



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1376d

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

June 8, 2001

Steve Popkin
Chief Operating Officer
East Los Angeles Doctors Hospital
Radiology Department
4060 East Whittier Blvd.
Los Angeles, CA 90023

W/L Number: 53 - 01
Inspection ID: 1926900007
CFN: 20-30,203
FEI: 1000519328

Dear Mr. Popkin:

We are writing to you because on May 22, 2001, your facility was inspected by a representative of the State of California 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 (MQSA), 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:

- Level 1: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 2 months of initial training in the interpretation of mammograms prior to April 28, 1999.

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 is 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 serious 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 and REPEATED Level 3 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 and REPEATED Level 3 findings are:

- Level 2: 5 of 5 random reports reviewed did not have identification of a qualified interpreting physician.
- Level 2: 5 of 5 random reports reviewed did not contain an acceptable assessment category.
- Level 2: The facility has not specified adequate procedures to be followed for infection control or did not follow them when required.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED] (12.5 CME's in 36 months,) met the continuing education

Page Three of Four
June 8, 2001

re: East Los Angeles Doctors Hospital
re: Warning Letter Number 53 - 01

equipment of having taught, or completed at least 15 category 1 continuing medical education units in mammography in 36 months.

- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.

- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.

- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.

- Level 2: The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required.

- Level 2: Medical audit and outcome analysis was not done separately for each individual.

- Level 3: The required personnel qualification documents were not available during the inspection. This is a REPEAT violation.

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
- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
1990 MacArthur Blvd.; suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

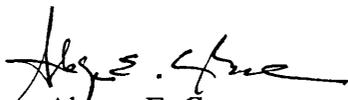
Page Four of Four
June 8, 2001

re: East Los Angeles Doctors Hospital
re: Warning Letter Number 53 - 01

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 content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number 949-798-7708.

Sincerely,



Alonza E. Cruse
District Director

cc:

State of California
Dept. of Health Services
Radiological Health Unit
550 South Vermont Avenue; Suite #601
Los Angeles, CA 90020