# Health Innovation Subcommittee

**Tuesday, January 30, 2018**
**3:30 PM – 4:30 PM**
**Mashburn Hall (306 HOB)**

**Richard Corcoran**
**Speaker**

**MaryLynn Magar**
**Chair**

# Committee Meeting Notice

## HOUSE OF REPRESENTATIVES

**(AMENDED 1/26/2018 4:04:58PM)**

**Amended(1)**

## Health Innovation Subcommittee

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| **Start Date and Time:** | Tuesday, January 30, 2018 03:30 pm |
| **End Date and Time:** | Tuesday, January 30, 2018 04:30 pm |
| **Location:** | Mashburn Hall (306 HOB) |
| **Duration:** | 1.00 hrs |

**Consideration of the following bill(s):**

HB 217 Payment of Health Care Claims by Hager
HB 735 Mammography by Harrell

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Monday, January 29, 2018.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Monday, January 29, 2018.

**NOTICE FINALIZED on 01/26/2018 4:04PM by Iseminger.Bobbye**

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 217 Payment of Health Care Claims
**SPONSOR(S):** Hager
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 162

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|---|---|---|---|
| 1) Health Innovation Subcommittee | | Grabowski | Crosier |
| 2) Appropriations Committee | | | |
| 3) Health & Human Services Committee | | | |

## SUMMARY ANALYSIS


Health insurers and health care providers often interact with one another prior to the delivery of care for insured patients. An initial interaction often consists of a contact from a provider to the insurer to verify that a patient has active insurance coverage. Once this verification is made, services are provided and claims generated.

If patients seek services for which they are not currently covered, there is no guarantee that a health insurer will pay for those services. For example, a patient may seek a service from a provider prior to that patient's effective date of coverage, after coverage has ended, or during a time in which the patient had not paid the applicable premium, later resulting in termination of coverage. If an insurer later determines that a patient was not eligible for coverage at the time of service delivery, a medical claim may be denied. When a claim is denied at a later date, it is commonly referred to as a retroactive denial.

In the instance of a retroactive denial, the provider may have already verified that the patient had active health insurance, provided services based on that verification, and in some cases already received payment. Retroactive denials can result in the provider or the patient covering the loss, despite the verified eligibility.

HB 217 amends ss. 627.6131 and 641.3155, F.S., to prohibit a health insurer or health maintenance organization (HMO) from retroactively denying a claim at any time because of insured ineligibility, if the insurer or HMO verified the eligibility of the patient at the time of treatment and provided an authorization number.

The bill has an indeterminate significant negative fiscal impact on the Statewide Medicaid Managed Care Program and a significant negative fiscal impact on the fully-insured HMO plan in the State Group Insurance Plan. The bill would also have an indeterminate negative fiscal impact on local government.

The bill applies to insurance policies entered into or renewed on or after January 1, 2019.

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

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

**Background**

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk-bearing entities.[1] The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. to individuals enrolled in the Medicaid program. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[2]

*Health Insurance Contracts*

All health insurance policies issued in the state of Florida, with the exception of certain self-insured policies[3], must meet certain requirements that are detailed throughout the Florida Insurance Code. Chapter 627, F.S., sets parameters and requirements for health insurance policies and ch. 641, F.S., provides requirements for insurance policies issued by HMOs. At a minimum, insurance policies must specify premium rates, services covered, and effective dates. Insurers must document the time when a policy takes effect and the period during which the policy remains in effect.[4]

Responsibilities of insured patients are also reflected in insurance contracts. Contracts set premium payment schedules and require that payments must be made in a timely fashion. In cases where this requirement is not met, a health insurer or HMO may cancel coverage for nonpayment of premiums.[5]

Before cancellation can occur, however, covered patients are protected by grace periods that extend the time frame in which premium payments may be submitted. A grace period is a period of time following the due date of a premium payment in which the insurance policy remains in force, even if the premium payment has not been made. The grace periods for policies or contracts issued in Florida are set in the Insurance Code,[6] and vary based on the premium payment schedule.

Pursuant to ss. 627.608 and 641.31, F.S., insurance policies and health maintenance contracts stay in force during grace periods. If the insurer or HMO does not receive the full payment of the premium by the end of the grace period, coverage terminates as of the grace period start date and the insurer or HMO may deny any medical claims incurred during the grace period. When a claim is denied at a later date, it is referred to as a retroactive denial.

