

Mammographers: Take Notice

Information on a Regulation Update by the Food and Drug Administration

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ON MARCH 10, 2023, the Food and Drug Administration issued updates to mammography regulations that, among other changes, included a requirement for facilities to notify patients and providers about patients' breast density. The new rule adds to the Mammography Quality Standards Act.

The Centers for Disease Control and Prevention defines breast density as "the amount of fibrous and glandular tissue in a woman's breasts compared with the amount of fatty tissue in the breasts, as seen on a mammogram." According to the CDC, about half of all women are estimated to have heterogeneously dense or extremely dense breast tissue, the two categories considered to be dense breasts. The new regulations will require facilities to inform providers *and* patients if patients' breasts are "dense" or "not dense."

Even though mammography is considered the gold standard for breast cancer screenings, cancer can be masked in images of patients with dense breasts. Along with making early detection more difficult, having dense breast tissue is a risk factor for the development of breast cancer.

This notification change will enhance the FDA's ability to communicate directly with providers and patients, empowering them to make the best decisions about their care, according to a statement from the FDA.

Breast density reporting requirements have been implemented state by state since 2009. However, several states have minimal to no requirements for reporting breast density. The new regulation will standardize reporting and provide patients with more consistent information, according to JoAnn Pushkin, executive director of densebreast-info.org, a website dedicated to resources about breast density and why it matters in breast cancer screenings.

"This change will affect all facilities, whether they currently have density reporting or not," she said. "It will be new for states that don't report and will change reporting for those that have existing state laws."

She added that this amendment to the MQSA regulations has been a lengthy advocacy battle that's gone on for almost two decades. However, the change doesn't address additional tests that may be necessary for certain individuals at greater risk for breast cancer. That's why she is focusing her advocacy efforts on the proposed Find It Early Act, which would provide health coverage with no cost-sharing for those additional breast screenings. More information on the act is available at densebreast-info.org.

Other new regulations issued by the FDA in March:

- Assist interpreting physicians to better assess and categorize mammograms.
- Strengthen requirements related to the medical outcomes audit.
- Improve requirements for the retention and transfer of patient images and personnel records.

These updates aim to enhance the quality of all mammography programs. The changes in regulations will go into effect in September 2024. They are intended to modernize the MQSA rules by combining best practices in mammography and current science to improve breast cancer detection. The FDA states it will enhance oversight of mammography facilities, including in the key areas of enforcement and patient communication.

For more information on the regulation changes to breast density reporting, join the ASRT Live® presentation, "New FDA Policy on Breast Density," on Oct. 12 at noon Central time. Learn more and register for the webcast at asrt.org/ASRTLIVE. §



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numerous to name here.