

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/CS/HB 1059 Mammography Reports

**SPONSOR(S):** Health & Human Services Committee, Healthcare Regulation Subcommittee, Casello

**TIED BILLS:** IDEN./SIM. **BILLS:** SB 614

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	16 Y, 0 N, As CS	Speas	McElroy
2) Health & Human Services Committee	21 Y, 0 N, As CS	Speas	Calamas

### SUMMARY ANALYSIS

Breast cancer is one of the most common cancers in women, second only to skin cancer. In 2019, Florida recorded 3,084 breast cancer deaths out of approximately 44,800 total cancer deaths. Additionally, in 2019, more than 19,000 new breast cancer cases were diagnosed out of roughly 134,350 total new cancer cases.

Mammography is the most common screening test for breast cancer. A mammogram is an x-ray of the breast. Federal law requires mammogram facilities to send each patient a summary of the mammogram report written in lay terms within 30 days of the mammographic examination.

Approximately half of women over the age of 40 in the U.S. have dense breast tissue. Breast density refers to ratio of fatty tissue to glandular tissue (milk ducts, milk glands, and supportive tissue) on a mammogram. A dense breast has less fat than glandular and connective tissue. Dense breast tissue can make cancers more difficult to detect on a mammogram. Additionally, dense breasts have been identified as a risk factor for developing breast cancer.

Florida law currently requires each mammography facility to send a summary of a patient's mammography report, which meets federal requirements, to each patient. If the patient has dense breasts, the facility must include a notice to the patient that the mammogram shows that the patient's breast tissue is dense which makes it more difficult to detect some abnormalities in the breast and may also be associated with increased risk of breast cancer. This law stands repealed on June 30, 2023.

CS/CS/HB 1059 extends the repeal of the notification requirement from June 30, 2023, to September 10, 2024.

The bill does not have a fiscal impact on state or local government.

The bill becomes effective upon becoming law.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Background

#### **Breast Cancer**

Breast cancer is one of the most common cancers for women in the nation, second only to skin cancer.<sup>1</sup> In 2019, Florida recorded 3,084 breast cancer deaths out of approximately 44,800 total cancer deaths.<sup>2</sup> Additionally, in 2019, more than 19,000 new breast cancer cases were diagnosed, compared to the 136,347 total new cancer cases<sup>3</sup> diagnosed and reported to the statewide cancer registry.<sup>4</sup>

Risk factors for developing breast cancer include:

- Being a woman;
- Getting older;
- Inheriting certain gene mutations, including BRCA1 and BRCA2;
- Having changes in other genes;
- Having a family history of breast cancer;
- Having a personal history of breast cancer;
- Being certain races and ethnicities;
- Having dense breast tissue;
- Having certain benign breast conditions;
- Starting menstruation before age 12;
- Going through menopause after age 55;
- Having radiation to your chest; and
- Having exposure to diethylstilbestrol (DES).<sup>5</sup>

#### Breast Cancer Screening

Health care providers typically use three tests to screen for breast cancer: mammogram, clinical breast exam<sup>6</sup> and MRI (magnetic resonance imaging) in women with a high risk of breast cancer.<sup>7</sup>

Mammography is the most common screening test for breast cancer.<sup>8</sup> A mammogram is an x-ray of the breast.<sup>9</sup> Mammograms may find tumors that are too small to feel and may also find ductal carcinoma in situ (DCIS), abnormal cells in the lining of a breast duct, which may become invasive cancer in some

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<sup>1</sup> National Cancer Institute, *Breast Cancer-Patient Version (Overview)*, <https://www.cancer.gov/types/breast> (last visited March 3, 2023).

<sup>2</sup> Department of Health, Florida Statewide Cancer Registry, *Florida Annual Cancer Report: Number of Cancer Deaths by County, Florida, 2019*, [https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport2019/Table\\_No\\_T16\\_\(2019\).pdf](https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport2019/Table_No_T16_(2019).pdf), (last visited March 3, 2023).

<sup>3</sup> Department of Health, Florida Statewide Cancer Registry, *Florida Annual Cancer Report: Number of New Cancer Cases by Sex and Race, 2019*, <https://fcds.med.miami.edu/inc/publications.shtml>, (last visited March 3, 2023).

