date of corrective action/reinstatement: 9/10/98

  Status of facility: Performing mammography

- Warrack Hospital
  2449 Summerfield Road
  Santa Rosa, CA 94505
  Facility ID # 145664

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Equipment testing, radiation dose

  Corrective action: Photo timer repaired

  Date of inspection/adverse action: 4/29/98

  Date of corrective action/reinstatement: 5/5/98

  Status of facility: Performing mammography

- Los Angeles Metropolitan Medical Center
  2231 South Western Ave
  Los Angeles, CA 90018
  Facility ID # 187856

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Personnel qualifications

  Corrective action: Technologist applied for and was issued a certificate

  Date of inspection/adverse action: 7/28/98

  Date of corrective action/reinstatement: 8/4/98

  Status of facility: Performing mammography

- Imaging Centers of Anaheim – Tan Tran, M.D., Inc.
  1110 West La Palma Avenue, Suite 3
  Anaheim, CA 92801
  Facility ID # 187120

  Adverse action: Facility license suspension (temporary or permanent)

  Reason for action: Equipment testing, phantom
  Lack of quality control (QC) program

  Corrective action: Equipment corrected (8/9/98)
  QA program established (8/6/98)

  Date of inspection/adverse action: 8/6/98

  Date of corrective action/reinstatement: 8/9/98

  Status of facility: Performing mammography

ILLINOIS

- Tiffani Kim Institute
  310 West Superior Street
  Chicago, IL 60610-3516
  Facility ID # 221677

  Adverse action: Restrictions or similar sanctions (10/30/98)
  Enjoined facility from mammography until certified (10/30/98)
  Fines/penalties (civil or administrative) (1123/98)

  Reason for action: Lack of MQSA certification and lack of State certification

  Corrective action: Certified 12/1/98 by ACR per fax
  Civil penalty of $15,000 assessed, reduced to $10,000 per agreed settlement order (5/3/99).

  Date of inspection/adverse action: 10/30/98

  Date of corrective action/reinstatement: 12/1/98

  Status of facility: Performing mammography

NEVADA

- The Elko Clinic
  762 14th Street
  Elko, NV 89201
  Facility ID # 111682

  Adverse action: Fines/penalties (civil or administrative) resulting from 10/15/97 inspection – See *Mammography Facility Performance for Calendar Year 1997*.

  Reason for action: Quality control (QC) program

  Corrective action: Management oversight of QC program
  Fine resulted from period when QC was not being properly conducted prior to the 10/15/97 inspection and was negotiated during 1998. Final fine was $17,000. Facility paid $5,700 on 2/2/99 with $11,300 suspended for 2 years. [Note that at time of 10/15/97 inspection, new QC procedures were in place.]

  Date of inspection/adverse action: 4/97, self discovery of problem by new technologist

  Date of corrective action/reinstatement: 10/15/97

  Status of facility: Performing mammography

- William B. Ririe Hospital
  1500 Avenue H
  Ely, NV 89301
  Facility ID # 172270

  Adverse action: Facility license suspension (temporary or permanent) (3/3/98)
  Fines/penalties (civil or administrative) (5/6/99)

  Reason for action: Lack of State authorization
  Equipment testing, phantom
  Quality control (QC) program

  Corrective action: Facility re-submitted for state certification after initial denial (application denied due to operation without State credential).
  Processor QC program re-established with qualified mammographer under management supervision.
  Management oversight of the program was implemented , including daily oversight of QC program.
  Final fine of $20,000 imposed with $10,000 paid and $10,000 suspended for 2 years.

  Date of inspection/adverse action: 3/3/98

  Date of corrective action/reinstatement: 4/27/98

  Status of facility: Performing mammography

TEXAS

- Best Care Clinic
  4009 Bellaire Boulevard, Suite K
  Houston, TX 77025
  Facility ID # 202853

  Adverse action: Facility license revocation
  Other State action: enforcement conference

  Reason for action: Personnel qualifications
  Quality control (QC) program

  Corrective action: Revocation process began after facility failed to attend enforcement conference. Revocation was aborted after voluntary withdrawal by facility.

  Date of inspection/adverse action: 10/21/98

  Date of corrective action/reinstatement: 5/26/99

  Status of facility: Not performing mammography

- Palo Pinto General Hospital
  400 Southwest 25th Avenue
  Mineral Wells, TX 76067
  Facility ID # 129726

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

  Reason for action: Quality Control (QC) program

  Corrective action: Facility submitted corrective action plan.
  Patient notification was conducted under State law.

  Date of inspection/adverse action: 2/25/98

  Date of corrective action/reinstatement: 4/22/98

  Status of facility: Performing mammography

- Linden Municipal Hospital
  404 North Kaufman Street
  Linden, TX 75563-0032
  Facility ID # 200741

  Adverse action: Other State action: enforcement conference

  Reason for action: Quality control (QC) program

  Corrective action: Facility agreed to corrective action plan.
  Patient notification was conducted under State law.

  Date of inspection/adverse action: 4/22/98

  Date of corrective action/reinstatement: 5/26/98

  Status of facility: Performing mammography

- Parkview Regional Hospital
  312 East Glendale
  Mexia, TX 76667
  Facility ID # 199356

  Adverse action: Other State action: emergency and desist order (2/19/98)
  Remedial or corrective action plan(s) required by State authorities (10/22/98)

  Reason for action: QC program

  Corrective action: Facility submitted corrective action plan (3/17/98). Enforcement conference was called due to findings on follow up inspection.
  Facility agreed to corrective action plan.
  Patient notification was conducted under State law.

  Date of inspection/adverse action: 2/19/98 and 10/22/98

  Date of corrective action/reinstatement: 3/17/98 and 10/22/98

  Status of facility: Performing mammography

- Memorial Mother Francis
  4000 South Loop 256
  P.O. Box 4070
  Palestine, TX 75802
  Facility ID # 151126

  Adverse action: Other State action: enforcement conference

  Reason for action: Quality control (QC) program

  Corrective action: Facility agreed to corrective action plan.
  Patient notification was conducted under State law.

  Date of inspection/adverse action: 7/15/98

  Date of corrective action/reinstatement: 11/20/98

  Status of facility: Performing mammography

- Coulter Imaging L.L.C.
  1900 Coulter, Unit N
  Amarillo, TX 79159
  Facility ID # 179333

  Adverse action: Other State action: emergency cease and desist order (4/20/98)
  Remedial or corrective action plan(s) required by State authorities (5/5/98)

  Reason for action: Equipment testing: phantom
  Quality control (QC) program

  Corrective action: Facility complied with corrective action plan (5/28/98).
  Facility attended enforcement conference and agreed to corrective action plan (5/5/98).
  Patient notification was conducted under State law.

  Date of inspection/adverse action: 4/20/98, 5/5/98

  Date of corrective action/reinstatement: 5/28/98, 5/5/98

  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 FDA Mammography Website, http://www.fda.gov/cdrh/mammography, provides a listing of all FDA-certified mammography facilities by selected State (or U.S. territory) and ZIP code.

National Technical Information Service. The list is available for a fee on 3½" DOS diskettes in ASCII format. For a computer diskette containing a complete list of all FDA-certified facilities, write:

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

or call:

1-800-363-2068
1-703-605-6060

The NTIS order number for a 1-year subscription of the list, updated quarterly is: SUB-5386.

The NTIS order number for a single diskette is: SUB-5386/Code D01.