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**RE:** FDA National Mammography Quality Advisory Committee review of the Institute of Medicine recommendation report for the Reauthorization of the Mammography Quality Standards Act (MQSA)

I appreciate the opportunity to submit a statement for review and consideration by the FDA concerning the IOM Committee's recommendations for improving MQSA. For over 9 years, I have practiced as a clinical breast radiologist subspecializing in the early detection and diagnosis of breast diseases.

Listed below are issues that need to be reviewed and addressed by both the FDA and IOM Committees, as you prepare recommendations for reauthorization of the Mammography Quality Standards Act (MQSA).

## **I. Interpreting Physician Performance Standards**

If the intent of screening mammography is to reduce the mortality and morbidity of breast cancer, then early interruption of the disease is paramount. Over the past 100 years, we have seen advances in surgical techniques that have significantly improved patient morbidity but not mortality. Likewise, we now have chemo and hormonal therapies that have allowed moderate improvement in patient mortality. However, it is the advent of early detection and diagnosis, which interrupts breast cancer early in its natural history, that has resulted in the greatest reduction in mortality from breast cancer. Since the initiation of MQSA, we have seen improvements in the technical aspects of screening mammography given the standards required for certification. However, even if we have the best equipment, x-ray film-screen systems, technologists, quality assurance programs, and viewing condition but lack high-quality interpretation of the screening mammograms, we severely limit the potential of early detection.

This is clearly demonstrated in the randomized, clinical trials for screening mammography as tumor size and stage at detection drives subsequent mortality rates. In order to assure high-quality interpretation, a performance audit must be obtained, reviewed, and action taken when deficiencies are noted. A screening mammography interpretation performance audit should include:

- 1) Average size (mean and median size) of the screen detected invasive carcinoma for women participating in 12-or-24 month screening intervals;
- 2) Total screening volume/year;
- 3) Recall rate; and
- 4) Positive predictive value for BIRADS™ 4 and BIRADS™ 5 categories.

In order to help achieve acceptable screening mammography performance standards, radiology residency and breast imaging fellowship training as well as post-graduate training programs that properly instruct high-quality screening interpretation are critical. Although there are many mammography/breast-imaging programs offered for CME each year, unfortunately many simply do not provide the type of education that will allow direct improvement in screening mammography interpretive skills.

## **II. Interpreting Physician Performance Standards and Patient Access**

Many will argue that if the physician performance standards are set to ensure a high standard of care, then access to women in many communities will be lost as many general radiologists may not be able to achieve and/or maintain the required standards. This issue can and has been successfully addressed by other countries to include Sweden and United Kingdom. Although the total number of screening mammograms interpreted per year may serve as a surrogate performance marker, items 1), 3), and 4) listed above provide an objective measure of performance. If inappropriately low interpreting physician performance standards are set by MQSA to simply afford greater access, mortality rates will likely not be reduced and overall cost of care will increase. Reasonable and preferably high interpreting physician performance standards need to be instituted.

An exemplary model of post-graduate training success can be found by examining the interpreting physician performance improvements achieved by private practice ((X-Ray Associates of New Mexico) radiologists in Albuquerque, NM (Linver et al. *Radiology* 184:39-43, 1992; Linver MN, *Seminars in Breast Disease*, 6(3):128-132, 2003). Similar models of post-graduate training with proven success need to become a fundamental part of physician CME for screening mammography/breast imaging.

On a similar issue, communities and medical institutions of sufficient size should strive toward creating interdisciplinary breast care teams, which help provide improved overall care, efficient use of resources, and substantial reduction in medical costs (enclosure 2).

## **III. Breast Ultrasound Examination and Procedures: Establishing a Universal Training and Accreditation Standard**

With the use of screening mammography, the majority of breast cancers are initially detected in the pre-clinical phase (i.e., non-palpable). However, other imaging modalities, especially breast ultrasound, are frequently used in the diagnostic evaluation of the screen detected abnormalities

to further segregate which patients may require a biopsy for definitive tissue diagnosis. Given the advancement in training and technology, most breast biopsies can be performed under image-guidance to include ultrasound and stereotactic-guided breast biopsies. In 1996, through the joint efforts of the American College of Radiology (ACR) and American College of Surgery (ACS), we have the stereotactic-guided breast biopsy accreditation, but which remains under voluntary accreditation. However, breast ultrasound and ultrasound-guided breast biopsies have multiple guidelines and accreditations from various institution and agencies to include the ACR, ACS, American Society of Breast Surgeons (ASBS), and American Institute of Ultrasound in Medicine (AIUM). **Both the FDA and IOM committee members need to investigate why there are multiple and varied physician training guidelines and accreditations for breast ultrasound examinations and procedures.** The FDA and IOM should insist on a single, universal standard for ultrasound examination and procedure training guidelines and accreditations so that multiple standards are not propagated. Even amongst radiologists, there is a wide disparity of performance and interpretation for breast ultrasound (Baker JA. Soo MA. *Radiology* 223(1):229-238, 2002). A universal accreditation program will help ensure that not only mammography but also other breast imaging examinations and procedures meet an acceptable MQSA standard for accreditation. If the FDA and/or IOM through the MQSA does not require and enforce a universal practice standard for breast ultrasound examinations and procedures, then the 'qualification' for breast ultrasound will simply fall to whomever can afford the equipment regardless prior training and performance level.

In the very near future, universal standards and accreditation should also be established for breast MRI and imaging-guided breast tumor ablation.

#### **IV. Future Radiology Staffing for Breast Care**

Although not directly related to MQSA, a major issue to be considered is the dwindling number of radiologists and training residents that have a desire to provide mammography/breast imaging services. The relatively low reimbursement rates and high exposure to malpractice litigation must be addressed and appropriate incentives need to be provided to prevent radiologists from abandoning mammography/breast imaging services. Creative solutions to include providing graduated re-imburement rates for mammography/breast imaging services based on physician performance and creating a balanced, knowledgeable national committee to review and arbitrate medical malpractice suits along with placing caps on punitive damages (tort reform) will be important.

Should you have questions or need additional information, please contact me. Appreciate your review and consideration of my recommendations.