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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
Nashville Branch Office
Plus Park Blvd.
Nashville, TN 37217

Telephone: 615/781-5380
Facsimile: 615/781-5391

August 25, 2003

VIA FEDERAL EXPRESS
OVERNIGHT DELIVERY

FACILITY ID #117226

Jeri Underwood, CEO
Parkridge Medical Center, Inc., dba East Ridge Hospital
941 Spring Creek Road
East Ridge, TN 37412

Warning Letter No. 03-NSV-26

Dear Ms. Underwood:

An inspection of your facility was conducted on August 14, 2003, by a representative of the State of Tennessee acting on behalf of the U.S. Food and Drug Administration (FDA). This inspection revealed serious compromises in the quality of the mammography services offered by this facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, 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 recent inspection at this facility revealed the following Level 1 finding:

Level 1

Phantom QC records were missing for at least 4 weeks for unit 2, [redacted], DMR+, Mammo Room 1. [See 21 CFR 900.12(e)(2)(i)-(iv).]

This specific deficiency noted above appeared on the MQSA Post Inspection Report which was given to this facility by the state inspector along with instructions on how to respond to this finding. Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at this facility, it represents a 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 Direct 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 MQSA standards, seeking suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography. [See 42 U.S.C. §263b(h)-(j) and 21 CFR 900.12(j).]

In addition, you should address the following Level 2 deficiency that also was listed on the inspection report:

Level 2

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, [redacted], DMR+, Mammo Room 1. [See 21 CFR 900.12(c)(2)(i),(ii).]

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

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 violations. Your response should include:

- The specific steps you have taken to correct the Level 1 and Level 2 violations as outlined in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record-keeping procedures relating to quality control or any other records that are appropriate to the noncompliance finding (NOTE: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies submitted).

If your facility is unable to complete these corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections 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 the State of Tennessee. Should you have questions regarding the technical aspects of this letter or concerning MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

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.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director, New Orleans District

CED:krs