HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1331 CS Mammography
SPONSOR(S): Brown and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 2470

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Judiciary Committee	8 Y, 4 N, w/CS	Thomas	Hogge
2) Health Care Appropriations Committee			
3) Justice Council			
4)			
5)			

SUMMARY ANALYSIS

The bill would make a number of policy changes relating to mammography services and related litigation.

- ***Citations/Continuing Education.*** The bill authorizes the issuance of citations and additional continuing education in lieu of disciplinary action for a first offense against a physician alleging failure to diagnose breast cancer through the interpretation of a mammogram.

- ***Presumption of Informed Consent.*** The bill provides for a statutory mechanism of patient informed consent for mammograms. A physician or entity using the statutory form of informed consent is presumed to have acted within the appropriate standard of care in the interpretation of a mammogram unless the physician or entity fails to detect an abnormality that is clear and obvious to a reasonable physician under specified conditions.

- ***Admissibility of Evidence.*** The bill provides that a subsequent mammogram performed more than three months after the alleged incorrectly read mammogram may not be used by an expert witness or the finder of fact in determining the failure to diagnose breast cancer.

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

The bill takes effect July 1, 2005.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Promote Personal Responsibility: The bill modifies provisions relating to liability in certain medical malpractice civil actions.

B. EFFECT OF PROPOSED CHANGES:

General Background

Radiology

A radiologist is a licensed medical or osteopathic physician who is trained to diagnose diseases by obtaining and interpreting medical images through the use of imaging techniques such as X-rays, ultrasound, computed tomography, and magnetic resonance imaging. A radiologist must graduate from an accredited medical school, pass a national licensing examination, and complete a residency of at least 4 years of graduate medical education. These health care practitioners are usually board-certified to practice in the field of radiology by the American Board of Radiology or the American Osteopathic Board of Radiology. Chapter 458, F.S., governs the practice of medicine and chapter 459, F.S., governs the practice of osteopathic medicine.

A radiologic technologist is trained to operate radiographic equipment to produce images. The radiologic technologist may explain the imaging procedure to the patient, and assist in positioning the patient for imaging specific areas of the patient's body as prescribed by the referring physician. Radiologic technologists are licensed under part IV, ch. 468, F.S., by the Department of Health (DOH).

Mammography

Mammography is an imaging technique that uses an x-ray to give a picture of the internal structure of the breast. According to the American Cancer Society (ACS), mammography detects approximately 90 percent of the breast cancers in women without symptoms. Breast cancer accounts for nearly one of every three cancers diagnosed in women in the United States. The ACS estimates that 212,930 new cases of invasive breast cancer will be diagnosed in 2005 (approximately 1,690 of which will be diagnosed in men). 40,870 women and 460 men are expected to die from breast cancer in 2005.[1]

Female breast cancer death rates decreased by 2.3 percent annually between 1990 and 2000. Survival of breast cancer is attributable to several factors including early detection and new methods of treatment. Recommendations for the age and frequency at which women should receive mammograms have changed over time. The U.S. Preventive Services Task Force recommends mammography screening every one to two years after age 40. The ACS recommends annual mammograms for women aged 40 and older.

The U.S. Congress enacted the Mammography Quality Standards Act of 1992[2] to ensure that mammography is safe and reliable and that breast cancer is detected in its most treatable stages. The Act requires all mammography facilities to meet stringent quality standards, be accredited by an accreditation body that has been approved by the U.S. Food and Drug Administration, and be inspected annually.

[1] Breast Cancer Facts and Figures 2003-2004, American Cancer Society, 2003.
[2] See Pub. L. No. 102-539, 106 Stat. 3547 (42 U.S.C. §§ 201) approved on October 27 1992.

The Efficacy of Mammograms

Mammograms Not Justified

Over the past several years, there has been debate as to the efficacy of mammogram screenings. Researchers Peter Gøtzsche and Ole Olsen received enormous attention from the national media, scientists, breast cancer survivors, and the general public following the publication of an article in *The Lancet* in 2000.[3] In reply to a 1999 study showing no decrease in breast cancer mortality in Sweden, the authors decided to review the quality of the mammography trials and a Swedish study that analyzed pooled results from previous studies.

The authors reported a systematic review of eight randomized trials of screening mammography. The authors judged that six of the eight trials were inadequate because of imbalances in selection and randomization, particularly by age, and that these trials used flawed methods, particularly as far as the randomization is concerned. Results from the two trials that they believed were correctly randomized showed that there was no effect on breast cancer mortality or on overall mortality. Therefore, the authors conclude that screening by mammography for breast cancer is unjustified.[4]

Mammograms Justified

A committee of the Institute of Medicine of the National Academy of Sciences reviewed the same evidence as Gøtzsche and Olsen but reached the opposite conclusion.[5] The committee concluded that, "the preponderance of the evidence suggests that if a woman without any signs or symptoms of breast cancer has mammograms at regular intervals, she will substantially decrease her risk of dying from this disease." The stated reason for the differing conclusions is that by excluding certain trials, Gøtzsche and Olsen introduced new biases to their study. "When all the results are pooled, the data show a clear benefit from mammography."[6]

Mammograms and the Detection of Cancer

Even through the debate of the effectiveness of mammography, radiologists have long known that some breast cancers go undetected on screening mammograms. A variety of reasons may explain this finding. Some breast cancers simply are not seen on mammograms and may remain hidden by dense tissue until a lump is felt. Other cancers are difficult to see because they blend into the background of fibroglandular tissue and are glossed over at screening. On retrospective evaluation, these cancers occasionally may be detected; however, they also may be missed a second time because they blend into the tissue so well. Other cancers are located in areas difficult to visualize (e.g., subtle calcifications located on the burned-out edge of the film).