The Insurance Code is silent on whether the insurer or HMO may advise a health care provider that a patient has not paid the applicable premium, and that the policy or health maintenance contract may be terminated in the future, possibly resulting in a retroactive claim denial.

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[1] S. 20.121(3), F.S.
[2] S. 641.21(1), F.S.
[3] The Employee Retirement Security Act of 1974 (ERISA). 29 U.S.C. ch. 18 § 1001 et seq. ERISA regulates certain self-insured plans, which represent approximately 50 percent of the insureds in Florida. These plans cannot be regulated by state law.
[4] S. 627.413(1)(d), F.S.
[5] SS. 627.6043(1) and 641.3108 (2), F.S.
[6] SS. 627.608 and 641.31(15), F.S.; The grace period of an individual policy must be a minimum of 7 days for weekly premium; 10 days for a monthly premium; and 31 days for all other periods. The grace period of a HMO contract must be at least 10 days. For group policies, if cancellation is due to nonpayment of premium, the insurer may not retroactively cancel the policy to a date prior to the date that notice of cancellation was provided to the policyholder unless the insurer mails notice of cancellation to the policyholder prior to 45 days after the date the premium was due. Such notice must be mailed to the policyholder's last address as shown by the records of the insurer and may provide for a retroactive date of cancellation no earlier than midnight of the date that the premium was due.

*Florida's Prompt Payment Laws*

Florida's prompt payment laws govern payment of provider claims submitted to insurers and HMOs, including Medicaid managed care plans, in accordance with ss. 627.6131 and 641.3155, F.S., respectively.[7] These provisions detail the rights and responsibilities of insurers, HMOs, and providers for the payment of medical claims. The statutes provide a process and timeline for providers to pay, deny, or contest the claim, and also prohibit an insurer or HMO from retroactively denying a claim because of the ineligibility of an insured or subscriber more than one year after the date the claim is paid.[8]

Federal Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act of 2010 (PPACA) introduced a set of claims-related requirements for insurers offering plans through the federally-facilitated and state-based insurance exchanges. The Act guarantees access to coverage and mandates certain essential health benefits, among other directives.[9] To address affordability issues, federal premium tax credits and cost-sharing subsidies are available to assist eligible low and moderate-income individuals to purchase qualified health plans on a state or federal exchange.[10] In Florida, 1,588,628 individuals enrolled through the federal exchange received a premium tax credit for plan year 2016.[11]

Individual health insurance plans purchased via the exchanges with a federal premium tax credit are not subject to the grace periods in Florida law. Instead, PPACA requires insurers and HMOs to provide a grace period of at least three consecutive months before cancelling the policy or contract of a federally subsidized enrollee who is delinquent if the enrollee previously paid 1-month's premium.[12] During the first month of the grace period, the insurer must pay all appropriate claims for services provided.

For the second and third months, an insurer may pend claims and then must notify affected providers that an enrollee has lapsed in his or her payment of premiums and there is a possibility the insurer may deny the payment of claims incurred during the second and third months.[13]

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[7] The prompt pay provisions apply to HMO contracts and major medical policies offered by individual and group insurers licensed under ch. 624, F.S., including preferred provider policies and an exclusive provider organization, and individual and group contracts that only provide direct payments to dentists.

[8] SS. 627.6131(11) and 641.3155(10), F.S

[9] The Patient Protection and Affordable Care Act (Pub. Law No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. Law No. 111–152), which amended several provisions of the PPACA, was enacted on March 30, 2010.

[10] In general, individuals and families may be eligible for the premium tax credit if their household income for the year is at least 100 percent but no more than 400 percent of the federal poverty line for their family size. For residents of one of the 48 contiguous states or Washington, D.C., the following illustrates when household income would be at least 100 percent but no more than 400 percent of the federal poverty line in computing your premium tax credit for 2017:
$12,060 (100%) up to $48,240 (400%) for one individual; $16,240 (100%) up to $64,960 (400%) for a family of two; and $24,600 (100%) up to $98,400 (400%) for a family of four. U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Poverty Guidelines*, available at: https://aspe.hhs.gov/poverty-guidelines (last accessed November 13, 2017).

[11] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Health Insurance Marketplace Premiums After Shopping, Switching, and Premium Tax Credits, 2015-2016* (Apr. 12, 2016), *available at* https://aspe.hhs.gov/system/files/pdf/198636/MarketplaceRate.pdf (last accessed November 13, 2017).

