

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 735 Mammography

SPONSOR(S): Health & Human Services Committee; Health Innovation Subcommittee; Harrell

TIED BILLS: IDEN./SIM. **BILLS:** SB 164

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	10 Y, 0 N, As CS	Royal	Crosier
2) Health & Human Services Committee	20 Y, 0 N, As CS	Royal	Calamas

SUMMARY ANALYSIS

Breast cancer is one of the most common cancers in women, second only to skin cancer. In 2014, Florida recorded 2,845 breast cancer deaths out of 42,551 total cancer deaths. Additionally, 15,570 new breast cancer cases were reported out of 110,602 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.

Among the risk factors for developing breast cancer are dense breasts. Almost half of all women between 40 and 74 years of age (about 25 million nationally) are identified as having dense breasts. 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. Denser breast tissue appears white on a mammogram. Because tumors also appear white on a mammogram, they can be harder to find when there is dense breast tissue.

CS/HB 735 codifies the federal requirement that each facility that performs mammography to send a summary of a patient's mammography report to each patient. In addition to the federal requirements, if the patient has dense breasts, the bill requires the summary of the mammography report 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 bill repeals the notice requirement effective June 30, 2023.

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

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Breast cancer is one of the most common cancers in women, second only to skin cancer.¹ 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

Risk factors for developing breast cancer are:

- 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).⁴

Breast Cancer Screening

Three tests are used by health care providers to screen for breast cancer: mammogram, clinical breast exam⁵ and MRI (magnetic resonance imaging) in women with a high risk of breast cancer.⁶ Mammography is the most common screening test for breast cancer.⁷ A mammogram is an x-ray of the breast.⁸ Federal law and regulations specifically define mammography as a radiographic image of the breast produced through mammography.⁹ 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 women.¹⁰ Women 40 to 74 years of age who have screening

¹ National Cancer Institute, Breast Cancer-Patient Version (Overview), <https://www.cancer.gov/types/breast> (last visited January 26, 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/FloridaAnnualCancerReport2014/Table_No_T16_\(2014\).pdf](https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport2014/Table_No_T16_(2014).pdf), (last visited January 26, 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/FloridaAnnualCancerReport2014/Table_No_T2_\(2014\).pdf](https://fcds.med.miami.edu/downloads/FloridaAnnualCancerReport2014/Table_No_T2_(2014).pdf), (last visited January 26, 2018).

⁴ 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 January 26, 2018).

⁵ 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 else that seems unusual. National Cancer Institute, Breast Cancer Screening, <https://www.cancer.gov/types/breast/patient/breast-screening-pdq> (last visited January 27, 2018).

⁶ National Cancer Institute, Breast Cancer Screening (Patient Version), <https://www.cancer.gov/types/breast/patient/breast-screening-pdq>, (last visited January 26, 2018).

⁷ Id.

⁸ Id.

⁹ 10 42 U.S.C. §263b(5) and (6); 21 CFR 900.2.

¹⁰ Supra, FN 6.

mammograms have a lower chance of dying from breast cancer than women who do not have screening mammograms.¹¹

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.¹² With a 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.¹³ 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.¹⁴ 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.

Mammograms are less likely to find breast tumors in women younger than 50 years than in older women.¹⁵ This may be because younger women have denser breast tissue that appears white on a mammogram. Because tumors also appear white on a mammogram, they can be harder to find when there is dense breast tissue.¹⁶ Almost half of all women between 40 and 74 years of age (about 25 million nationally) are identified as having dense breasts.¹⁷ Breast density refers to ratio of fatty tissue to glandular tissue (milk ducts, milk glands, and supportive tissue) on a mammogram.¹⁸ A dense breast has less fat than glandular and connective tissue. Besides making a mammogram hard to read, dense breasts are also a risk factor for breast cancer.¹⁹

The United States Preventive Services Task Force (USPSTF)²⁰ 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.²¹ 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.²² Current evidence is insufficient to assess the benefits and harms of mammograms for women age 75 and older.²³

¹¹ Id.

¹² Id.

