



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

m35301

MAR 10 2000

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

Certified Mail  
Return Receipt Requested

Paulette A. Shaw, Director, Imaging Services  
KPC Medical Management, Inc.  
9500 N. Haven Avenue  
Rancho Cucamonga, CA 91730

**W/L 40-00**  
**Inspection ID: 1878310006**

Dear Ms. Shaw:

We are writing to you because on 12/07/1999, your facility U.S. Family Care, 27555 Ynez Road, Suite 300, Temecula, CA 92612, was inspected by a representative of the state of California, acting in behalf of the Food and Drug Administration (FDA). This 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 level 1 finding at your facility:

**Phantom QC records were missing for 6 weeks for unit 1, Bennett X-Ray Corp., 150G, room Mammo Room**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received 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 facility, 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 performing further mammography.

In addition, there were two level-2 findings that were listed on the inspection report provided to you at the close of the inspection. These level-2 findings are:

- 1. 3 of 10 random reports reviewed did not contain an assessment category for site U.S. Family Care.**
- 2. There was no designated reviewing interpreting physician for site U.S. Family Care.**

On January 17, 2000 you responded to the listed level-1 and level-2 above. Based on your response, we considered that your explanations and corrective actions were acceptable. The corrections you have implemented will be evaluated during your next inspection.

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/dmgrp.html> <<http://www.fda.gov/cdrh/dmgrp.html>>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely yours,

  
Acting District Director