

Original PICC 1/21/00 HFI-35



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service M33701

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4500
FAX: 504-253-4566

January 21, 2000

WARNING LETTER NO. 2000-NOL-13

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Robert P. Oliver, M.D.
Chief Radiologist
Delta Regional Medical Center
1400 East Union Street
Greenville, Mississippi 38701

Dear Dr. Oliver:

We are writing to you because on January 12, 2000, your facility was inspected by a representative of the State of Mississippi, acting in behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act of 1992, 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 the following Level 1 finding at your facility:

[REDACTED] (QC) records were missing for eight (8) weeks for unit 2, [REDACTED]

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem has been identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing 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, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

██████████ records were missing two (2) consecutive days for processor 1, ██████████
██████████ and,

Ten random mammography reports reviewed did not contain an assessment category.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations; and,
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control ██████████

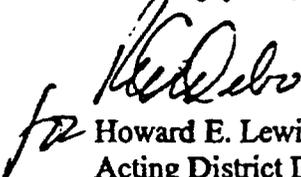
Please submit your response to:

Patricia K. Schafer, Compliance Officer
U.S. Food & Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127
Telephone: (504) 253-4500

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection 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>.

If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Stacy G. Marshall at (504) 253-4554.

Sincerely yours,



Howard E. Lewis
Acting District Director
New Orleans District Office