<sup>4</sup> See at <https://www.floridahealth.gov/diseases-and-conditions/cancer/cancer-registry/index.html>, (last visited March 3, 2023).

<sup>5</sup> American Cancer Society, *Breast Cancer Risk Factors You Cannot Change*, <https://www.cancer.org/cancer/breast-cancer/risk-and-prevention/breast-cancer-risk-factors-you-cannot-change.html>, (last visited March 3, 2023).

<sup>6</sup> A clinical breast exam is an exam of the breast by a doctor or other health professional. The doctor will carefully feel the breasts and under the arms for lumps or anything that seems unusual. National Cancer Institute, *Breast Cancer Screening*, <https://www.cancer.gov/types/breast/patient/breast-screening-pdq> (last visited March 3, 2023).

<sup>7</sup> National Cancer Institute, *Breast Cancer Screening (Patient Version)*, <https://www.cancer.gov/types/breast/patient/breast-screening-pdq>, (last visited March 3, 2023).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.* Federal law and regulations specifically define mammography as a radiographic image of the breast produced through mammography. 42 U.S.C. §263b(5) and (6); 21 CFR 900.2.

women.<sup>10</sup> Women 50 to 69 years of age who have screening mammograms have a lower chance of dying from breast cancer than women who do not have screening mammograms.<sup>11</sup>

There are two types of mammograms. A screening mammogram is used to check for breast cancer in individuals who have no signs of cancer or symptoms of the disease.<sup>12</sup> A screening mammogram usually captures two or more X-ray pictures of each breast. The second type of mammogram is a diagnostic mammogram, which is used to check for breast cancer after a lump or another sign or symptom of cancer has been identified. Besides a lump, other signs of breast cancer can include breast pain, thickening of the skin of the breast, nipple discharge, or a change in breast size or shape; however, these may also be signs of benign conditions.<sup>13</sup> Early detection of breast cancer with screening mammography allows for treatment to begin earlier in the course of the disease, possibly before it has spread.

### *Breast Density and Mammograms*

The United States Preventive Services Task Force (USPSTF)<sup>14</sup> recommends that women age 50 to 74 with no signs of breast cancer have a mammogram screening every two years. USPSTF recommends women younger than age 50 talk with their health care providers about the risks and benefits of whether to have mammograms and how often.<sup>15</sup> In 2020, the National Cancer Institute reported that approximately 73 percent of women in Florida aged 40-plus and 79 percent aged 50 to 74 had a mammogram within the past two years, both percentages that either met or exceeded the national averages.<sup>16</sup> Current evidence is insufficient to assess benefits and harms of mammograms for women age 75 and older.<sup>17</sup>

Breast density refers to ratio of fatty tissue to glandular tissue (milk ducts, milk glands, and supportive tissue) on a mammogram.<sup>18</sup> A dense breast has less fat than glandular and connective tissue. Along with making a mammogram harder to read, dense breasts are also a risk factor for breast cancer.<sup>19</sup> Mammograms are less likely to detect breast tumors in women younger than 50 years old.<sup>20</sup> This may be because younger women have denser breast tissue, which appears white on a mammogram. Because tumors also appear white on a mammogram, tumors they can be harder to find among dense breast tissue.<sup>21</sup> Approximately half of women over the age of 40 in the U.S. have dense breast tissue.<sup>22</sup>

### Mammography Regulation

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<sup>10</sup> Supra, footnote 6.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> The United States Preventive Services Task Force (USPSTF) is an independent, volunteer group of national experts in prevention and evidence-based medicine. The Task Force makes evidence-based recommendations about clinical preventive services, such as screenings, counseling services, and preventive medicines. Each recommendation receives a letter grade (A, B, C, or D or an I statement) based on the strength of the evidence and the balance of the benefits and harms of the preventive service. The recommendation applies only to people who have no signs or symptoms of the specific disease or condition, and address only services offered in the primary care setting or services referred by a primary care physician. The USPSTF is administratively supported by the Agency for Healthcare Research and Quality (AHRQ) and must make an annual report to Congress. See <https://www.uspreventiveservicestaskforce.org/Page/Name/about-the-uspstf>, (last visited March 3, 2023).

