DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

June 1, 2001

Dear Mammography Quality Advocate:

Under the Mammography Quality Standards Act (MQSA) of 1992, we are required to prepare an annual report of adverse actions taken against mammography facilities. The purpose of the report is to assist health professionals and consumers evaluate the performance of their mammography facilities. The document (attached) is titled "**Mammography Facility Adverse Event Report - 2000."** We encourage you to make this information available to your constituents, especially physicians and the general public.

The report includes the following:

- background information, and
- a list of facilities and individuals against which adverse actions were taken in 2000.

You will find this report, along with other MQSA related documents, on our mammography web site, http://www.fda.gov/cdrh/mammography. Select "Publications," then select "Reports" from the list of choices in the orange box.

If you have any questions about this report, please send them to Patti Hoage at pah@cdrh.fda.gov.

Sincerely yours,

CAPT John L. McCrohan, USPHS
Director
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs
Center for Devices and Radiological Health

Enclosures

MAMMOGRAPHY FACILITY ADVERSE EVENT REPORT - 2000

BACKGROUND

Congress enacted the Mammography Quality Standards Act (MQSA) in 1992, marking the first time mammography facilities were required by the federal government to meet strict quality standards. The intent of MQSA is to assure the quality of mammography nationwide. Mammography can detect breast cancer in its earliest, most treatable stages. Studies show that widespread use of mammography can reduce deaths from breast cancer by one-third. In the fall of 1998, Congress re-authorized MQSA, extending the program to 2002.

Congress charged the Food and Drug Administration (FDA) with implementing and enforcing MQSA. With the help of the National Mammography Quality Assurance Advisory Committee, we developed interim regulations, initiated an inspection program, and issued comprehensive final regulations that became effective on April 28, 1999. The final regulations toughen the 1994 interim standards for personnel, equipment, quality assurance and quality control, and reporting of exam results as well as requirements for accreditation bodies.

Of particular importance to women is the MQSA regulation that requires mammography facilities to give patients an easy-to-read report of the results of their mammogram. Prior to MQSA, mammography facilities were not required to communicate results directly to patients and, instead, sent results only to the referring physician. Referring physicians will continue to receive the results. Self-referred patients with no designated health-care provider will receive both the simplified report and the one doctors normally receive.

MQSA also clarifies a facility's responsibility to retain and transfer mammograms to a patient's physician or to the patient directly, regardless of whether the transfer is permanent or temporary. This is important because it aids diagnosis by allowing doctors to compare old mammograms with new ones.

To help patients understand these and other changes that affect them, we developed and widely distributed a brochure titled "*Mammography Today – Questions and Answers for Patients on Being Informed Consumers*." You can find the brochure on our web site at http://www.fda.gov/cdrh/mammography, select "Consumers," and then select the brochure.

We have been conducting inspections under the final regulations since July 1999. A study of inspection findings shows an increase in serious and moderate non-compliances. However, we are confident that the number of citations will decrease as all of us in the mammography community become more familiar with requirements under the final regulations.

As of April 2001, there were 9,725 MQSA certified mammography facilities operating in the United States. Of these, 9,407 were fully certified. The remaining facilities are provisionally certified and in the process of becoming accredited.

In order to gather data for this report, we consulted with and received reports from the following entities:

- The Inspector General, Health and Human Services (HHS), Health Care Financing Administration (HCFA) for data about fraud, abuse, kickbacks and false billing under Medicare and Medicaid.
- The five MQSA accreditation bodies for reports of revocation of accreditation.
- FDA's Outreach and Compliance Branch, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, Center for Devices and Radiological Health, for actions taken against mammography facilities.
- FDA's Office of Criminal Investigations for criminal prosecution against individuals associated with mammography facilities.
- All States and U.S. territories for actions they have taken against mammography facilities.

MEDICARE/MEDICAID ACTIONS

The HHS Inspector General lists no conviction data under **Medicare** for cases related to mammography facilities in 2000. This includes prosecutions or convictions of mammography facilities under federal or State laws relating to fraud and abuse, false billings or kickbacks.

The HHS Inspector General also reports that no **Medicaid** actions were taken against mammography facilities in 2000.

ACCREDITATION BODY ACTIONS

Each year, we ask all of the accreditation bodies to report if they revoked the accreditation of any facilities accredited by them. Revocation means withdrawal of a facility's accreditation prior to the expiration date for reasons other than voluntary withdrawal by the facility. Currently, there are five FDA-approved accreditation bodies – the American College of Radiology (ACR) and the States of Arkansas, California, Iowa and Texas.