¹³ Id.

¹⁴ Id.

¹⁵ Id.

¹⁶ Id.

¹⁷ Id.

¹⁷ 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 January 26, 2018).

¹⁸ The American Society of Breast Surgeons Foundation, Breast Density Legislation, <https://breast360.org/en/topics/2017/01/01/breast-density-legislation/> (last visited January 26, 2018).

¹⁹ Supra, FN 4.

²⁰ 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 January 26, 2018).

²¹ 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 January 26, 2018)

²² National Cancer Institute, Florida State Profile, <https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statername=florida#t=1>, (last visited January 26, 2018).

²³ Supra, FN 21.

Federal Regulation of Mammography

The federal Mammography Quality Standards Act (MQSA)²⁴ contains requirements related to 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. The term does not include any facilities of the Department of Veteran Affairs.²⁵

A certificate issued by the Food and Drug Administration 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.²⁶

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 must make reasonable attempts to reach the patient and the referring physician, if there is one, as soon as possible.²⁷ Neither the federal law nor 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.

State Regulation of Health Care Providers

Department of Health

The Division of Medical Quality Assurance (MQA), within the Department of Health (DOH), has general regulatory authority over health care practitioners.²⁸ The MQA works in conjunction with 22 boards and six councils to license and regulate seven types of health care facilities and more than 40 health care professions, including physicians and radiologists.²⁹ Each profession is regulated by an individual practice act and by ch. 456, F.S., which provides general regulatory and licensure authority for the MQA. Ch. 456 provides DOH with the authority to discipline any licensee that fails to comply with a statutory or legal obligation.³⁰

Agency for Health Care Administration

The Division of Health Quality Assurance (HQA), housed within the Agency for Health Care Administration (AHCA), licenses, certifies, and regulates 40 different types of health care providers, including hospitals.³¹ Certain health care providers³² are regulated under part II of ch. 408, F.S., which is the Health Care Licensing Procedures Act (Act), or core licensing statutes. The Act provides uniform

²⁴ 42 U.S.C. § 263b.

²⁵ 21 C.F.R. § 900.1.

²⁶ 21 C.F.R. § 900.12(c)(2) and (3).

²⁷ *Id.*

²⁸ Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.

²⁹ Facilities include dental laboratories, electrolysis facilities, massage establishments, nonresident sterile compounding facilities, office surgery facilities, optical establishments, pain management clinics, and pharmacies. Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan, Fiscal Year 2014-2015*, 3 and 14, available at <http://mgawebteam.com/annualreports/1415/#6> (last visited March 13, 2017).

³⁰ Section 456.072(1)(k), F.S.

³¹ Agency for Health Care Administration, *Health Quality Assurance*, 2017, available at <http://ahca.myflorida.com/MCHQ/> (last visited February 6, 2018).