<sup>15</sup> U.S. Preventive Services Task Force, U.S. Preventive Services Task Force Issues Final Recommendations on Screening for Breast Cancer (January 12, 2016), [www.uspreventiveservicestaskforce.org/Home/GetFile/6/250/breastcanfinalrsbulletin/pdf](https://www.uspreventiveservicestaskforce.org/Home/GetFile/6/250/breastcanfinalrsbulletin/pdf), (last visited March 3, 2023).

<sup>16</sup> As of 2020, approximately 73 percent of women nationwide aged 40-plus and 78 percent aged 50 to 74 had a mammogram within the past two years. National Cancer Institute, *Florida State Profile*, <https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statername=florida#t=1>, (last visited March 23, 2023).

<sup>17</sup> Supra, footnote 21.

<sup>18</sup> The American Society of Breast Surgeons Foundation, *Breast Density Legislation*, <https://breast360.org/en/topics/2017/01/01/breast-density-legislation/> (last visited March 3, 2023).

<sup>19</sup> Supra, footnote 4.

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> FDA, News Release, *FDA Updates Mammography Regulations to Require Reporting of Breast Density Information and Enhance Facility Oversight*, <https://www.fda.gov/news-events/press-announcements/fda-updates-mammography-regulations-require-reporting-breast-density-information-and-enhance>, March 9, 2023 (last visited March 14, 2023).

## *Federal Standards*

The federal Mammography Quality Standards Act (MQSA)<sup>23</sup> contains requirements for the accreditation and operation of mammography facilities. The MQSA defines facility as a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including operating equipment to produce a mammogram, processing the mammogram, interpreting the initial mammogram, and maintaining the viewing conditions for that mammogram.

A certificate issued by the Food and Drug Administration (FDA) is required for all mammography facilities, subject to the provisions of the MQSA. To obtain a certificate, facilities must meet various quality standards set forth in federal law and regulations, including the requirement to communicate mammography results to patients and health care providers.<sup>24</sup>

The MQSA requires mammogram facilities to send each patient a summary of the mammogram report written in lay term within 30 days of the mammographic examination. However, if the assessment is found to be “suspicious” or “highly suggestive” of malignancy, “the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.”<sup>25</sup>

### *Breast Density Notification - Federal Regulation*

In March 2023, the FDA released a final rule<sup>26</sup> which updates mammography regulations issued under the MQSA and the Federal Food, Drug, and Cosmetic Act (FD&C Act). The rule is set to become effective September 10, 2024. One of the major updates to regulations under the MQSA requires facilities to provide information to patients regarding the density of their breasts.

The rule requires that the summary of the mammography report, written in lay terms and often referred to as the “lay summary,” identifies to the patient whether the patient has “dense” or “not dense” breast tissue and includes a prescribed paragraph on the significance of breast density.<sup>27</sup>

The rule also establishes four categories for reporting breast tissue density in the mammography report that is provided to the patient's referring healthcare provider.<sup>28</sup> FDA's oversight and enforcement<sup>29</sup> of facilities will strengthen with the amended regulations, so that physicians can better categorize and assess mammograms.

### *Breast Density Notification – State Regulation*

As of January 2023, 38 states, including Florida, and the District of Columbia require some level of breast density notification after a mammogram.<sup>30</sup> Some states require only general notification, and others require that a patient be informed about her own breast density. The components of those notification laws vary, but the intent of the notification is to give women who have dense breasts the necessary information to assist them with further action.<sup>31</sup> Most states' prescribed notices encourage women to talk with their health care providers about their results and to discuss available options.

## **Breast Density Notification Laws by State<sup>32</sup>**

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<sup>23</sup> 42 U.S.C. § 263b.

<sup>24</sup> 21 C.F.R. § 900.12(c)(2) and (3).

<sup>25</sup> *Id.*

<sup>26</sup> Food and Drug Administration, *Final Rule*, <https://www.govinfo.gov/content/pkg/FR-2023-03-10/pdf/2023-04550.pdf>, March 10, 2023, (last visited March 20, 2023).

<sup>27</sup> *Id.* at 15126.

