



M34731

PURGED

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

February 14, 2000

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 19

George C. Halverson
Chief Executive Officer
HealthPartners, Inc.
8100 - 34th Avenue
Minneapolis, Minnesota 55440

Dear Mr. Halverson:

On February 2, 2000, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA) inspected your HealthPartners, Inc.—Arden Hills Medical Center facility, 3930 Northwoods Drive, Arden Hills, MN (inspection ID #1149910005). This inspection revealed serious regulatory problems involving the performance of 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. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-Compliance:

1. On six days during the past year your HealthPartners, Inc.—Arden Hills Medical Center site processed mammograms through a film processor *M6B, 6AN, 6AW* when the quality control limits were exceeded. Federal regulation requires that no mammography (clinical) films be processed through an out-of-control film processor.

Page Two

George C. Halverson
February 14, 2000

Level 2 Non-Compliances:

2. There is no written procedure for handling mammography consumer complaints at HealthPartners, Inc.—Arden Hills Medical Center site. See Title 21, Code of Federal Regulation, Part 900.12(h)(1)(2)(3)(4) [21 CFR 900.12(h)(1)(2)(3)(4)] for specific requirements.
3. There is no written procedure for mammography infection control at your HealthPartners, Inc.—Arden Hills Medical Center site. See 21 CFR 900.12(e)(13)(i), (ii), and (iii) for specific requirements.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious 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, the Standards, suspension or revocation of your facility's FDA certificate, 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 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, FDA, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

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, FDA, P.O. Box 6057,

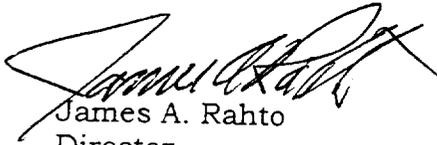
Page Three

George C. Halverson
February 14, 2000

Columbia, MD 21045-6057 (1-800-838-7715) or through the internet at
<http://www.fda.gov/cdrh/mammography/index.html>.

If you have specific questions about mammography facility requirements or about
the content of this letter please feel free to call Mr. Garvin at (414) 771-7167
ext. 12.

Sincerely,



James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: Stuart J. Poljack, M.D.
Accreditation Body Contact
HealthPartners Inc.—Arden Hills Medical Center
3930 Northwoods Drive
Arden Hills, MN 55112

Sue McClanahan
Supervisor, Section of Radiation Control
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, VA 22091