



RI Department of Health
Three Capitol Hill
Providence, RI 02908-5097

March 12, 2024

TTY: 771
www.health.ri.gov

Susan R. Donovan, Chair
House Committee on Health and Human Services
State House
82 Smith St.
Providence, RI 02903

RE: H 7734 – An Act Relating to Health and Safety – Dense Breast Notification and Education

Dear Chair Donovan:

Please accept this letter concerning H 7734, legislation that would amend the notice requirement to patients to follow the mandated US Food and Drug Administration (FDA) national reporting standards following a mammogram. Although the Rhode Island Department of Health (RIDOH) applauds the intent of this legislation, it proposes amendments (see attachment).

FDA's Division of Mammography Quality Standards is the federal government agency tasked with oversight of the regulations/requirements of the Congressionally enacted *Mammography Quality Standards Act (MQSA)*. *MQSA* authorized the FDA to develop standards that would be enforced through strict accreditation, certification, and inspection of equipment and personnel at mammography facilities. Inspection and enforcement of federal requirements under *MQSA* are exclusively the domain of the FDA. FDA's final rule regarding the new standards will be implemented no later than September 10, 2024. The following link includes the new FDA rule and relevant information (<https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/important-information-final-rule-amend-mammography-quality-standards-act-mqsa>).

RIDOH has already notified mammography facilities in Rhode Island about the new FDA rule. At that time, all FDA *MQSA* inspections will be conducted with the expectation that these requirements are met. The ambiguity and variance of the application of Rhode Island's current requirements from facility to facility have been, at times, challenging for facility administrators and physicians. FDA's final rule regarding breast density notification should provide clarity to this matter. Similarly, RIDOH's proposed amendments to H 7734 also provide clarity regarding dense breast notification by requiring facilities to include the federally mandated reporting standard for language in the patient notification notice.

Thank you for the opportunity to comment on this legislation.

Sincerely,

A handwritten signature in blue ink, appearing to read "Utpala Bandy" followed by "for".

Utpala Bandy, MD, MPH
Interim Director

CC: The Honorable Members of the House Committee on Health and Human Services
The Honorable Rebecca M. Kislak
Nicole McCarty, Chief Legal Counsel
Lynne Urbani, Director of House Policy

H 7734 – RIDOH Proposed Amendments
(RIDOH's proposed amendments are in green font)

It is enacted by the General Assembly as follows:

SECTION 1. Section 23-12.9-2 of the General Laws in Chapter 23-12.9 entitled "Dense Breast Notification and Education" is hereby amended to read as follows:

3 23-12.9-2. Public policy goals — Department of health.

~~(a)~~ The department of health, ~~through the Rhode Island Cancer Council~~, is authorized and mandated to implement the following public health policy goals as they relate to dense breast notification in Rhode Island. ~~Commencing on October 1, 2014, a~~All healthcare facilities that perform mammography examinations shall include in the summary of the mammography report to be provided to a patient by mail, electronically, or otherwise, information that identifies the patient's individual ~~Breast Tissue Classification based on the Breast Imaging Reporting and Data System established by the American College of Radiology~~ breast density as mandated by the U.S. Food and Drug Administration. ~~If the~~ ~~(b)~~ The facility ~~determines that a patient has heterogeneously or extremely dense breasts, the summary of the mammography report shall also include the following notice:~~

~~"Your mammogram indicates that you have dense breast tissue. Dense breast tissue is relatively common and is found in about forty percent (40%) of women. The presence of dense tissue can make it more difficult to detect cancers in the breast by mammography because it can hide small abnormalities and may be associated with an increased risk. Hence, you may benefit from supplementary screening tests, which may include a breast ultrasound screening, or a breast MRI examination, or both, depending on your individual risk factors.~~

~~We are providing this information to raise your awareness of this important factor and to encourage you to discuss your dense breast tissue, as well as other breast cancer risk factors, with your healthcare provider. Together, you can decide which screening options are right for you. A report of your results was sent to your physician. You should contact your physician if you have any questions or concerns about this report."~~

~~(1) IF NOT DENSE: "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer.~~

~~Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."~~

~~(2) IF DENSE: "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."~~

~~(c) A written report from the facility to referring providers shall include assessment of breast density, classified as one of the following:~~

- ~~(1) The breasts are almost entirely fatty;~~
- ~~(2) There are scattered areas of fibroglandular density;~~
- ~~(3) The breasts are heterogeneous dense, which may obscure small masses; or~~
- ~~(4) The breasts are extremely dense, which lowers the sensitivity of mammography.~~

22 SECTION 2. This act shall take effect upon passage.