



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1611d

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

## WARNING LETTER and FINAL CLOSE-OUT LETTER

**Certified Mail**  
**Return Receipt Requested**

August 8, 2001

Richard Finer, M.D.  
Magan Medical Clinic, Inc.  
420 West Rowland Street  
Covina, CA 91723

W/L Number: 70 - 01  
Inspection ID: 1215250008  
CFN: 2029588  
FEI: 1000518850

Dear Dr. Finer:

We are writing to you because on June 18, 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. This inspection revealed that your facility failed to comply with the MQSA as specified in 42 U.S.C. 263b(f) and Title 21, Code of Federal Regulations (CFR), Section 900.12. 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: X-ray unit #2 (an [REDACTED] machine, model [REDACTED], serial number [REDACTED]), located in room #2, has been used clinically for at least a year and is not accredited.

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

Page Two of Three  
August 8, 2001

re: Magan Medical Clinic, Inc.  
re: Warning Letter Number 70 - 01

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, there were Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- 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 24 months.

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

- Level 2: Failed to produce documents verifying that the radiologic technologist, [REDACTED] (12 CEU's in 36 months), met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months.

- Level 2: X-ray unit #3 (an [REDACTED] machine, model [REDACTED], serial number [REDACTED]), located in room #3, is not accredited.

On July 23, 2001, [REDACTED] (Director of Radiology) responded by letter to the noncompliances found during the inspection as referenced in this Warning Letter. Based on her response, your facility has now met the annual MQSA inspection requirement. The corrective action you have implemented will be evaluated during your next inspection.

Although no further communication on this matter is anticipated, if any further response is needed, you may reply to:

Page Three of Three  
August 8, 2001

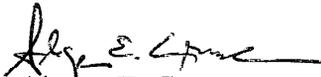
re: Magan Medical Clinic, Inc.  
re: Warning Letter Number 70 - 01

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>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to 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  
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Los Angeles, CA 90020

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