[12] Example of grace period: Premium is not paid in May. Premium payments are made in June and July, but May remains unpaid, the grace period would end July 31. Coverage would be cancelled retroactively to the last day of May. See https://www.healthcare.gov/apply-and-enroll/health-insurance-grace-period/ (last accessed November 13, 2017); 45 C.F.R. s. 155.430.

[13] 45 C.F.R. s. 156.270

Florida's Statewide Medicaid Managed Care Program

The Florida Medicaid program is a partnership between the federal and state governments. In Florida, AHCA oversees the Medicaid program, while the Department of Children and Families (DCF) and the federal Social Security Administration make determinations regarding Medicaid eligibility.[14]

The Statewide Medicaid Managed Care (SMMC) program consists of the Managed Medical Assistance (MMA) program and the Long-Term Care (LTC) program. [15] AHCA contracts with managed care plans to provide services to eligible recipients. The MMA program covers medical and acute care services for plan enrollees. Most Florida Medicaid recipients who are eligible for the full array of Medicaid benefits are enrolled in an MMA plan. The LTC program covers nursing facility and home and community-based services to eligible adults.

Medicaid managed care plans are responsible for paying claims in accordance with federal and state law and contractual requirements, including s. 641.3155, F.S.,[16] which allows HMOs to deny a claim retroactively because of insured or subscriber ineligibility up to one year after the date of payment of the claim.

The Florida Medicaid Provider General Handbook and Florida Medicaid service-specific coverage policies and handbooks, incorporated by reference in the Statewide Medicaid Managed Care (SMMC) contract, require providers to verify each recipient's eligibility each time they provide a service.[17] Although an enrollee may have eligibility on file at the time a service was authorized, the enrollee may have subsequently become ineligible.

Section 1903(d)(2)(C) of the Social Security Act gives states up to one year to recover any overpayments made through the Medicaid program. This law requires states to return the federal matching portion on overpayments made by the state or the health plan, which could include payments retroactively denied. Section 409.913(1)(e), F.S., defines "overpayment" to include any amount that is not authorized to be paid by the Medicaid program whether as a result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse, or mistake. Section 409.907, F.S., prohibits AHCA from demanding repayment from a provider in any instance in which the Medicaid overpayment is attributable to error of DCF in eligibility determination.

**Effect of Proposed Changes**

HB 217 amends ss. 627.6131 and 641.3155, F.S., the prompt payment laws, to prohibit a health insurer or HMO from retroactively denying a claim at any time because of insured ineligibility, if the insurer or HMO verified the insured's eligibility at the time of treatment and provided an authorization number. This prohibition applies to plans providing individual and group health insurance policies, but does not apply to federally-subsidized plans purchased on the federal health exchange.

The bill provides certainty of payment for insureds and providers who have received authorization numbers from insurers and HMOs. If an authorization number is granted and a service provided, but the insurer or HMO later determines that a patient was not eligible, the insurer or HMO must cover the claim. The bill prevents insurers and HMOs from issuing retroactive denials or recouping payments for services provided when a patient's eligibility is rescinded during a later claims audit.

The prohibition on retroactive denial applies to insurance policies and HMO contracts entered into or renewed on or after January 1, 2019.

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[14] Department of Children and Families, *Medicaid*, available at: http://www.myflfamilies.com/service-programs/access-florida-food-medical-assistance-cash/medicaid (last accessed November 14, 2017).
[15] Part IV of ch. 409, F.S.
[16] S. 409.967(2)(j), F.S.
[17] Agency for Health Care Administration. "SMMC Plans – Model Contract". Available at http://www.fdhc.state.fl.us/medicaid/statewide_mc/plans.shtml (last accessed January 28, 2018).

