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 164
INTRODUCER:	Senator Grimsley
SUBJECT:	Mammography
DATE:	January 22, 2018
REVISED:	

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

I. Summary:

SB 164 requires facilities that perform mammography to send a patient a summary report that includes specific information describing the patient's mammogram and to include a statutorily prescribed notice if the patient has heterogeneously or extremely dense breasts.

The bill is effective July 1, 2018.

II. Present Situation:

Breast cancer is one of the most common cancers in women, second only to skin cancer.[1] Although breast cancer can occur in both men and women, it is rare in men. In 2014, Florida recorded 2,845 breast cancer deaths out of 42,551 total cancer deaths.[2] Additionally, 15,570 new breast cancer cases were reported out of 110,602 total new cancer cases.[3] No cases for men are recorded in the Florida Cancer Statewide Registry.

Some risk factors for breast cancer are related to life-style and others may include factors that individuals have no control over. Lifestyle or behavioral risk factors that may increase an individual's chances of developing breast cancer include:

- Drinking alcohol: Compared with non-drinkers, women who have two to five drinks daily, have about 1.5 times the risk of women who do not drink alcohol;

[1] National Cancer Institute, *Breast Cancer-Patient Version (Overview)*, https://www.cancer.gov/types/breast (last visited Jan. 18, 2018).

[2] Department of Health, Florida Cancer Statewide Registry, *Florida Annual Cancer Report: 2014 Incidence and Mortality (Table 16 – Number of Cancer Death by County, Florida 2014)*, https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport/2014/Table_No_T16_(2014).pdf (last visited Jan. 18. 2018

[3] Department of Health, Florida Cancer Statewide Registry, *Florida Annual Cancer Report: 2014 Incidence and Mortality (Table 2 – Number of New Cancer Cases by County, Florida 2014)*, https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport/2014/Table_No_T2_(2014).pdf (last visited Jan. 18, 2018).

- Being overweight or obese after menopause: Having more fat tissue after menopause can raise estrogen levels and increase a woman's chances of getting breast cancer;
- Lacking physical activity: To reduce the risk, adults should get at least 150 minutes of moderate intensity or 75 minutes of vigorous intensity activity per week;
- Not having children: Women who have not had children or who had their first child after age 30 have a slightly higher breast cancer risk overall;
- Using birth control: Women using oral contraceptives have a slightly higher risk than women that never used them;
- Using hormone therapy after menopause: Use of combined hormone therapy after menopause increases the risk of breast cancer while the use of estrogen alone does not seem to increase the risk much; but if used long-term (more than 10 years), estrogen therapy has been found in some studies to increase the risk of ovarian and breast cancer; and
- Breastfeeding: May slightly lower breast cancer risk, especially if it is continued for one and a half years to two years.[4]

Along with these lifestyle or behavioral risk factors, there are some risk factors that are out of a person's control, such as:

- Being a woman;
- Getting older;
- Inheriting certain genes, 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).[5]

As to the risk factor for dense breasts, almost half of all women between the ages of 40 and 74 (about 25 million nationally) are identified as having dense breasts.[6] Having "dense" breasts makes it more difficult to find and accurately identify breast cancers on a mammogram.[7] Breast density refers to ratio of fatty tissue to glandular tissue (milk ducts, milk glands, and supportive tissue) on a mammogram.[8] A dense breast has less fat than glandular and connective tissue.

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[4] American Cancer Society, *Lifestyle-related Breast Cancer Risk Factors*, https://www.cancer.org/cancer/breast-cancer/risk-and-prevention/lifestyle-related-breast-cancer-risk-factors.html, (last visited Jan. 18, 2018).
[5] 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 Jan. 18, 2018).
[6] 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 (last visited Jan. 18, 2018).
[7] *Id.*
[8] The American Society of Breast Surgeons Foundation, *Breast Density Legislation*, https://breast360.org/en/topics/2017/01/01/breast-density-legislation/ (last visited Jan. 19, 2019).

