DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
93498d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

September 13, 2002

Margo Kaatz, R.N.
Care Center Administrator
The Patricia L. Scheifly Breast Health Center
12393 Washington Blvd.
Whittier, CA 90602-2502

W/L Number: 43 - 02
Inspection ID: 1726190045
CFN: 20-29,916
FEI: 1000519067

Dear Nurse Kaatz:

We are writing to you because on July 29, 2002, your facility was inspected by a representative of the State of California acting on behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b , and the Quality Standards for Mammography set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 and Level 2 findings at your facility:

- Level 1: Phantom quality control (QC) records were missing for the weeks of September 17th , November 19th, and December 3rd of 2001 plus the weeks of January 7th and April 22nd of the year 2002 for unit #2 (a [redacted] machine, model [redacted], serial number [redacted]), which is located in room #1. This is a violation of 21 C.F.R. § 900.12(e)(2).

- Level 1: Phantom QC records were missing for the weeks of September 17th, November 19th, and December 3rd of 2001 plus the weeks of January 7th and April 22nd of the year 2002 for unit #3 (a [redacted] machine, model [redacted], serial number [redacted]), which is located in room #4. This is a violation of 21 C.F.R. § 900.12(e)(2).

- Level 2: Mammograms were processed in processor #1 (a [redacted] machine, model [redacted]), which is located in the darkroom, when it was out of limits on April 29th and April 30th of the year 2002. No second strips were done and patient mammograms were not cancelled for the day. This is a violation of 21 C.F.R. § 900.12(e)(1).

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law that may result in FDA imposing regulatory sanctions. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC) and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek civil money penalties of 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 a court injunction against performing further mammography (see 42 U.S.C. §§ 263b(h) through (j) of the MQSA).

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 receive 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;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; 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
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

re: The Patricia L. Scheifly Breast Health Center
re: Warning Letter Number 43 – 02

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 (telephone number: 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 Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

Alonza E. Cruse
District Director