



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

98-PHI-07

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

December 9, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Bulger
President and Chief Executive Officer
Jeannette District Memorial Hospital
600 Jefferson Ave.
Jeannette, PA 15644

GEN.	SPEC.
RELEASE	
F# _____	DATE _____
Reviewed by: <i>Wm. W. Kumpf</i>	

Facility ID: 174128

Dear Mr. Bulger:

On November 26, 1997, an investigator from the Food and Drug Administration (FDA) visited your satellite facility, Norwin Healthcare Center, 12279 Rt. 30, North Huntingdon, PA 15642, and collected information that revealed a serious regulatory problem involving the mammography operations at this facility. Under a Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility is required to have a valid FDA MQSA certificate to perform mammography. Only facilities that have applied to an approved accreditation body and either 1) are being evaluated for accreditation by that body, or 2) have been accredited by that body are entitled to a certificate.

The accreditation process is a necessary requirement of the law for every facility that performs mammography. This process helps to protect the health of women by ensuring that a facility is qualified to perform quality mammography. The evidence collected by the FDA shows that your satellite facility performed mammography without a valid FDA MQSA certificate.

The original FDA MQSA Certificate for Norwin Healthcare Center, expired on September 18, 1997. Our investigator found that this facility performed mammography examinations after this date and without a valid certificate or Interim Notice on the following days, 9/26,29/97, 10/7,9,16,21/97, and 11/4,5,11,12/97. Approximately [redacted] patients were given mammography exams during this time period.

Performing mammography without a valid certificate is 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, assessing civil Money penalties up to \$10,000 or obtaining a court injunction against further mammography.

FDA became aware of this situation during an MQSA inspection of Jeannette District Memorial Hospital by an inspector from the State of Pennsylvania. This inspector was planning to inspect Norwin Healthcare Center on November 14, 1997, however he noticed that their FDA Certificate had expired on September 18, 1997. He advised Ms. Jan Casale, Medical Imaging Manager, to stop performing mammography at Norwin. Norwin Healthcare Center applied for an "Interim Notice" from FDA on 11/14/97 and received it on November 19, 1997. This Interim Notice was needed because the ACR had not completed review of Norwin's application for reaccreditation.

The ACR has subsequently completed their review of Norwin's application for reaccreditation and sent them a letter indicating that Norwin was granted accreditation for an additional three years till November 19, 2000. Norwin's new FDA Certificate is forthcoming and will expire on December 19, 2000.

Please inform this office in writing within fifteen (15) working days from the date you receive this letter, **of the specific steps you will take to assure that in the future your facility will only perform mammography examinations when you are in possession of a valid FDA MQSA Certificate.** Please submit your response to:

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

Finally, you should understand that there are other FDA requirements pertaining to mammography. This letter pertains only to the issue of the performance of mammography under a valid FDA MQSA certificate 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/dmqrp.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Robert E. Davis at 412-644-3394.

Sincerely,



Diana Kolaitis
District Director
Philadelphia District

cc: Jim Potter
Director, Government Relations
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