

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 Health Regulation Committee

BILL: SB 96

INTRODUCER: Senator Ring

SUBJECT: Mammogram Reports

DATE: January 7, 2011

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Brown	Stovall	HR	Pre-meeting
2.	_____	_____	BI	_____
3.	_____	_____	BC	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill amends three sections of Florida Statutes related to health insurance policies and health maintenance contracts to require that mammography reports provided to patients include information about breast density.

The effective date of the bill is October 1, 2011.

This bill substantially amends the following sections of the Florida Statutes: 627.6418, 627.6613, and 641.31095.

II. Present Situation:

A mammogram is an X-ray of the breast. Mammograms known as screening mammograms may be routinely performed periodically as a tool to screen for breast cancer in patients who have no symptoms. Mammograms are also performed with patients who have symptoms, such as a lump or pain, or who have a suspicious change seen on a screening mammogram, and are known as diagnostic mammograms.¹

Florida Insurance Mandates

Sections 627.6418, 627.6613, and 641.31095, F.S., currently contain mandates for accident or health insurance policies, group, blanket, or franchise accident or health insurance policies, and health maintenance contracts, respectively, to cover mammograms under certain parameters and requirements. Those parameters and requirements include coverage of a baseline mammogram

¹ American Cancer Society, *Mammograms and Other Breast Imaging Procedures*, p. 1.

and coverage of mammograms performed annually, biennially, or on a more frequent basis, depending on the age of the patient, recommendations 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.²

Sections 627.6418, 627.6613, and 641.31095, F.S., do not require mammogram reports to be provided to patients, nor do other provisions of Florida Statutes. The Agency for Health Care Administration and the Department of Health do not regulate health care providers or facilities regarding the issuance of mammogram reports, deferring to federal regulations and accreditation requirements, except to the extent that the Florida Board of Medicine has acted upon complaints and disciplined physicians who failed to contact patients about suspicious mammogram reports.³ The Board has treated this type of violation as a standard of care or malpractice matter pursuant to s. 458.331(1)(t), F.S.

Federal Regulations

The federal Mammography Quality Standards Act (MQSA)⁴ contains requirements related to the accreditation and operation of mammogram 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 the following: operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. The term does not include a facility of the Department of Veterans Affairs.⁵

A certificate issued by the Food and Drug Administration is required for lawful operation of all mammogram facilities subject to the provisions of the MQSA. To obtain a certificate, facilities are required to meet various quality standards set forth in federal regulations, including the requirement to communicate mammography results to patients and health care providers.⁶

Mammogram facilities are required to send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "suspicious" or "highly suggestive of malignancy," the facility must make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.⁷ Facilities are not required to include specific information about breast tissue density in the report summary sent to patients.

² The federal Patient Protection and Affordable Care Act prohibits copayments and deductibles for preventive services, including breast cancer mammography screenings every 1 to 2 years for women over age 40, as of September 23, 2010.

³ Email from the Florida Department of Health to staff in the Florida Senate Committee on Health Regulation, January 6, 2011, 9:47 am EST (on file with committee staff).

⁴ See 42 USC 263b.

⁵ See 21 CFR § 900.2(q).

⁶ See 21 CFR § 900.11(a).

⁷ See 21 CFR § 900.12(c)(2),(3).

Scientific Research

Recent medical research has produced findings about breast tissue density as it relates to breast cancer screening via mammography and the risk of developing breast cancer. Breasts contain both dense tissue (glandular tissue and connective tissue, collectively known as fibroglandular tissue) as well as fatty tissue that is much less dense. Fatty tissue appears dark on a mammogram, whereas dense tissue and tumors appear as white areas. Because fibroglandular tissue and tumors have similar density and can have a similar appearance on mammograms, tumors can be more difficult to detect in women with denser breast tissue.⁸

Women with denser breast tissue are also more likely to develop breast cancer. Women with dense tissue in 75 percent or more of the breast have a risk of breast cancer four to six times as great as the risk among women with little or no dense breast tissue.⁹