Mammography

A mammogram is an X-ray picture of the breast. Federal law and regulations specifically define mammography as a radiographic image of the breast produced through mammography.[9,10] Mammography serves as an important screening tool in the early detection of breast cancer and has the potential benefit to reduce the chance that a woman will die from breast cancer.

The United States Preventive Services Task Force (USPSTF)[11] recommends that women age 50 to 74 with no signs of breast cancer have a screening mammogram every two years and that women prior to age 50 should talk with their health care providers about the risks and benefits of whether to have mammograms and when to have them.[12] Approximately 74 percent of female Floridians age 40-plus and 78 percent from age 50 to 74 report having had a mammogram within the past two years, both percentages that either meet or exceed the national averages.[13] Current evidence is insufficient to assess the benefits and harms of mammograms for women age 75 and older.[14]

The most serious harms to having a mammogram are either an over-diagnosis or a false diagnosis. With an over-diagnosis, a woman is diagnosed with a breast cancer that would not have been a harm to her health during her lifetime.[15] The over-diagnosed patient is still treated and may receive over-treatment, including surgery, chemotherapy, and radiation which can have serious side effects.[16] A false diagnosis of breast cancer can have a similar result to an over-diagnosis with unnecessary tests, follow-up procedures, anxiety, and the side effects of any treatments.[17]

Types of Mammograms

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.[18] With a

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[9] 42 U.S.C. §263b(5) and (6).
[10] 21 CFR 900.2(y)
[11] 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 Jan. 18, 2018).
[12] 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 (last visited Jan. 18, 2018).
[13] National Cancer Institute, Florida State Profile, https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statename=florida#t=1 (last visited Jan. 18, 2018).
[14] *Supra* note 12, at 4.
[15] *Id*.
[16] *Id*.
[17] *Id*.
[18] National Cancer Institute, *Breast Cancer Screening (Patient Version)*, https://www.cancer.gov/types/breast/patient/breast-screening-pdq (last visited Jan. 18, 2018).

screening mammogram, usually two or more X-ray pictures are taken 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.[19] 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.[20] Early detection of breast cancer with screening mammography means that treatment can be started earlier in the course of the disease, possibly before it has spread.

BI-RADS Reporting System

The American College of Radiology (ACR) has established a uniform way for radiologists to report mammogram findings. The system, developed in 1993, is called the Breast Imaging Reporting and Database System or BI-RADS and includes seven standardized categories or levels.[21] The vast majority of screening mammograms are classified as BI-RADS 1 and 2 which means the patient had a negative (BI-RADS 1) or normal (BI-RADS 2) mammogram with other findings described in the report and should continue her routine screening.[22] Although there are seven classifications, there are only four outcomes: (1) additional imaging studies; (2) routine interval mammography; (3) short-term follow-up; and (4) biopsy.[23]

The BI-RADS system also has four categories of breast density that may be reported and the radiologist selects the category that best describes the level seen on the mammography film.[24] The categories of density are rates from least to highest are:

- The breasts are almost entirely fatty;
- There are scattered areas of dense glandular tissue[25] and fibrous connective tissue,[26] together known as fibroglandular density;
- The breasts are heterogeneously dense, which means they have more of these areas of fibroglandular density. This may make it hard to see small masses in the breast tissue on a mammogram; and
- The breasts are extremely dense, which makes it hard to see tumors in the breast tissue on a mammogram.

Besides making a mammogram hard to read, as noted above, dense breasts are a risk factor for breast cancer.[27]

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[19] *Id*.
[20] *Id*.
[21] Margaret M. Eberl, MD, et al., *BI-RADS Classification for Management of Abnormal Mammograms,* J AM BOARD FAM MED, 19:161, 161(2006).
[22] *Id* at 161 and 163.
[23] *Id*.
[24] *Id*.
[25] A gland is defined as an organ that makes one or more substances, such as hormones, digestive juices, sweat, tears, saliva, or milk. Endocrine glands release the substances directly into the bloodstream. Exocrine glands release the substances into a duct or opening to the inside or outside of the body. *See* https://www.cancer.gov/Common/PopUps/popDefinition.aspx?id=CDR0000046386&version=Patient&language=English.
[26] Connective tissue is defined as supporting tissue that surrounds other tissues and organs. Specialized connective tissue include bone, cartilage, blood, and fat. *See* https://www.cancer.gov/Common/PopUps/popDefinition.aspx?id=CDR0000044013&version=Patient&language=English.
[27] *Supra* note 5.

