DEPARTMENT OF HEALTH & HUMAN SERVICES

94943d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

August 27, 2004

VIA FEDEX

Re: MQSA Inspection ID # 2311790001

Robin Mitchell, Manager
Center for Comprehensive Medicine
4160 S. Pecos Road # 12
Las Vegas, NV 89106

Dear Robin Mitchell,

On March 23, 2004, a representative of the State of NV, acting in behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA) which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following violations of the MQSA at your facility:

Level 1: The system to communicate results is not adequate for the site Center for Comprehensive Medicine because: There is no system in place to provide timely lay summaries to patients. [21 CFR 900.12(c)].

Level 2: There was no designated audit (reviewing) interpreting physician for the Center for Comprehensive Medicine. [21 CFR 900.12(f)(3)].

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. [21 CFR 900.12(a)(1)(ii)(A)].

Level 2: The interpreting physician [redacted] (0 CME credits in 36 months), did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period. [21 CFR 900.12(a)(1)(ii)(B)].

These violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility. FDA may take additional actions, which may include, but are not limited to, the following:

- Requiring your facility to undergo an Additional Mammography Review;
- Placing your facility under a Directed Plan of Correction;
- Charging your facility for the cost of on-site monitoring;
- Seeking 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;
- Seeking to suspend or revoke your facility's FDA certificate; and
- Seeking a court injunction enjoining further mammography.

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within fifteen (15) working from the date you received this letter. Your response should address the findings listed above and include:

1. The specific steps you have taken to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;
2. The specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and
3. Sample records that demonstrate compliance for the level 2 non-compliances listed. Note: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies of records you submit.

You should also correct the item identified as Level 3 Non-compliance on the facility post inspection report from March 23, 2004.

If your facility is unable to complete corrective action within 15 working days, you should state the reason for the delay and provide a timeframe within which corrections will be completed. Please submit your response to this letter to:

Don A. Leeseberg, Jr., Radiological Health Specialist
United States Food & Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility 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/cdrh/mammography/index.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Don A. Leeseberg, Jr., Radiological Health Specialist at 510-337-6877.

Sincerely yours,

Barbara J. Cassens
District Director

cc:

[redacted]
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