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**Effective September 10, 2024 Final Rule to Amend the Mammography Quality Standards Act (MQSA)**

On March 10, 2023, the FDA issued the final rule to amend the MQSA regulations. Facilities subject to the MQSA must comply with all applicable requirements, including the breast density notification, no later than September 10, 2024.

<https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/important-information-final-rule-amend-mammography-quality-standards-act-mqsa>

Regarding the California Health and Safety Code (HSC), Section 123222.3(b)(3), if a facility abides by the FDA breast density requirements, the CA specific breast density notification is not required as it is inconsistent with FDA MQSA requirements. The Radiologic Health Branch, RHB, will not be citing facilities that abide solely by the FDA dense breast notification requirements prior to September 10, 2024.

California Health and Safety Code Section 123222.3

(a) A health facility at which a mammography examination is performed shall, if a patient is categorized by the facility as having heterogeneously dense breasts or extremely dense breasts, based on the Breast Imaging Reporting and Data System established by the American College of Radiology, include in the summary of the written report that is sent to the patient, as required by federal law, the following notice:

Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer.

This information about the results of your mammogram is given to you to raise your awareness and to inform your conversations with your doctor. Together, you can decide which screening options are right for you. A report of your results was sent to your physician.

(b)(1) This section shall not be deemed to create a duty of care or other legal obligation beyond the duty to provide notice as set forth in this section.

(2) This section shall not be deemed to require a notice that is inconsistent with the provisions of the federal Mammography Quality Standards Act (42 U.S.C. Sec. 263b) or any regulations promulgated pursuant to that act.

(c) This section shall remain in effect only until January 1, 2025, and as of that date is repealed.

