



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service M5235n

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

March 2, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 223153

John O. Simmons, M.D., C.E.O.
Columbia Regional Medical Center, L.L.C.
1114 West 7th Street
Columbia, TN 38401

Quayle
3/5/01
JEL

Warning Letter No. 01-NSV-16

Dear Dr. Simmons:

Your facility was inspected on February 23, 2001 by a representative of the State of Tennessee on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

The system to communicate results is not adequate for site Columbia Regional Medical Center, L.L.C. because:

There is no system in place to provide timely lay summaries.

Note: Lay summaries for mammograms are not being provided for or sent to patients recommended for biopsy.

This specific deficiency appeared on the Post Inspection Report which was sent to your facility by the state inspector along with instructions on how to respond to this finding. This deficiency may be symptomatic of a serious problem that could limit information being provided to patients in a timely manner.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these identified deficiencies and to promptly initiate permanent corrective actions.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.

Columbia Regional Medical Center, L.L.C.
John O. Simmons, M.D., C.E.O.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of any similar violation.

If your facility is unable to complete this corrective action within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to Paula Richardson, State of Tennessee. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:KRS:man

cc: State of Tennessee
Nashville Environmental Assistance Center
Department of Radiological Health
711 R.S. Gass Boulevard
Nashville, TN 37216
ATTN: Paula Richardson

Dept. Of Environment and Conservation
2700 Middlebrook Pike, Suite 220
Knoxville, TN 37921
ATTN: Darlene Nalepa-Whitmill

Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191