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

B. SECTION DIRECTORY:

**Section 1:** Amends s. 627.6131, F.S., relating to payment of claims.
**Section 2:** Amends s. 641.3155, F.S., relating to prompt payment of claims.
**Section 3:** Provides an effective date of July 1, 2019.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill would have a significant indeterminate negative impact on the SMMC. Participating HMOs would lose the ability to retroactively deny claims based on a recipient's eligibility and recoup overpayments from providers as appropriate. In addition, the SMMC program would still be required to return the federal share of overpayments to the federal government.[18]

   The bill would have a significant negative fiscal impact on the State Group Health Insurance Program's (SGHI) fully insured plan. Initial estimates on impact suggest a $0.23 increase per member, per month for the Capital Health Plan (CHP) HMO.[19] The financial impacts may be passed along to the state by way of premium rate adjustment.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   The bill would have an indeterminate negative fiscal impact on local governments. To the extent that the prohibition on retroactive denials increases costs to insurers and HMOs, those costs may be passed on to entities that contract with insurers and HMOs for employee health insurance, including local governments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will have an indeterminate negative fiscal impact on health insurers and HMOs. The bill creates a financial liability for a health insurer or HMO that provides authorization for services to an individual who is later deemed ineligible for coverage. In such cases, the insurer or HMO will have no mechanism to recoup any payments made to providers.

D. FISCAL COMMENTS:

None.

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[18] Agency for Health Care Administration. *Agency Bill Analysis for HB 217.* November 13, 2017. On file with staff of the Health Innovation Subcommittee.

[19] Department of Management Services. *Agency Bill Analysis for HB 217.* December 14, 2017. On file with staff of the Health Innovation Subcommittee.

## III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the payment of health care claims; amending s. 627.6131, F.S.; prohibiting a health insurer from retroactively denying a claim under specified circumstances; providing applicability; amending s. 641.3155, F.S.; prohibiting a health maintenance organization from retroactively denying a claim under specified circumstances; providing applicability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (11) of section 627.6131, Florida Statutes, is amended to read:

627.6131 Payment of claims.—

(11) A health insurer may not retroactively deny a claim because of insured ineligibility:

(a) At any time, if the health insurer verified the eligibility of an insured at the time of treatment and provided an authorization number. This paragraph applies to policies entered into or renewed on or after January 1, 2019.

(b) More than 1 year after the date of payment of the claim.

Section 2. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:



CODING: Words ~~stricken~~ are deletions; words underlined are additions.

641.3155 Prompt payment of claims.—

(10) A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility:

(a) At any time, if the health maintenance organization verified the eligibility of a subscriber at the time of treatment and provided an authorization number. This paragraph applies to contracts entered into or renewed on or after January 1, 2019.

(b) More than 1 year after the date of payment of the claim.

Section 3. This act shall take effect July 1, 2018.

COMMITTEE/SUBCOMMITTEE ACTION

| | | |
|---|---|---|
| ADOPTED | __ | (Y/N) |
| ADOPTED AS AMENDED | __ | (Y/N) |
| ADOPTED W/O OBJECTION | __ | (Y/N) |
| FAILED TO ADOPT | __ | (Y/N) |
| WITHDRAWN | __ | (Y/N) |
| OTHER | ______ | |

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Hager offered the following:

**Amendment**

Remove everything after the enacting clause and insert:

Section 1. Subsection (11) of section 627.6131, Florida Statutes, is amended to read:

627.6131 Payment of claims.—

(11) A health insurer may not retroactively deny a claim because of insured ineligibility<u>:</u>

<u>(a) For services rendered during the relevant grace period described in s. 627.608, provided that the health insurer verified the eligibility of an insured at the time of treatment and provided an authorization number. This paragraph applies to policies entered into or renewed on or after January 1, 2019.</u>

(b) More than 1 year after the date of payment of the claim.

Section 2. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:

641.3155 Prompt payment of claims.—

(10) A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility:

(a) For services rendered during the grace period described in s. 641.31(15)(a), provided that the health maintenance organization verified the eligibility of a subscriber at the time of treatment and provided an authorization number. This paragraph applies to policies entered into or renewed on or after January 1, 2019. This paragraph does not apply to Medicaid managed care plans pursuant to part IV of chapter 409.

(b) More than 1 year after the date of payment of the claim.

Section 3. This act shall take effect July 1, 2018.

HB 735

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 735 Mammography
**SPONSOR(S):** Harrell
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 164

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|---|---|---|---|
| 1) Health Innovation Subcommittee | | Royal | Crosier |
| 2) Health & Human Services Committee | | | |

### 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.

HB 735 requires each facility that performs mammography to send a summary of a patient's mammography report, which meets federal requirements to each patient. If the patient has dense breasts, the bill requires 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 the act 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 exam[5] 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

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[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/FloridaAnnualCancerReport/2014/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/FloridaAnnualCancerReport/2014/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]

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[11] Id.
[12] Id.
[13] Id.
[14] Id.
[15] Id.
[16] 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?statename=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]

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.[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.