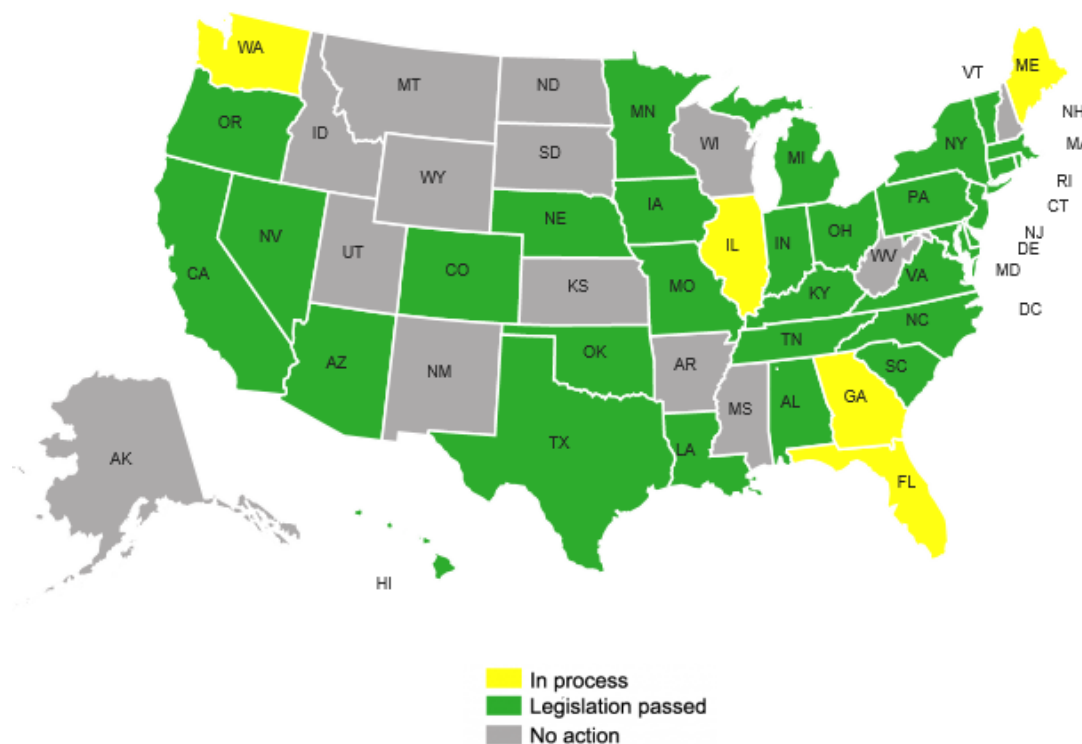
³² “Provider” means any activity, service, agency, or facility regulated by the agency and listed in s. 408.802, F.S.

licensing procedures and standards for 29 provider types, including hospitals.³³ In addition to the Act, each provider type has an authorizing statute, which includes unique provisions for licensure beyond the uniform criteria. In the case of conflict between the Act and an individual authorizing statute, the Act prevails.³⁴ AHCA does not have authority to discipline licensees for violations of statutory or legal obligations outside ch. 408, the licensee’s authorizing statutes or agency rules adopted pursuant to those statutes.³⁵

Breast Density Notification in Other States

As of January 2018, 31 states have laws requiring that women be notified of their breast density, and four additional states recommend but do not require notification.³⁶ 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.³⁷ 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.³⁸

Breast Density Notification Laws by State³⁹



³³ S. 408.802, F.S.

³⁴ S. 408.832, F.S.

³⁵ E-mail correspondence with AHCA staff (on file with the Health and Human Services Committee).

³⁶ Supra, FN 18.

³⁷ 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).

³⁸ Dense-breasts-info.org, Legislation and Regulations – What is required?, <http://densebreast-info.org/legislation.aspx>, (last visited January 26, 2018).

³⁹ Supra, FN 37.

Effect of the Bill

CS/HB 735 creates s. 381.933, F.S., which codifies the federal requirement that each facility that performs mammography send a summary of a patient's mammography report to each patient. In addition to the federal requirements, if the patient has dense breasts, the bill requires the summary of the mammography report 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 bill defines facility, mammography, and mammography report as having the same meaning as the definitions for those terms in the MQSA.

The bill states it does not create a specific duty, standard of care, or other legal obligation beyond the duty to provide the notice required under this section. The bill also states that it does not create a requirement to provide a notice that is inconsistent with the notice requirements of the MQSA or any regulations that are promulgated pursuant to that act; however the MQSA does not currently require notification of dense breast tissue.

DOH has the authority to discipline licensees that fail to comply with the notice requirement.⁴⁰

The bill repeals the notice requirement effective June 30, 2023.

The bill provides an effective date of the act of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 404.031, F.S., relating to definitions.

Section 2: Amends s. 404.22, F.S., relating to radiation machines and components, inspection.

Section 3: Creates s. 404.221, F.S., relating to mammography reports.

Section 4: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

⁴⁰ Section 456.072(1)(k), F.S provides DOH with the authority to discipline any licensee that fails to comply with a statutory or legal obligation.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 7, 2018, the Health and Human Services Committee adopted an amendment that:

- Removed rulemaking authority for DOH and AHCA.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.