DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

CIN WL –02-13124-0
April 9, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Robert Prichard
Senior Executive Officer
Alliance Primary Care
3200 Burnet Ave.
1 Ridgeway
Cincinnati, OH 45219

RE: Alliance Primary Care Diagnostic Center
350 Thomas More Parkway, Suite 200
Crestview Hills, KY 41017
MQSA Facility I.D.#: 221255

Dear Dr. Prichard:

Ms Julie Keightley, a representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected the above-mentioned facility on March 20, 2002. The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) 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 violation of Section 354(f) of the Act, 42 U.S.C. § 263b(f), at your facility (identified on your inspection report):

Quality Assurance – *Equipment* – (21 CFR 900.12(e)(2))

Your records showed that your facility processed mammograms when the phantom quality control records were missing during eight consecutive weeks of operation in December 2001 and January 2002.

The inspection revealed that during the weeks of December 10-14, 17-21, (24, 26-28), 2001, December 31, 2001, January 2-4, 2002, January 7-11, 14-18, 21-25 and January 28-February 1, 2002, your facility did not perform the required weekly quality control tests on the mammography unit used to perform mammography.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, this violation of the law may result in FDA taking regulatory action(s) without further notice to you. Regulatory 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 performing further mammography. (See Sections 354(h) through (j) of the Mammography Quality Standards Act of 1992, 42 U.S.C. §§ 263b(h)-(j)).

You must act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

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

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please **send a copy** to the State radiation control office:

Ms. Julie Keightley
Commonwealth of Kentucky
Radiation Control
275 East Main St.
Frankfort, KY 40621

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 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.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
KY/JKeightley

Ms. Laura Kruthoffer
Manager
Alliance Primary Care Diagnostic Center
350 Thomas More Parkway
Suite 200
Crestview Hills, KY 41017

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Program
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