



HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: CFN 1124257
Facility ID: 147108
Inspection ID# 471080007

Public Health Service

m4123n
Food and Drug Admin.
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-3591
FAX: (410) 962-3321

July 5, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John Lowder, M.D., Head Physician
Winchester Women's Specialists
1870 Amherst Street
Suite 2-E
Winchester, Virginia 22601

Dear Dr. Lowder:

Your facility was visited on June 20, 2000 by a representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving mammography performed 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 public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

The system your facility has in place to communicate patient results is inadequate, in that it does not provide timely lay summaries (results to patients and referring physicians within 30 days of the date of the examination) or communicate serious or highly suggestive cases as soon as possible (results to patients and referring physicians within 5 days).

This problem is identified as a Level 1 finding because it identifies a failure to comply with significant MQSA requirements.

The following Level 2 findings were also cited during the inspection:

Your facility has no written procedure in place for handling consumer complaints.

During a random review of mammography reports, 9 of 10 reports did not contain an assessment category.

John Lowder, M.D.
Page 2
July 5, 2000

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent violations 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 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, MQSA 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 receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Nancy L. Rose
Compliance Officer

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 may 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>.

If you have specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely yours,



Lee Bowers
District Director

John Lowder, M.D.

Page 3

July 5, 2000

cc: Fred Gorisch, Radiation Safety Specialist
Bureau of Radiological Health
Division of Health Hazards Control
Department of Health
Main Street Station
1500 East Main, Room 240
Richmond, Virginia 23219

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091