### Florida Regulation of Mammography Machines

Any person who owns or operates a radiation machine in the state of Florida, including a mammography machine, must register the machine with the Department of Health (DOH).[28] DOH is authorized to inspect radiation machines for safety and quality assurance standards set forth in statute and DOH rule.[29] Radiation machines used for mammography must meet accreditation criteria of the American College of Radiology or similar criteria established by DOH.[30] Section 404.22, F.S. defines mammography as radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast. All radiation machines used for mammography must be specifically designed to perform mammography and may only be used to perform mammography.[31]

### 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.[32] 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.[33] Most states' prescribed notices encourage women to talk with their health care providers about their results and to discuss the

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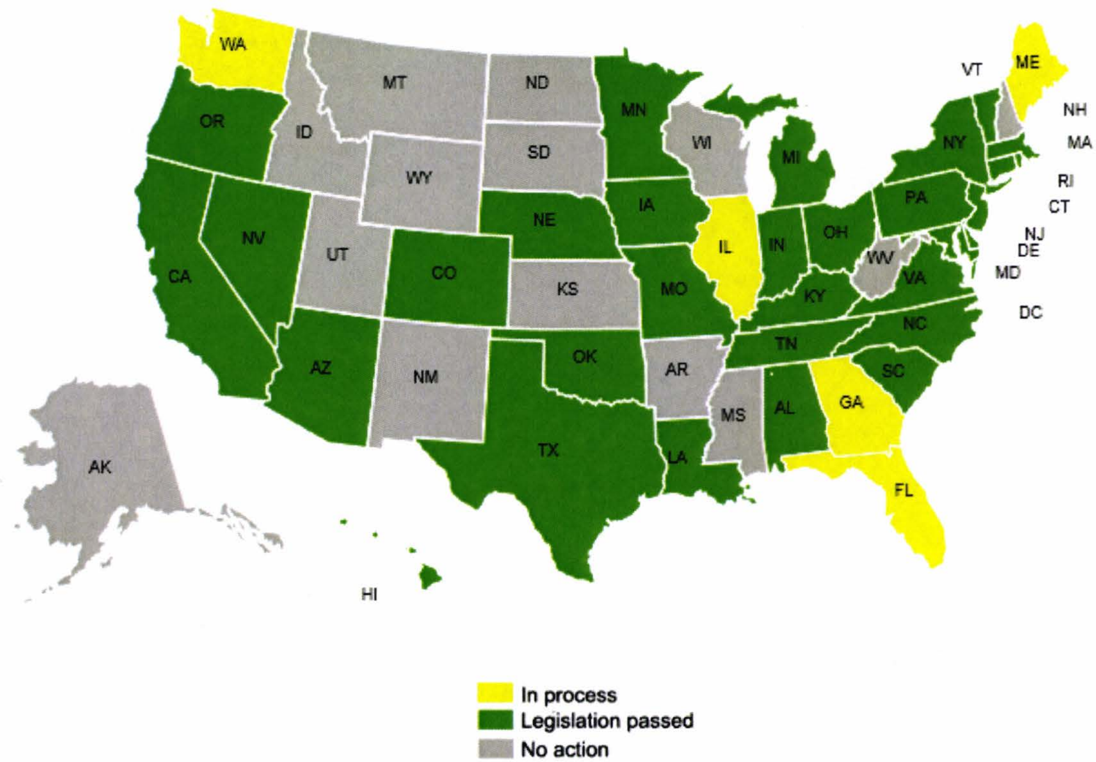
[24] 42 U.S.C. § 263b.
[25] 21 C.F.R. § 900.1.
[26] 21 C.F.R. § 900.12(c)(2) and (3).
[27] Id.
[28] Section 404.22, F.S.
[29] Id.
[30] Id.
[31] Id.
[32] Supra, FN 18.
[33] Marijke Vroomen Durning, Diagnostic Imaging, Breast Density Notification Laws by State – Interactive Map (June 12, 2017), http://www.diagnosticimaging.com/breast-imaging/breast-density-notification-laws-state-interactive-map, (last visited January 26 2018).

possible options available. Six states also require insurance coverage for comprehensive ultrasound screenings or other supplemental screenings for women identified with dense breasts.[34]

**Breast Density Notification Laws by State**[35]




## Effect of the Bill

HB 735 creates s. 402.221, 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. If the patient has dense breasts, the bill requires 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 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.