Younger women are more likely than older women to have dense breast tissue. As a woman ages, her breasts usually become more fatty as glandular tissue atrophies.¹⁰ Breast glands that produce milk form small lobes called breast lobules. Age-related atrophy of breast lobules is called lobular involution. Normal lobular involution is inversely associated with breast cancer risk. Having no or partial lobular involution is associated with a higher risk of breast cancer than having complete involution. Having a combination of no involution and dense breast tissue is associated with higher risk of breast cancer than having complete involution and non-dense breast tissue. Those two factors are independently associated with breast cancer incidence; combined, they are associated with an even greater risk.¹¹

Mammography

The National Cancer Institute (NCI) recommends that women age 40 and older should have screening mammograms every 1 to 2 years and that women who are at higher than average risk of breast cancer should talk with their health care providers about whether to have mammograms before age 40 and how often to have them.¹²

There are two methods for recording and storing images produced by mammograms: conventional and digital. Both use X-rays to produce an image of the breast; however, in conventional mammography, the image is stored directly on film, whereas in digital mammography, an electronic image of the breast is stored as a computer file. This digital information can be enhanced, magnified, or manipulated for further evaluation more easily than information stored on film. Except for the difference in how the image is recorded and stored, there is no other difference between the two types of mammography.¹³

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. Results from

⁸ National Cancer Institute, *Mammogram Fact Sheet*, September 22, 2010.

⁹ Boyd, et al., Mammographic Density and the Risk and Detection of Breast Cancer, *The New England Journal of Medicine*, January 18, 2007, p. 228.

¹⁰ Supra, note 8.

¹¹ Ghosh, et al., Independent Association of Lobular Involution and Mammographic Breast Density With Breast Cancer Risk, *Journal of the National Cancer Institute*, November 17, 2010, p. 1716.

¹² Supra, note 8.

¹³ Supra, note 8.

randomized clinical trials and other studies show that screening mammography can help reduce the number of deaths from breast cancer among women ages 40 to 74, especially for those over age 50.¹⁴ However, studies conducted to date have not shown a benefit from regular screening mammography in women under age 40 or from baseline screening mammograms (mammograms used for comparison) taken before age 40.¹⁵

Magnetic Resonance Imaging (MRI)

MRI is a technology that uses magnets and radio waves to produce detailed cross-sectional images of breast tissue and other internal body structures. MRI does not use X-rays.

Breast MRI is not recommended as a routine breast cancer screening tool for women at average risk for breast cancer. However, it is recommended for screening women who are at higher risk. The American Cancer Society (ACS) recommends that women at high risk of breast cancer (about 20 percent or greater lifetime risk based on a detailed family history or a history of radiation treatments at a young age), should get an MRI and a mammogram every year beginning at age 30. The ACS further recommends that women at moderately increased risk (15 percent to 20 percent lifetime risk) should discuss with their health care providers the benefits and limitations of adding MRI screening to a yearly mammogram, and this group includes women with extremely dense breast tissue.¹⁶

Ultrasound

Also known as sonography, ultrasound uses high-frequency sound waves to look inside a part of the body. Echoes from the sound waves are detected and translated by a computer into a black and white image shown on a computer screen. Ultrasound does not use X-rays. Breast ultrasound is sometimes used to evaluate breast problems that are found during a screening or diagnostic mammogram or during physical exam. Breast ultrasound is not routinely used for screening. Ultrasound is useful for examining some breast masses and it is the only way to tell if a suspicious area is a cyst without putting a needle into the area to remove fluid. Breast ultrasound may also be used to help doctors guide a biopsy needle into some breast lesions or areas of concern.¹⁷

The American College of Radiology (ACR) has stated that appropriate indications for breast sonography include evaluation of breasts with areas suspicious for malignancy or highly suggestive of malignancy in a setting of dense fibroglandular tissue. In such cases, sonography may be used for detection of an underlying mass that may be obscured on a mammogram.¹⁸

Breast Imaging Reporting and Database System (BI-RADS)

BI-RADS[®] is a quality assurance guide, produced by the ACR, designed to standardize breast imaging reporting and facilitate outcome monitoring. BI-RADS[®] serves as a comprehensive guide providing standardized breast imaging terminology, report organization, and assessment

¹⁴ National Cancer Institute, *Breast Cancer Screening (PDQ®)*, September 3, 2010.