Other Detection Methods

Magnetic Resonance Imaging (MRI) is technology that uses magnets and radio waves to produce detailed cross-sectional images of breast tissue and other internal body structure. For breast MRIs, a special MRI machine is required which uses dedicated breast coils. Finding a facility with a dedicated breast MRI equipment may be difficult and if a biopsy is needed later, the patient may be required to find a different facility for that procedure.

The American Cancer Society (ACS) does not recommend the use of an MRI for routine breast cancer screenings, but if one is used it should be used in addition to, not instead of a screening mammogram.[28] The ACS suggests that women who are at high risk for breast cancer based on certain factors get both an MRI and a mammogram every year, including women who:

- Have a lifetime risk of breast cancer of about 20 to 25 percent greater, according to risk assessment tools that are based primarily on family history;
- Have a known BRCA1 or BRCA2 gene mutation;
- Have a first degree relative (parent, brother, sister, or child) with a BRCA1 or BRCA2 gene mutation, and have not had genetic testing themselves;
- Had radiation therapy to the chest when they were between the ages of 10 and 30 years; or
- Have Li-Fraumeni Syndrome, Cowden Syndrome, or Bannayan-Riley-Ruvalcaba Syndrome, or have first-degree relatives with one of these syndromes.[29]

A breast ultrasound is often used to examine a breast change that has been viewed on a mammogram. It is also useful for viewing breast changes that cannot be seen on a mammogram, but can be felt; or for changes in women with dense breast tissue.[30] Breast ultrasound uses soundwaves to make a computer picture of the inside of the breast. A gel that is put on the skin and a transducer which is moved across the skin is used to show the underlying tissue structure. The sound waves and echoes make a black and white picture on the screen.[31] An automated ultrasound is also an option as is the use of a second handheld transducer in order to get more pictures.

A newer technology for mammography are 3D screenings. The USPSTF has not made a recommendation on the use of 3D screening as a primary tool saying that it is not clear whether the technology will result in improved health, quality of life, or fewer deaths among women screened.[32]

The other methods, ultrasound and MRI, were also reviewed specifically by the USPSTF for how they could assist with screening women with dense breasts.[33] For all three alternative methods, the USPSTF graded the practices an "I" which means the Task Force concluded that

[28] American Cancer Society, *Breast Cancer Early Detection and Diagnosis*, https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/american-cancer-society-recommendations-for-the-early-detection-of-breast-cancer.html, (last visited Jan. 19, 2018).
[29] American Cancer Society. *Breast MRI Scans*, https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/breast-mri-scans.html (last visited Jan. 19, 2018).
[30] American Cancer Society, *Breast Ultrasound*, https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/breast-ultrasound.html (last viewed Jan. 19, 2018).
[31] *Id.*
[32] *Supra* note 12, at 3.
[33] *Supra* note 12, at 3.

the current evidence is inconclusive to assess the balance of benefits and harms of the service. The evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.[34]

Federal Regulations

The federal Mammography Quality Standards Act (MQSA)[35] contains requirements related to the accreditation and operation of mammography facilities. Such a facility is defined 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. The term does not include any facilities of the Department of Veteran Affairs.[36]

A certificate issued by the Food and Drug Administration is required for lawful administration of 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.[37]

Mammogram facilities are required 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 is required to make reasonable attempts to reach the patient and the referring physician, if there is one, as soon as possible.[38] Neither the federal law or the regulation requires the facility to include specific information about breast tissue density in the report summary sent to the patient or the referring physician.

