DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 13, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 – 38.

Jeff K. Meyer
Chief Executive Officer
Osceola Medical Center
301 River Street, P.O. Box 218
Osceola, Wisconsin 54020

Dear Mr. Meyer:

On July 26, 2002, a representative of the State of Wisconsin acting on behalf of the Food and Drug Administration (FDA), inspected your facility (FDA Certificate #129262). 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. Based on the documentation your site presented at the time of the inspection, the following Level 1 non-compliance was documented at your facility:

Level 1 Non-Compliance

The system to communicate results is not adequate for the Osceola Medical Center site because there is no system in place to provide timely written lay summaries to **all** mammography patients within 30 days of their examination. Patient notification must be in writing.

Title 21, Code of Federal Regulations, Part 900.12(c)(2) states: Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall

make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

The lack of a system to ensure timely lay summaries was noted on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action against your facility. 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, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

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 the violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- 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 submitted copies.)

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI, 53226-1305.

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/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements or about the content of this letter, please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

James A. Rahto
Director
Minneapolis District

TWG/ccl

xc:

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