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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

September 2, 2003

VIA FEDERAL EXPRESS
NEXT DAY DELIVERY

FACILITY ID #188771

John Philips, Administrator
Hardy Wilson Memorial Hospital
233 Magnolia Street
P.O. Box 889
Hazlehurst, MS 39083

Warning Letter No. 03-NSV-28

Dear Mr. Phillips:

On August 6, 2003, a representative of the State of Mississippi acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious compromises in the quality of the mammography services offered by this facility. Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Post Inspection Report that the inspector left with the facility at the close of the inspection. The violations are again identified below:

Level 1

The system to communicate results is not adequate for site Hardy Wilson Memorial Hospital because:

- There is no system in place to provide timely lay summaries. [See 21 CFR 900.12(c)(2)(i),(ii).]

Level 2 (Repeat)

Mammograms were processed in processor 1, [redacted], Room X-Ray Department at site Hardy Wilson Memorial Hospital, when it was out of limits on at least 2 but less than 5 days. [See 21 CFR 900.12(e)(1)(i),(ii),(iii).]

Note: Since the second noncompliance is a repeat finding, we have concerns regarding corrective actions that your facility put into place as outlined in a letter from your facility dated August 22, 2002, in which you addressed this same noncompliance found during our inspection of August 6, 2003. To correct this item, it will be necessary that you outline a program of oversight to ensure similar noncompliances will not be found in any subsequent inspections.

In addition, you should address the following Level 2 deficiencies that were also listed on the inspection report:

Level 2

The facility has not specified adequate procedures to be followed for infection control or did not follow them when required at site Hardy Wilson Memorial Hospital. [See 21 CFR 900.12(e)(13)(i), (ii), (iii).]

Corrective actions for processor QC failures were not documented at least once for processor 1, [redacted], Room X-Ray Department at site Hardy Wilson Memorial Hospital. [See 21 CFR 900.12(d)(2).]

There is no designated audit (reviewing) interpreting physician for site Hardy Wilson Memorial Hospital. [See 21 CFR 900.12(f)(3).]

Additionally, it was noted that the mammograms did not have all the required information on the films. [See 21 CFR 900.12(c)(5).]

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at this facility, FDA may take additional actions, including, but not limited to, the following:

- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring,
- seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- Seeking to suspend or revoke your facility's FDA certificate
- Seeking a court injuction against further monography

See 42 USC 263b(h)-(j) and CFR 900.12(j)

It is your responsibility to ensure adherence to each requirement of MQSA and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies as identified and to promptly initiate permanent corrective actions.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violations. Your response should include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

3. sample records that demonstrate proper record keeping (NOTE: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies submitted).

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Mississippi. Should you have questions regarding the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

Sincerely,

Carl E. Draper
Director, New Orleans District

CED:krs

Enclosure: Charles E. Busby letter dated 8/22/02

cc:
State of Mississippi
X-Ray Branch
3150 Lawson Street
P.O. Box 1700
Jackson, MS 39215-1700
ATTN: Jimmy Carson

cc: Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091