



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

WARNING LETTER

December 6, 2000

Certified Mail
Return Receipt Requested

Paul Belton
Vice President of Compliance
SHARP Chula Vista Imaging Center
752 Medical Center Court, Suite 105
Chula Vista, CA 92010

W/L Number: 11 - 01
Inspection ID: 1619270006
CFN: 20-29,836
FEI: 1000519019

Dear Mr. Belton:

We are writing to you because on October 26, 2000, 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 repeat Level 2 finding, that was listed on the MQSA Facility Inspection Report provided to you at the close of the inspection, is:

- Level 2: The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.

This problem was presented to you because it identifies a failure to meet a significant MQSA requirement. Further, this is a repeat of the same problem noted in your previous inspection.

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.

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re: SHARP Chula Vista Imaging Center
W/L Number: 11 - 01

It is necessary for you to act on this matter immediately.

We are in receipt of a letter sent to the County of San Diego/Department of Environmental Health (dated October 30, 2000) by [REDACTED], M.D. (President & CFO) of San Diego Diagnostic Radiology Medical Group, Inc. The letter explains that Dr. [REDACTED] will complete the required reading of 960 patient examinations prior to December 31, 2000.

Please provide certification and any support documentation that Dr. [REDACTED] has completed the required number of patient examinations as soon as possible and with said certification and documentation being sent to us on or before January 16, 2001. In the interim of Dr. [REDACTED] becoming qualified, please assure that he works under the direct supervision of a MQSA-qualified physician. Additionally, in your response, please include the following:

- if Dr. [REDACTED] is the author of the follow-up response letter/certification and if he is writing on San Diego Diagnostic Radiology Medical Group, Inc. letterhead stationary, please have Dr. [REDACTED] state that he has the authority to speak for Sharp Chula Vista Imaging Center;

- 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).

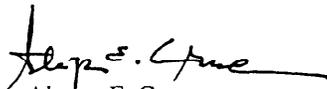
Please submit your response to:

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 (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 Ms Beverly Thomas (MQSA Auditor) at telephone number (949) 798-7708.

Sincerely,


Alotza E. Cruse
District Director