

DIAGNOSTIC CLINIC

Main Office: 1551 West Bay Drive, Largo, FL 33770 9164 '00 MAR 29 110:50
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March 15, 2000

Docket No. 99D-4910, Dockets Management Branch
Division of Management Systems & Policy
Office of Human Resources & Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA- 305)
Rockville, MD 20852

RE: CFR 900.12 (b)(8)(i)

I wish to express my concern over the proposed requirement for fine adjustment compression controls operable from both sides of the patient.

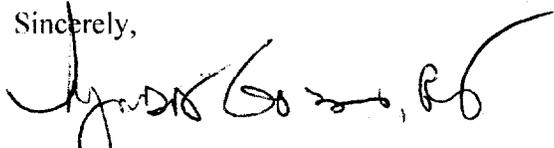
As I see it there are at least two very good reasons this proposed legislation should not be passed in the final regulation:

First, quality is always our first consideration. This proposed requirement does not effect the quality of the mammograms. I have one machine with the capability and two without. There is no difference in the images produced that would result in the enhancement of the interpretation, nor would it help in the diagnosis of any more breast cancers.

Second, as everyone is aware in order to survive in the healthcare industry it is necessary to find ways to reduce the cost of delivering that care. Purchasing equipment at a cost of approximately \$75,000 a unit for one item is not a cost-effective measure. If the quality were a proven issue or the safety of the patient was an issue then the cost would be justified. But I don't see where either of those points has been proven.

Please consider all points when determining the final regulation. I would appreciate being contacted with your final decision at: Diagnostic Clinic 1551 West Bay Drive, Largo, FL 33770

Sincerely,



Lynda Goins, R.T. (R)
Imaging Clinical Administrator

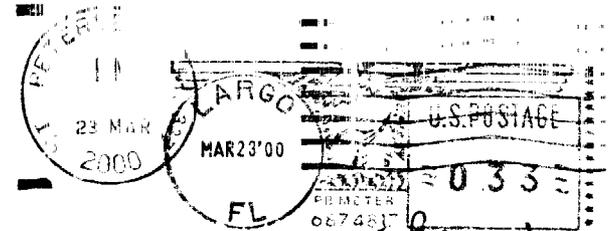
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RETURN SERVICE REQUESTED
Radiology



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FOOD AND DRUG ADMINISTRATION
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