Breast Density Notification in Other States

As of January 2018, there are 31 states with laws requiring that women be notified of their breast density and there are four additional states that recommend but do not require notification.[39] 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.[40] Most states' prescribed notices encourage women to talk with their health care providers about their results and to discuss the possible options available. Six states also require insurance coverage for comprehensive ultrasound screenings or other supplemental screenings for women identified with dense breasts.[41]

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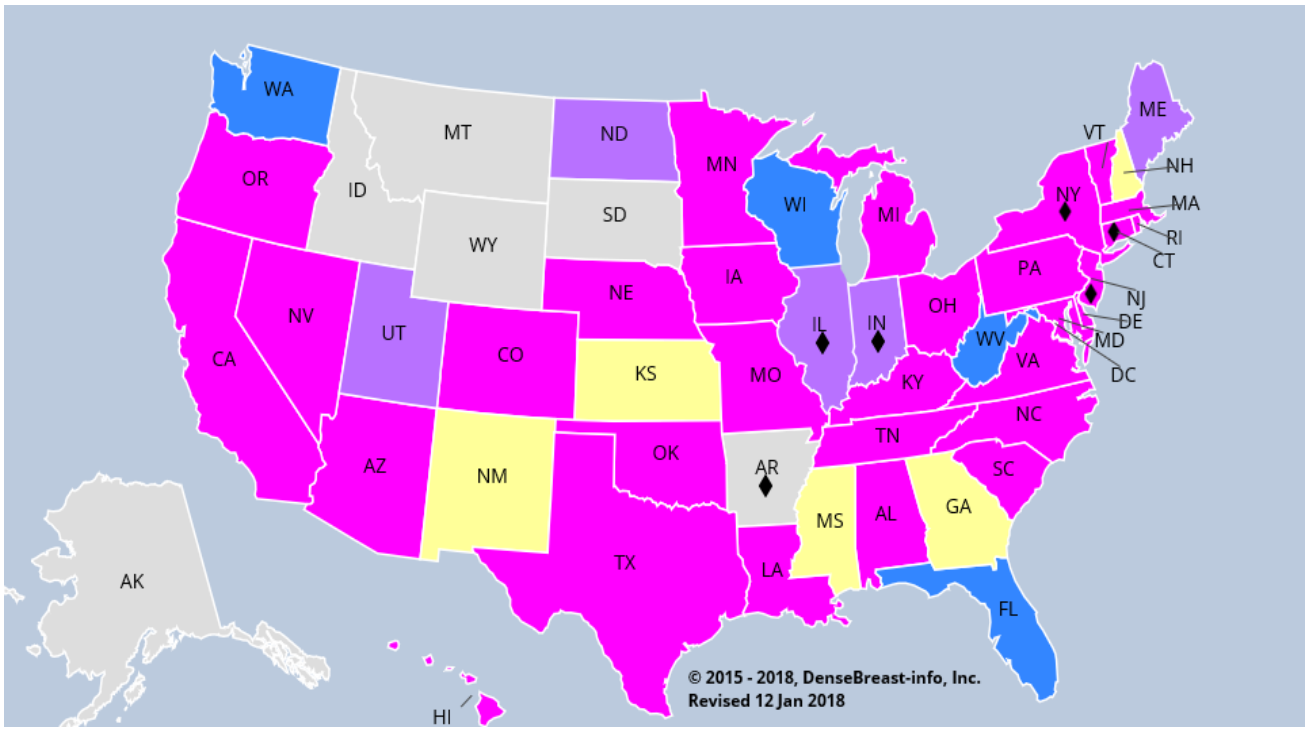
[34] U.S. Preventive Services Task Force, *Grade Definitions* https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions (Jan. 18, 2018).
[35] 42 U.S.C. § 263b.
[36] 21 C.F.R. § 900.1
[37] 21 C.F.R. § 900.12(c)(2) and (3).
[38] *Id.*
[39] *Supra* note 8.
[40] Marijke Vroomen Durning, Diagnostic 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 Jan. 19, 2018).
[41] Dense-breasts-info.org, *Legislation and Regulations – What is required*, http://densebreast-info.org/legislation.aspx (Jan. 19, 2018).