The American College of Radiology reported two revocations for the following facilities:

1. Steven J. Bier, M.D.
   2488 Grand Concourse
   Bronx, New York 10458
   FDA facility ID: 140780

2. Steven J. Bier, M.D.
   New York Diagnostic Medical Services
   102 Park Avenue
   Yonkers, New York 10703

FDA facility ID: 216861

These two facilities are not currently practicing mammography. See the New York section below.

The States of Arkansas, Iowa, and Texas reported no revocations in 2000. At this time, the State of California does not revoke, but rather issues cease and desist orders under State regulations. California issued two such orders. See the California section below.

FDA ACTIONS

MQSA Actions

Women's Mobile Diagnostic, Ltd.
360 Gardner Street
Philadelphia, PA 19116

FDA facility ID:	219956
Adverse action:	Facility continued throughout 2000 to be under a Directed Plan of Correction (DPC) issued on 11/1/99.
Reason for action:	Monitoring of the facility, performed while it was under the DPC, revealed continuing quality control problems, and phantom image problems. FDA requested the American College of Radiology to perform an onsite facility visit, which was performed in April, 2000.
Status of facility:	Performing mammography under a Directed Plan of Correction

FDA's Office of Criminal Investigations

Adverse Action:	Criminal prosecution of an individual Jacquelyn Dearth – Case Closed 12/15/2000.
Reason for action:	Ms. Dearth had been carrying out her duties as a mammography technologist with no license. She forged her state radiological license and her American Registry of Radiologic Technologists (ARRT) card.
Charge:	Title 18 USC, Section 1001 – False Statements.
Result:	The defendant pled guilty and was sentenced to one year of supervised probation.

STATE'S 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.

Adverse actions reported here were taken by States. We included only cases that compare to those that could be the subject of adverse actions under MQSA. A total of eight States reported adverse actions for calendar year 2000.

California

Panorama Diagnostic & Imaging
8121 Van Nuys Boulevard, #111
Panorama City, CA 91402

FDA facility ID: 185082

Adverse action: State issued a Cease and Desist Order.

Reason for action: Failed 3 of 5 mammograms in the additional mammography review ordered by the State of California.

Status of facility: Not performing mammography.

California Breast Care Centers - Mobile
3540 Wilshire Boulevard, #701
Los Angeles, CA 90010

FDA facility ID: 186437

Adverse action: State issued a Cease and Desist Order and a patient/physician notification was conducted.

Reason for action: Failed 5 of 5 mammograms in the additional mammography review ordered by the State of California.

Status of facility: Not performing mammography.

Hawaii

Straub Clinic and Hospital Incorporated - Mililani Clinic
95-1249 Meheula Parkway
Mililani, HI 96789

FDA facility ID: 210955

Adverse action: State served a Notice of Finding and Violation, and financial penalties were imposed.

Reason for action: An MQSA inspection on March 17, 2000, revealed the facility was performing mammography without a valid certificate from September 23, 1999, until March 16, 2000. Hawaii Administrative Rules, Chapter 11-45, Radiation Control, requires all facilities providing mammography services to be FDA certified.

Corrective action: Straub was fined $30,000, $22,500 of which will be held in abeyance as long as Straub complies with three conditions, as follows: 1) submit a corrective action plan specifying management responsibility; 2) submit a written report every six months for three years, to the Department of Health about the compliance status of all mammography facilities under Straub; and that 3) the above conditions be considered under the State "Radiation Facility License" application for Straub Mililani Clinic.

Status of facility: Performing mammography.

Michigan

Contemporary Imaging Associates, P.C.
19900 Haggerty Road, Suite 101
Livonia, MI 48152

FDA facility ID: 108084

Adverse action: Cited for having 1,300 mammography exams read by a physician who was not Board Certified in Radiology during an August 31, 2000, inspection.

Reason for action: A locum tenens (temporary) physician read 1,300 exams from September 1999 to March 2000. Board Certification in Radiology is required by the State.

Corrective action: Facility advised to have all 1,300 exams re-read by a Board Certified radiologist. Notice of corrective action received on October 14, 2000.

Status of facility: Performing mammography.

Missouri

North County Radiology (Dr. Smita Parikh)
11634 West Florissant Avenue
Florissant, MO 63033

FDA facility ID: 155754

Adverse action: State withdrew authorization to perform mammography on May 10, 2000. On May 22, 2000, FDA required facility to conduct a patient/physician notification (PPN).

Reason for action: Facility failed to comply with State requirements for mammographic quality control which affected clinical image quality.

Corrective action: Facility reinstated by State of Missouri to perform mammography on August 10, 2000. Notification by FDA that PPN was completed successfully on November 9, 2000.

