DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

December 12, 2002

VIA FEDERAL EXPRESS

Sidney Wolinsky, President
Primary Care Plus
5085 Morganton Road
Suite 100
Fayetteville, NC 28314

Inspection ID # 2236620003

WARNING LETTER
(03-ATL- 8)

Dear Mr. Wolinsky:

Your facility was inspected on November 5, 2002, by a representative of the North Carolina Department of Environment and Natural Resources (DENR), Division of Radiation Protection, acting on behalf of the United States Food and Drug Administration (FDA). This inspection revealed a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, 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 recent inspection at your facility revealed the following Level 1 and Level 2 findings:

Level 1 Noncompliance:

- The system to communicate results is not adequate because there is no system in place to provide timely lay summaries. Lay letters are not provided for "incomplete" assessments. [21 CFR § 900.12(c)(2)]

- Your facility failed to produce documents verifying that the interpreting physicians, [redacted] and [redacted] met the initial requirement of holding a valid state license to practice medicine. [21 CFR § 900.12(a)]

- Your facility failed to produce documents verifying that the interpreting physicians, [redacted] and [redacted] met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 3 months of initial training in the interpretation of mammograms. [21 CFR § 900.12(a)]

- Your facility failed to produce documents verifying that the radiologic technologist, [redacted], met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body. [21 CFR § 900.12(a)]

Level 2 Noncompliance:

- Your facility has not specified adequate procedures to be followed for infection control or did not follow them when required. [21 CFR § 900.12 (e)(13)]

- Your facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required. [21 CFR § 900.12(h)]

- Medical audit and outcome analysis has not been evaluated by the medical audit reviewer for the year 2000. [21 CFR § 900.12 (f)]

- Your facility failed to produce documents verifying that the interpreting physicians, [redacted], and [redacted] (0 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category I continuing medical education units in mammography in 36 months. [21 CFR § 900.12(a)]

- Your facility failed to produce documents verifying that the interpreting physicians [redacted] and [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months. [21 CFR § 900.12(a)]

- Your facility failed to produce documents verifying that the interpreting physicians, [redacted] and [redacted], met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months. [21 CFR § 900.12(a)]

- Your facility failed to produce documents verifying that the interpreting physicians, [redacted] and [redacted], met the initial requirement of having 60 hours of category I medical education in mammography. [21 CFR § 900.12(a)]

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These conditions represent 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 (DPC), charging your facility for the cost of on-site monitoring, seeking civil money penalties, suspending or revoking your facility's FDA certificate, or seeking 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 after receiving 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;
- Sample records that demonstrate proper recordkeeping procedures, if the noncompliance relates to quality control or other records. **(Note: Patient names or identification should be deleted from any copies submitted.)**

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and time within which corrections will be completed. Please send the original copy of your response to: Serene A. Kimel, Compliance Officer, U.S. Food and Drug Administration, 60 8th St., NE Atlanta, GA 30309. You should also send a copy of your response to the North Carolina DENR, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609-7221 and to Thomas Clarida, U.S. Food and Drug Administration, 5701 Executive Center Drive, Suite 104, Charlotte, NC 28212.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter concerns only the findings of your recent 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/index.html.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas Clarida at 704-344-6116.

Sincerely yours,

Dawn L. Todd-Murrell

Dawn Todd-Murrell, Acting Director
Atlanta District

Cc: [redacted]