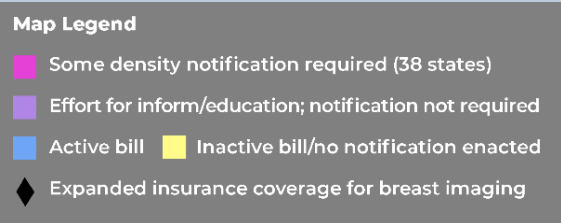
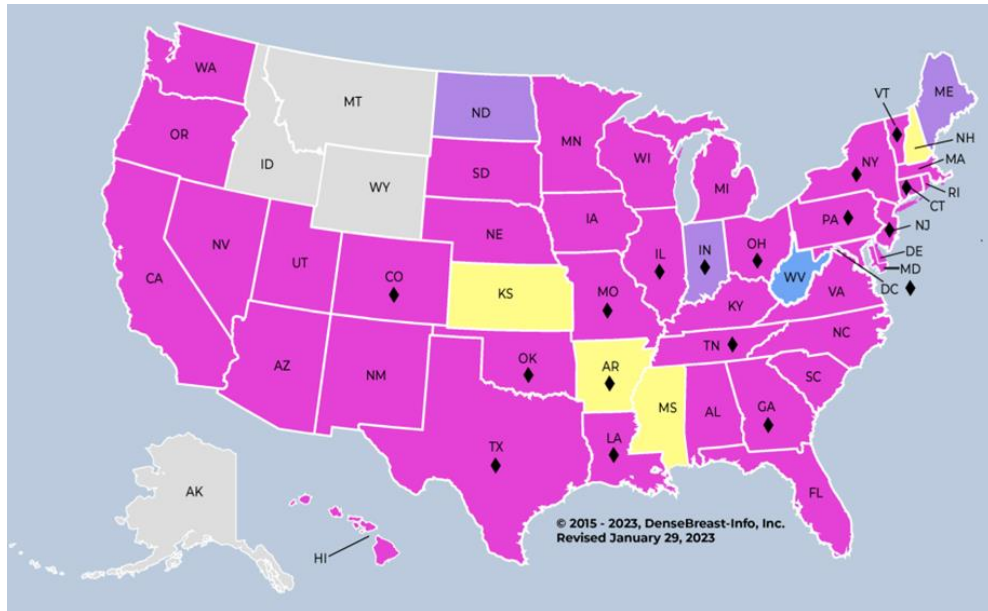
<sup>28</sup> *Id.*

<sup>29</sup> FDA considers 18 months to be a reasonable amount of time for facilities to achieve compliance with the new rule's requirement. *Id.* at 15134.

<sup>30</sup> *Supra*, footnote 18.

<sup>31</sup> Marijke Vroomen Durning, *Diagnostic Imaging, Breast Density Notification Laws by State – Interactive Map* (June 12, 2017), <http://www.diagnosticimaging.com/breast-imaging/breast-density-notification-laws-state-interactive-map>, (last visited January 26 2018).

<sup>32</sup> DenseBreast-info, Inc., *State Legislation Map*, <https://densebreast-info.org/legislative-information/state-legislation-map/>, revised January 29, 2023, (last visited March 24, 2023).



Florida law<sup>33</sup> codifies the federal requirement that each facility that performs mammography send a summary of a patient’s mammography report to each patient. The law requires, for patients with dense breasts, the summary of the mammography report to also include a notice to the patient that the mammogram shows that the patient’s breast tissue is dense which makes it more difficult to detect some abnormalities in the breast and may also be associated with increased risk of breast cancer.

The law stands repealed on June 30, 2023.

**Effect of the Bill**

CS/CS/HB 1059 amends the repeal of the s. 381.933, F.S., from June 30, 2023, to September 10, 2024. This ensures that facilities will continue to provide dense breast notification with a patient’s mammography report until the federal notification requirement becomes effective in September 2024.

The bill is effective upon becoming law.

**B. SECTION DIRECTORY:**

- Section 1:** Amends s. 381.933, F.S., relating to mammography report.
- Section 2:** Provides the bill will take effect upon becoming law

**II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

**A. FISCAL IMPACT ON STATE GOVERNMENT:**

- 1. Revenues:
  - None.

<sup>33</sup> Section 381.933, F.S.  
 STORAGE NAME: h1059c.HHS  
 DATE: 3/27/2023

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Agency for Health Care Administration has sufficient rulemaking authority to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 27, 2023, the Health and Human Services Committee adopted one amendment and reported the bill favorably as a committee substitute. The amendment extends the repeal of the dense breast notification requirement from June 30, 2023, to September 10, 2024. The analysis is drafted to the committee substitute passed by the Health and Human Services Committee.