



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

16954

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

WARNING LETTER

Certified Mail
Return Receipt Requested

August 14, 2001

Brian C. Wilson, M.D.
Bolsa Medical Group
10362 Bolsa Avenue; Suite #110
Westminster, CA 92683

W/L Number: 71 - 01
Inspection ID: 1971030007
CFN: 2030286
FEI: 1000519372

Dear Dr. Wilson:

We are writing to you because on July 16, 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: The system to communicate results is not adequate because there is no system in place to provide timely medical reports. For example, patient number 31441 (mammography conducted on June 14, 2001), there was no report or documentation of a letter being sent to the patient notifying her of the medical results.

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

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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 and a **repeated** Level 3 finding that were listed on the inspection report provided to you at the close of the inspection. These Level 2 repeated Level 3 findings are:

- Level 2: Phantom quality control (QC) records were missing for the weeks of December 8th and December 26th of 2000 for unit #2 (a [REDACTED] machine, model [REDACTED]) which is located in the mammography room. However, mammography was performed on December 4th through 9th and December 18th through 23rd and December 26th of the year 2000.

- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial requirement of having forty (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 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] (zero [0] CME's in thirty-six [36] months) met the continuing education requirement of having taught or completed at least fifteen (15) category 1 continuing medical education (CME) units in mammography in 36 months.

- Level 2: Ten (10) of ten (10) random reports reviewed did not have identification of a qualified interpreting physician.

- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED] (zero [0] CME's in thirty-six [36] months) met the continuing education requirement of having taught or completed at least fifteen (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-six (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 requirement of having forty (40) hours of medical education in mammography prior to 4/28/99.

- Level 2: Medical audit and outcome analysis was not done for the facility as a whole.

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

- Level 2: Medical audit and outcome analysis was not performed annually. No audit had been performed to date of the inspection.

- Level 2: There is no designated audit (reviewing) interpreting physician.

- Level 2: There were no examples of, nor attempts, to get biopsy results.

- Level 2: Failed to produce documents verifying that the radiologic technologist, [REDACTED], met the continuing experience requirement of having performed two hundred (200) mammography examinations 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 initial requirement of having forty (40) hours of medical education in mammography prior to April 28, 1999.

- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED] (zero [0] CME's in thirty-six [36] months) met the continuing education requirement of having taught or completed at least fifteen (15) category 1 continuing medical education units in mammography in 36 months.

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- 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 3: The QA program is inadequate in that the missing or incomplete items are personnel responsibilities (this is a **REPEAT** violation). Additionally, the facility has a new mammography imaging system. There was no current technique chart posted in the mammography room or on the unit. The technique chart remained from the previous unit, but those techniques were not correct for the new [REDACTED] machine, model [REDACTED], serial number [REDACTED] system.

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
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

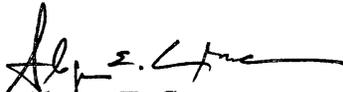
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography 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>.

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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, Region #5
1800 East Lambert; Suite #125
Brea, CA 92821-4370