Status of facility: Performing mammography.

New Jersey

Union City Diagnostic Center
120-152 48th Street
Union City, NJ 07087

FDA facility ID: 199679

Adverse action: Fines/penalties (civil or administrative).

Reason for action: Facility operated mammography equipment when the quality assurance program did not meet requirements of N.J.A.C. 7:28-15.4(j). This was noted in September 2000.

Corrective action: In compliance with N.J.A.C. 7:28-15.4(J).

Status of facility: Performing mammography.

Women's Health Care Group, PC
870 Palisades Avenue, Suite 305
Teaneck, NJ 07666

FDA facility ID: 154997

Adverse action: Fines/penalties (civil or administrative)

Reason for action: Facility operated mammography equipment when the quality assurance program did not meet requirements of N.J.A.C. 7:28-15.4(j). This was noted in September 2000.

Corrective action: In compliance with N.J.A.C. 7:28-15.4(J).

Status of facility: Performing mammography.

New York

Steven J. Bier, M.D.
2488 Grand Concourse
Bronx, NY 10458

FDA facility ID: 140780

Adverse action: Combined efforts between FDA and New York State resulted in a patient/physician notification. Facility closed by New York State.

Reason for action: Cancer detection rates at this facility were substantially lower than other facilities participating in a CDC/NY State program. The facility failed a film review required by New York State.

Status of facility: Not performing mammography.

Steven J. Bier, M.D.
New York Diagnostic Medical Services
102 Park Avenue
Yonkers, New York 10703

FDA facility ID: 216861

Adverse action: Combined efforts between FDA and New York State resulted in a patient/physician notification. Facility closed by New York State.

Reason for action: Cancer detection rates at this facility were substantially lower than other facilities participating in a CDC/NY State program. The facility failed a film review required by New York State.

Status of facility: Not performing mammography.

South Carolina

Carolina Hospital Systems-Kingstree
500 Nelson Blvd.
Kingstree, SC 29556

FDA facility ID: 175265

Adverse action: State ordered facility to stop performing mammography on February 11, 2000.

Reason for action: Repeatedly failing to comply with Regulation R. 61-64 by performing patient mammograms when quality control (QC) parameters exceeded control limits, failure of the phantom images, failure to perform required QC tests, and failure to maintain records of required QC tests.

Status of facility: Not performing mammography.

Texas

Crystal Woman Foundation
908 Hialeah, Suite C
Seabrook, TX 77586

FDA facility ID: 213694

Adverse action: Assessed an administrative penalty of $10,000. Denial of accreditation on April 28, 2000. Patient/physician notification conducted.

Reason for action: Failure of clinical image review.

Status of facility: Not performing mammography

Doctor's Hospital - Tidwell
510 West Tidwell
Houston, Texas 77091

FDA facility ID: 207167

Adverse action: Placed on increased inspection frequency January 21, 2000, and required to conduct a patient/physician notification.

Reason for action: Facility did not perform processor evaluation and phantom image evaluation from April 13, 1999, through November 22, 1999.

Corrective action: Facility hired a new quality control technologist.

Status of facility: Performing mammography.

Golden Plains Community Hospital
200 South McGee Street
Borger, TX 79007

FDA facility ID: 114124

Adverse action: Placed on increased inspection frequency June 14, 2000, and required to conduct a patient/physician notification.

Reason for action: Quality control program. Operating parameters were not monitored for more than six months.

Corrective action: Placed on increased inspection frequency.

Status of facility: Performing mammography.

Brownsville Medical Center
1040 West Jefferson
Brownsville, TX 78520

FDA facility ID: 181958

Adverse actions: Administrative and financial penalties, August 10, 2000.

Reason for actions:
1) Quality control program (January 27, 2000). Facility failed to monitor performance of the mammography film processor on a daily basis.

2) Two months after they had been reminded to add the unit to their accreditation body record, facility was found operating the unit while it was still not accredited (August 2000).

Corrective action: Added the unit to the accreditation body record. Monitoring film processor performance.

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 a Food and Drug Administration (FDA) certificate or a similar certificate from a State certifying body. This certificate shows that the mammography facility is certified as meeting baseline quality standards for equipment, personnel, and practices under the Mammography Quality Standards Act (MQSA). Consumers and health professionals can locate certified facilities in their geographic 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 documentation on mammography and breast cancer is also available on request.

Internet

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

National Technical Information Service

The list is available on a computer diskette and sold as either a single issue (the most recent diskette) or a subscription (the diskette is updated quarterly).

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

To order a single disk, call 1-800-363-2068. The NTIS order number is SUB-5386/Code D01.