



DEPARTMENT OF HEALTH & HUMAN SERVICES

m3071n

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

October 15, 1999

WARNING LETTER NYK 2000-01

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Lucille Sheedy, CEO  
Wyoming County Community Hospital  
400 North Main Street  
Warsaw, New York 14569

RE: Facility ID Number 202762

Dear Ms. Sheedy:

Your facility was inspected on September 17, 1999 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration (FDA). 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, 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 inspection revealed the following Level 1 finding at your facility:

- ***The medical physicist [REDACTED] did not meet the alternative initial requirement of being licensed or approved by a state or certified by an FDA-recognized board.***

The inspector reports that the medical physicist made application to the state of Pennsylvania for approval but had not received approval as late as September 30.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Wyoming County Community Hospital

Page 2

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your 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 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; and/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 that you receive this letter:

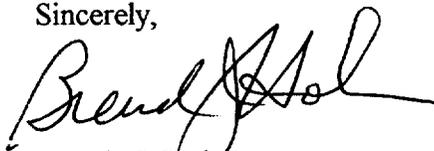
- the specific steps you have taken to correct the violation noted in this letter;
- each step your facility is taking to prevent the recurrence of a similar violation.

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

Finally, you should understand 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, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

If you have any questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,



Brenda J. Holman  
District Director