The map below shows which states currently require some density notification to patients and which states also require insurance coverage for supplemental screenings for dense breasts.[42]



Map Legend
Some density notification required (30 states)
Effort for inform/education; notification not required
Active bill Inactive bill/no notification enacted
♦ State with insurance coverage (6 states)

Florida Insurance Mandates

Sections 627.6418, 627.6613, and 641.31095, F.S., contain mandates for accident or health insurance policies, group, blanket, or franchise accident or health insurance policies, and HMOs, respectively, to cover mammograms under certain parameters and requirements. Those parameters and requirements include coverage of a baseline mammogram and coverage of mammograms performed annually, biennially, or on a more frequent basis, depending on the age of the patient, recommendation of the patient's physician, and the patient's risk of breast cancer as determined by personal or family history.

These statutes also allow copayments and deductibles to be applied to mammogram services while requiring health insurers and HMOs to make mammogram coverage available, as part of the application for coverage and for an appropriate additional premium, without mammogram services being subject to copayments and deductibles.

[42] *Id.*

All plans offered under the federal Marketplace and many other plans must offer breast cancer mammography screenings every one to two years for women over to age of 40 without charging a copayment or coinsurance, even if the patient has not met her yearly deductible.[43]

III. Effect of Proposed Changes:

Sections 1 and 2 re-locate the definition of mammography from s. 404.22, F.S., to s. 404.031, F.S.

Section 3 creates s. 406.221, F.S., to require each facility that performs mammography to send a summary of a patient's mammography report which meets federal requirements to each patient. The summary report must include information about breast density based on the Breast Density Reporting and Data System (BI-RADS) as established by the American College of Radiology. The patient report must also include the following specific notice:

> Your mammogram shows that your breast tissue is dense. Dense breast tissue is relatively common and is found in 40 percent of women. The presence of dense breast tissue makes it more difficult to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information is given to you so that you will be informed when you discuss your dense breast tissue and other breast cancer risk factors with your health care providers. Together, you can decide which screening options are right for you. A report of your results was sent to your primary physician.

Section 4 provides an effective date of the act as July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[43] *See* 45 C.F.R. §147.130, for the definition of coverage of preventive services by a group health plan, or a health insurance issuer offering group health insurance or individual insurance under the federal Patient Protection and Affordable Care Act (Act). The Act requires coverage of those preventive services rated as an A or B in the current recommendations of the United States Preventive Services Task Force and that those services be covered without any cost sharing requirements (such as copayments, coinsurance, or deductibles).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The health care providers and screening facilities would likely incur one-time costs to modify the format of existing mammography reports to comply with the new requirements.

The demand for additional screenings may also put pressure on the health care delivery system for expanded access by those patients who receive a notice which alerts them to seek additional services or to contact their provider.[44]

C. Government Sector Impact:

Women with dense breast tissue who were unaware of this fact until receiving the proposed notice may seek additional health care screenings for reassurance, especially if they had a higher screening mammogram score or BI-RADS classification. To the extent that such patients are in the Medicaid program, these additional screenings could have a state and federal fiscal impact for the cost of the additional mammograms, the reading of those mammograms, and the follow-up health care visits, including biopsies and surgery.

These changes do not impact those women who receive services through the veterans' health care system or Medicare. While the state law may result in the mammogram reports being altered with boilerplate language by all health care providers and facilities providing mammograms, payors are not required to cover follow-up appointments. This may result in confusion for those patients whose follow-up appointments and health care services are not covered by their insurers or health plans.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 404.031 and 404.22.

This bill creates section 402.221 of the Florida Statutes.

[44] The bill does not require insurers and health plans to pay for any follow-up screenings or services from the mammogram screenings.

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.