



Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

August 11, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 46

G. Edwin Howe
President
Aurora Health Care, Inc.
3030 West Montana Avenue
Milwaukee, Wisconsin 53215

Dear Mr. Howe:

We are writing to you because an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the mammography at your facility, CHAI Bayshore, Inc. (a.k.a. Bayshore Diagnostics, Bayshore Clinical Labs, ACL), 5757 West Oklahoma Avenue, Milwaukee, WI.

Under Federal law [the Mammography Quality Standards Act of 1992 (MQSA)], your facility is required to have a valid FDA MQSA certificate to perform mammography. Only facilities that have applied to an approved accreditation body and either (1) are being evaluated for accreditation by that body or (2) have been accredited by that body are entitled to a certificate. The accreditation process is a necessary requirement of the law for every facility that performs mammography. This process helps to protect the health of women by ensuring that a facility can perform quality mammography.

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The evidence collected by the FDA shows that your facility performed mammography without a valid FDA MQSA certificate, which is a violation of 42 U.S.C. 263b(b)(1). Your facility also failed to comply with quality assurance standards established under 42 U.S.C. 263b(f). These violations occurred over a three-year period from October 1994 until October 1997.

Performing mammography without a valid certificate is a violation of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, assessing civil money penalties up to \$10,000 or obtaining a court injunction against further mammography.

During FDA's investigation, Kenneth Jaglinski, Director of Sales and Marketing, stated that CHAI Bayshore would no longer perform mammography. If you have any other facilities that are operating without a valid FDA certificate you must inform FDA and cease such operations or apply for accreditation within 15 days.

We acknowledge that you have sent notification letters to the physicians for women who received mammograms at CHAI Bayshore between May 1994 and October 1997.

It is necessary for you to act on this matter immediately. Please inform this office in writing within 15 working days from the date you received this letter whether you have ceased performing mammography and how you plan to prevent these violations from recurring. Please submit your response to Acting Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

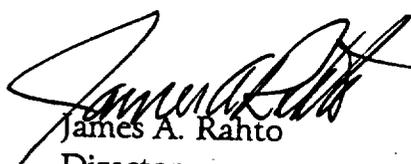
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to the issue of the performance of mammography under a valid FDA MQSA certificate and does not necessarily address other obligations you have under the law. You may obtain general 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 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 Mr. Philips.

Sincerely,


James A. Rahto
Director
Minneapolis District

JAR/ccl

xc: Dennis T. Rakowski
President
Aurora Health Care Ventures, Inc.
3030 West Montana Avenue
Milwaukee, WI 53215

Kenneth Jaglinski
Director of Sales and Marketing
CHAI Bayshore, Inc.
5757 W. Oklahoma Avenue
Milwaukee, WI 53219