

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 614

INTRODUCER: Senator Harrell

SUBJECT: Mammography Reports

DATE: March 3, 2023

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Brown	HP	Pre-meeting
2.			RC	

I. Summary:

SB 614 removes the statutory repeal date in s. 381.933, F.S., relating to mammography reports so that this section of statute does not sunset on June 30, 2023.

Section 381.933, F.S., enacted in the 2018 Legislative Session, requires a facility that performs mammography to send a summary of the patient's mammography report to the patient. If a facility determines that a patient has heterogeneously or extremely dense breasts, the summary must include a specific notice to raise the patient's awareness of dense breast tissue. The statute will be repealed on June 30, 2023, unless otherwise saved from repeal.

The act shall take effect upon becoming a law.

II. Present Situation:

What is dense breast tissue?

Dense breast tissue refers to the appearance of breast tissue on a mammogram. It is a normal and common finding.¹

Breast tissue is composed of milk glands, milk ducts and supportive tissue (dense breast tissue), and fatty tissue (non-dense breast tissue). When viewed on a mammogram, women with dense breasts have more dense tissue than fatty tissue. On a mammogram, non-dense breast tissue appears dark and transparent. Dense breast tissue appears as a solid white area on a mammogram, which makes it difficult to see through.

¹ The Mayo Clinic: Dense Breast Tissue: What it means to have dense breast tissue, last updated February 25, 2022; available at: <https://www.mayoclinic.org/tests-procedures/mammogram/in-depth/dense-breast-tissue/art-20123968> (last visited February 28, 2023).

The radiologist who analyzes the mammogram determines the ratio of non-dense tissue to dense tissue and assigns a level of breast density. Levels of density are described using a results reporting system called Breast Imaging Reporting and Data System (BI-RADS). The levels of density are often recorded in a mammogram report using letters. The levels of density are:

- A: Almost entirely fatty indicates that the breasts are almost entirely composed of fat. About 10 percent of women have this result.
- B: Scattered areas of fibroglandular density indicates there are some scattered areas of density, but the majority of the breast tissue is non-dense. About 40 percent of women have this result.
- C: Heterogeneously dense indicates that there are some areas of non-dense tissue while the majority of the breast tissue is dense. About 40 percent of women have this result.
- D: Extremely dense indicates that nearly all of the breast tissue is dense. About 10 percent of women have this result.

In general, women with breasts that are classified as heterogeneously dense or extremely dense are considered to have dense breasts. About half of women undergoing mammograms have dense breasts.

Reporting to Patients

Thirty-nine states require notification concerning dense breasts, while 29 states mandate specific language for such notifications.²

Section 381.933, F.S., relating to mammography reports was enacted in 2018. It defines “facility,” “mammography,” and “mammography report” to comport with the definitions in the Federal Food and Drug Administration’s (FDA) federal regulations under the Mammography Quality Standards Act.

Subsection (2) of this statute requires a facility that performs mammography to send a summary of the patient’s mammography report to the patient. Also, if a facility determines that a patient has heterogeneously or extremely dense breasts, the summary must include a specific notice to raise the patient’s awareness of dense breast tissue. This notice must state:

Your mammogram shows that your breast tissue is dense. Dense breast tissue is relatively common and is found in approximately 50 percent of women. The presence of dense breast tissue can make it more difficult to detect some abnormalities in the breast and may also be associated with an increased risk of breast cancer. This information about the result of your mammogram is given to you to raise your awareness. A report of your results was sent to your health care provider. Further recommendations may be added at the discretion of the interpreting radiologist. Please be aware that additional screening studies may not be covered by your insurance.

² Dense Breast-info: Comparative Analysis of State Density Inform Efforts and Insurance Coverage, revised October 10, 2022; available at: https://densebreast-info.org/wp-content/uploads/2022/12/Table.laws_ALPHA_10.9.22.copyright.pdf (last visited February 28, 2023).

The law provides that it does not create a duty, standard of care, or other legal obligation beyond the duty to provide notice as set forth in this subsection. The law further provides that it does not require a notice that is inconsistent with the federal Mammography Quality Standards Act or any regulation promulgated pursuant to that act.

The FDA has initiated a proposed regulation to, among other things, address reporting to patients identified with dense breasts.³ The proposed regulation was published on March 18, 2019, and a recent report indicated a final rule might be available in December, 2022; however, a final rule has not been published as of this writing.⁴

III. Effect of Proposed Changes:

SB 614 repeals the sunset of s. 381.933, F.S., found in subsection (3) of that section, and thereby retains in Florida law the requirement for a facility that performs a mammography to provide a summary of a mammography report to the patient, as provided under current law.

No changes are made to the statute as it currently exists, other than striking the repeal date.

The act takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

³ See: 84 FR 11669, 11685. Available at: <https://www.govinfo.gov/content/pkg/FR-2019-03-28/pdf/2019-05803.pdf> (last visited February 28, 2023).

⁴ See: RIN: 0910-AH04, Publication: Fall 2022, available at: <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0910-AH04> (last visited February 28, 2023).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.933 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.