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June 15, 2000

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To Whom It May Concern:

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This letter is an official comment to the U. S. Food and Drug Administration's (FDA) proposed regulations, State Certification of Mammography Facilities, 21 CFR Parts 16 and 900, Docket No. 99N-4578. This proposed regulation was printed in the Federal Register Volume 65, No. 62, on March 30, 2000. My main issue with the proposed regulations is the **\$509 FDA proposes to charge facilities in certifying states and the faulty Analysis of Impacts.**

First, I believe that **FDA does not have the statutory authority to charge the \$509 to facilities in certifying states.** The Mammography Quality Standards Act, paragraph R, authorizes the collection of **fees to cover the cost of inspections only.** The analysis states that the \$509 is to cover **inspection-related costs** that the FDA will incur. These inspection-related costs are identified as training for inspectors, calibration of their equipment, and functions related to the transfer of information. These activities are not part of the inspection and FDA can not legally charge for them considering that all inspection activities will be performed by the states. The collection of information is required by a separate portion of the Act, is not tied to inspections, and the cost of which was supposed to be covered by appropriations. This fee could not withstand a challenge in the courts. The FDA calls the \$509 an inspection support fee. Inspection support fees are not authorized in the Act.

The Analysis of Impacts does not include a justification or accounting to show that the \$509 is accurate and justified. When the first discussions of the States as Certifiers (SAC) were held, personnel with the FDA stated the they would need to get thirty to forty percent of the current fees to maintain their program. At the time, they could not provide figures to justify the amount. It's not coincidental that the \$509 represents 30% of the current fee. After almost three years of asking for documentation of the actual costs to support this amount, we still get the same answer, "the detail analysis has not been done, yet." Surely in three years, this information could have been generated. This makes one think that they must be

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June 15, 2000

hiding something. Shouldn't the justification for this amount be included in the Analysis of Impact.

The Analysis of Impact makes numerous assumptions that are erroneous, inaccurate and incomplete. All scenarios assume that current and past costs will, at a minimum, remain the same. This is not true. FDA costs will be reduced in SAC states because they will not be issuing certificates, corresponding with facilities and accreditation bodies, reviewing inspection findings, or performing enforcement activities to name a few. This reduction of activities was not accounted for in the FDA inspection-related fee, nor was it accounted for when discussing state costs. The states will have an increased cost for performing the above mention functions and this increase was not included in their analysis. The assumption that \$509 is an accurate figure is also flawed. The basis for this figure is all costs expended to date. The cost figures used included start-up cost. This covered training for the whole nation as well as equipment costs for these inspectors. It also covered software development. The training cost has dropped significantly and should remain at this reduced level because only replacements will need training. The equipment will only need to be replaced at intervals, resulting in annual costs significantly lower than equipping the entire country at one time. Software development should be close to zero today. The analysis stated that all fees are based on the national average. This has resulted in states with lower costs supporting states with higher costs and facilities in the lower costs' states shouldering an unfair proportion of the fees.

As stated previously, the FDA inspection support fee covers training of inspectors, calibration of their equipment, and functions related to the transfer of information. It has already been noted that information transfer is not related to inspections, but to the maintenance of a national data base, therefore it should not be included. Our state can pay for training and equipment calibration for much less than \$509 per facility. Our figures for these activities are less than \$200 per facility. I would prefer this approach since it would lower the costs for these facilities and reduce the cost of health care.

The approach the FDA is taking is unprecedented with regards to state and federal relations. I know of no other case where a federal program has been delegated to the states where the federal program still assesses the facilities in the states a fee, especially when that federal program is providing these facilities with no direct service. I strongly suggest that the FDA lobby Congress for additional appropriations for funding these non-inspection activities or lower the staffing level since their workload will decrease.

The primary reasons for states to assume the certification of mammography facilities are to reduce the regulatory burden on facilities, provide better and more timely service, and most importantly, to reduce the cost of health care. The \$509 assessment by the FDA will result in no cost reduction and as stated could and probably will result in higher costs. This is contrary to the statement in the Analysis of Impact section that their proposal complies with Executive Order 12866 and the

June 15, 2000

Regulatory Flexibility Act. This definitely does not minimize the impact of the rule on small entities. The claim that the \$509 fee is not an unfunded mandate may be technically correct but it is definitely an unauthorized and unjustified tax.

In summary, the \$509 fee to mammography facilities in SAC states is grossly unfair and unprecedented. The authority to collect this fee is very questionable and the amount has never been justified. It was arrived at by back calculating. The assumptions and methods used in the analysis are severely flawed. The numbers have never been justified or documented. It appears the \$509 figure was preset over three years ago based on what was needed to support current staffing levels. These staffing levels and workloads will be significantly less after the states take over the certification duties. If it is FDA's desire to maintain current staffing levels as well as fund these non-inspection related activities, I strongly urge them to seek additional appropriations. I am amazed that the federal accountants, lawyers, and Congress have accepted this proposal.

I appreciate the opportunity to comment on this issue. I look forward to the official response. If anyone has any additional questions, I can be reached at 803-737-7403 or by e-mail at okelletp@columb54.dhec.state.sc.us.

Sincerely,



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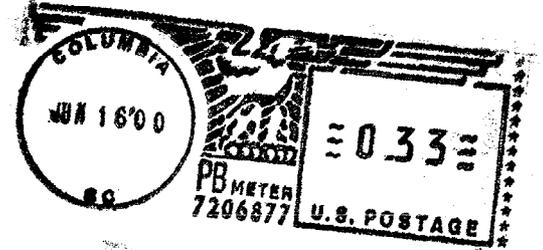


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