¹⁵ Supra, note 8.

¹⁶ Supra, note 1, pp. 4-5.

¹⁷ Supra, note 1, p. 20.

¹⁸ American College of Radiology, *ACR Practice Guideline for the Performance of a Breast Ultrasound Examination*, pp. 1-2.

structure, as well as a classification system for mammography, ultrasound, and MRI of the breast.¹⁹

The ACR indicates it is appropriate for mammography reports to include a statement regarding extremely dense breast tissue and that, for consistency, breast composition should be described for all patients using the following patterns:

1. The breast is almost entirely fat (less than 25 percent glandular)
2. There are scattered fibroglandular densities (approximately 25 percent to 50 percent glandular)
3. The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51 percent to 75 percent glandular)
4. The breast tissue is extremely dense. This may lower the sensitivity of mammography (greater than 75 percent glandular)²⁰

III. Effect of Proposed Changes:

The bill would amend three statutory mandates that currently require the coverage of mammography by health insurers and health maintenance organizations. Under the bill, the statutory language for those mandates would also contain two requirements related to mammography reports:

1. Each mammography report provided to a patient would have to include information about breast density based on the BI-RADS[®], and
2. Where applicable, such a report would be required to include the following notice:
“If your mammogram demonstrates that you have dense breast tissue, which could hide small abnormalities, you might benefit from supplementary screening tests, including a breast ultrasound screening or a breast MRI examination, or both, depending on your individual risk factors. A report of your mammography results, which contains information about your breast density, has been sent to your physician’s office and you should contact your physician if you have any questions or concerns about this report.”

The effective date of the bill is October 1, 2011.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

¹⁹ American College of Radiology, *The American College of Radiology BI-RADS[®] Atlas and MQSA: Frequently Asked Questions*, December 20, 2010, p. 1.

²⁰ *Ibid*, p. 3.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

The cost to private sector entities to include the required information in mammography reports is indeterminate.

C. Government Sector Impact:

The cost for government sector entities to include the required information in mammography reports is indeterminate. The legislation has no fiscal impact on the government sector in a regulatory sense.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill references mammography reports and the contents they must include, but the bill requires neither insurance carriers nor health care providers to actually issue mammography reports. Mammogram facilities are required to issue reports by federal law, not Florida law.

Under requirement 1 (see Section III. Effect of Proposed Changes), it is not clear exactly what information about breast density would have to be communicated to patients. This lack of clarity could lead to wide variance in the content of information relating to breast density included in mammography reports provided to patients.

Under requirement 2, it is not clear what circumstances would satisfy the “where applicable” condition and require the inclusion of the specified notice, which could lead to wide variance as to whether mammography reports provided to patients actually contain the notice.

The Office of Insurance Regulation (OIR) suggests that the amendment might be more appropriate in laws that govern medical practice, since mammogram facilities are required to provide mammography reports to patients while insurance carriers are not.

In addition, the OIR notes that the legislation applies only to those mammograms administered to an insured health plan participant and would not necessarily affect a significant number of women who are participants in public medical service programs, are covered by an employer's self-insured plan, or who may self-pay for the mammogram test without health care coverage.

The OIR further notes that while the bill's required notice language makes reference to supplemental tests (ultrasound, MRI, or both), the bill does not specifically require coverage for such procedures as the statutes currently require for mammograms.

VIII. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

- B. **Amendments:**

None.