The bill re-locates the definition of mammography from s. 404.22, F.S., to s. 404.031,F.S.

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.

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[34] Dense-breasts-info.org, Legislation and Regulations – What is required, http://densebreast-info.org/legislation.aspx,(last visited January 26, 2018).
[35] Supra, FN 33.

**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.

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

A bill to be entitled

An act relating to mammography; amending s. 404.031, F.S.; defining the term "mammography"; amending s. 404.22, F.S.; conforming a change made by the act; creating s. 402.221, F.S.; requiring facilities performing mammography to include certain information in a summary of the mammography report which must be provided to each patient; providing applicability; providing for future repeal; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (10) through (20) of section 404.031, Florida Statutes, are renumbered as subsections (11) through (21), respectively, and a new subsection (10) is added to that section, to read:

404.031 Definitions.—As used in this chapter, unless the context clearly indicates otherwise, the term:

(10) "Mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.

Section 2. Subsection (6) of section 404.22, Florida Statutes, is amended to read:

404.22 Radiation machines and components; inspection.—

(6) ~~(a) For purposes of this subsection, "mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.~~

~~(b)~~ All radiation machines used for mammography shall:

(a) Meet the accreditation criteria of the American College of Radiology or similar criteria established by the department.

(b) ~~(c) All radiation machines used for mammography shall~~ Be specifically designed to perform mammography.

(c) ~~(d) All radiation machines used for mammography shall~~ Be used exclusively to perform mammography.

The department shall adopt rules to implement ~~the provisions of~~ this subsection.

Section 3. Section 402.221, Florida Statutes, is created to read:

402.221 Mammography reports.—Each facility that performs mammography shall send a summary of a patient's mammography report to each patient in accordance with 21 C.F.R. s. 900.12(c). If a facility determines that a patient has heterogeneously or extremely dense breasts, the summary must include the following notice:

"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 results 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."

(1) This section does not create a duty, standard of care, or other legal obligation beyond the duty to provide notice as set forth in this section.

(2) This section does not require a notice that is inconsistent with the federal Mammography Quality Standards Act or any regulation promulgated pursuant to that act.

(3) This section is repealed June 30, 2023.

Section 4. This act shall take effect July 1, 2018.

COMMITTEE/SUBCOMMITTEE ACTION

| | |
|---|---|
| ADOPTED | ___ (Y/N) |
| ADOPTED AS AMENDED | ___ (Y/N) |
| ADOPTED W/O OBJECTION | ___ (Y/N) |
| FAILED TO ADOPT | ___ (Y/N) |
| WITHDRAWN | ___ (Y/N) |
| OTHER | ______ |

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Harrell offered the following:

**Amendment (with title amendment)**

Remove everything after the enacting clause and insert:

Section 1. Section 381.933, Florida Statutes, is created to read:

381.933 Mammography reports.-

(1) Definitions.- As used in this section:

(a) "Facility" has the same meaning as in 21 C.F.R. s.900.2(q).

(b) "Mammography" has the same meaning as in 21 C.F.R. s.900.2(aa).

(c) "Mammography report" has the same meaning as in 21 C.F.R. s.900.12(c).

<ins>(2) Mammography reports; results.-Each facility that performs mammography shall send a summary of a patient's mammography report to each patient in accordance with 21 C.F.R. s. 900.12(c). If a facility determines that a patient has heterogeneously or extremely dense breasts, the summary must include the following notice:</ins>

<ins>"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 results 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."</ins>

<ins>(a) This subsection does not create a duty, standard of care, or other legal obligation beyond the duty to provide notice as set forth in this subsection.</ins>

<ins>(b) This subsection does not require a notice that is inconsistent with the federal Mammography Quality Standards Act or any regulation promulgated pursuant to that act.</ins>

(3) Rules.-The Department of Health and the Agency for Health Care Administration may adopt rules to implement this section.

(4) This section is repealed June 30, 2023.

Section 2. This act shall take effect July 1, 2018.

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**T I T L E A M E N D M E N T**

Remove everything before the enacting clause and insert: An act relating to mammography; creating s. 381.933, F.S.; defining the terms "facility", "mammography", and "mammography report"; requiring facilities performing mammography to include certain information in a summary of the mammography report which must be provided to each patient; providing applicability; providing for future repeal; providing an effective date.