



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 5, 2000

REF: NYK-2000-03

Facility ID: 184259

Allen H. Kapit, M.D.
Radiologist
Manhattan Physician's Group, PC
4337 Broadway
New York, NY 10033

Dear Dr. Kapit:

Your facility was inspected on September 13, 2000 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. 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 system to communicate results is not adequate for your facility because:*
 - (a) *There is no system in place to provide timely medical reports;*
 - (b) *There is no system in place to provide timely lay summaries; and*
 - (c) *There is no system in place to communicate serious or highly suggestive cases as soon as possible.*

The specific problem noted above appeared on your MQSA Facility Inspection Reports 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.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, 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, or obtaining a court injunction against further mammography.

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There were also Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings were:

- (1) The radiologic technologist, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period.*
- (2) Your facility tracking system did not include all positive mammograms.*
- (3) There were no examples nor attempts to get biopsy results for your facility.*

It is necessary for you to act on these matters immediately. Please explain 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;
- each step your facility is taking to prevent the recurrence of similar violations; and
- sample records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our 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>.

Sincerely yours,



Robert L. Hart
Acting District Director
New York District

Manhattan Physicians Group, PC
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cc: Priscilla F. Butler, M.S.
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American College of Radiology
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cc: Dorothy Pender
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