Occasionally, cancers are missed for no other reason than a momentary distraction or inattention by the screening radiologist. The reasons for false-negative findings on mammography are difficult to determine, since it can be months to a year before the cancer is detected, by which time the cancer is

[3] Gotzche, Peter, et al. "Is Screening for Breast Cancer with Mammography Justifiable?" *The Lancet*, vol. 355:129-134, 2000.

[4] One of The Lancet editors published a commentary on the controversial political aspects of the Gøtzsche and Olsen publication.Horton, Lancet, 358:1284-85, 2001. In their reply to this commentary (Lancet, 358:1340-42, 2001), Gøtzsche and Olsen indicated that they obtained a Cochrane review, which confirmed their findings that mammography screening is not valuable and breast cancer mortality as an outcome measure is misleading. They also showed that screening leads to more aggressive treatment and more unnecessary surgical intervention, particularly on lesions that may not always develop into invasive breast cancer. They concluded that "any hope or claim that screening mammography with more modern technologies than applied in these trials will reduce mortality without causing too much harm will have to be tested in large well conducted randomized trials with all-cause mortality as a primary outcome."

[5] Henderson IC, Regular Mammograms Remain a Crucial Tool, NY Times, Feb. 9, 2002.

[6] See http://www.cbcrp.org/publications/newsletters/2002/page_14.php.

in a more advanced state. Unfortunately, mammograms with negative findings do not guarantee the absence of cancer, despite the wishes of both doctors and patients.[7]

Workgroup on Mammography Accessibility

In 2004, the Legislature, created the Workgroup on Mammography Accessibility, and directed the workgroup and the Office of Program Policy and Government Accountability (OPPGA) to study, report, and make recommendations concerning the availability, utilization, quality of care, and cost of mammography services.[8] The workgroup met nine times and heard presentations from the Department of Health, OPPGA, the Office of Insurance Regulation, the American Cancer Society and other experts.

Based on the workgroup's examination of this information, they concluded that:

> Although there appears to be sufficient machine capacity for the current mammography demand in Florida, a shortage of radiologists trained and willing to read mammograms coupled with population growth will lead to increased appointment wait times and longer delays in diagnosis. Low reimbursement rates, fear of lawsuits, high medical liability premiums, and the repetitive nature of reading mammograms, discourages radiologists from working in the field of mammography imaging.
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> Although Florida's mammography utilization rate compares favorably to the national rate, women enrolled in the non-HMO Medicaid have only four percent utilization rate. It is important to determine the reasons why this utilization rate is drastically low. Additionally, the utilization rate among Black women is lower than the statewide utilization rate.
>
> The workgroup requests that the Florida Legislature take a proactive stance to ensure future availability and accessibility to quality mammography services in Florida. If action is not taken now, more cancers will go undetected, delays in treatment will increase, and more unnecessary deaths will occur.[9]

The workgroup made the following recommendations:

- A limitation on non-economic damages for allegations of negligence in providing interpretations of mammograms of:
  - (a) Regardless of the number of such practitioner defendants, non-economic damages shall not exceed $150,000 per claimant;
  - (b) Notwithstanding paragraph (a), the total non-economic damages recoverable by all claimants from all such practitioners shall not exceed $300,000.
- The creation of a multi-agency breast cancer steering committee, in honor of and named after Representative Carole Green, to promote and enhance the use of annual mammograms, with emphasis given to medically underserved women.
- Change the burden of proof in alleged medical liability cases involving breast cancer from the greater-weight or preponderance-of-the-evidence to the clear-and-convincing standard.
- The legislative and judicial branches of Florida government should evaluate if it is constitutional to consider exempting practitioners interpreting mammograms from Amendment 8.
- Seek to reduce or eliminate health insurance co-payments, co-insurance, and deductibles as barriers to annual mammography screenings; seek to provide a mechanism for uninsured women to receive mammograms at low or no cost.
- Create a public records exemption for information obtained by state healthcare agencies from the Food and Drug Administration (FDA), and other federal entities, for the purpose of

[7] See http://www.emedicine.com/radio/byname/mammography---computer-aided-detection.htm.
[8] Chapter 2004-57, L.O.F.
[9] "Report of the Workgroup on Mammography Accessibility," December 15, 2004.

assessing the status of, or improving, the public health, safety, and welfare of the people in Florida.
- Examine the feasibility of using a panel, consisting of radiologists, to review presuit films and digital images for "probable cause" before advancing the case for further legal action.
- Require the Department of Health's Bureau of Radiation Control (BORC), to maintain an electronic database that tracks the annual number of mammograms performed per machine.

OPPAGA Report

The following are the relevant findings and conclusions from the OPPAGA report regarding the provision of mammography services in Florida:

> Several factors may limit access to mammography services in Florida. The cost of services and the requirement to identify a primary care provider limits access for low income women who lack health insurance. For women in Florida's Medicaid Program, low reimbursement rates and facility admission criteria can serve as barriers to obtaining screening mammography services. Demand for mammography may soon exceed existing equipment capacity, which could result in additional limitations on access for low-income women. Finally, referral patterns of primary care physicians may contribute to limited accessibility for women with insurance.
>
> The fear of medical malpractice lawsuits is causing some radiologists to limit the number of mammograms they interpret. However, we were unable to substantiate this concern because the necessary information is either not available, invalid, or inconclusive. Regardless of the actual condition, concerns by interpreting physicians over medical malpractice lawsuits may contribute to long wait times for mammography services at some facilities. Some radiologists who interpret mammograms at facilities with long wait times are limiting their services due to increased concerns about medical malpractice liability lawsuits.[10]

Effect of Proposed Changes

Legislative Findings

The bill provides legislative findings regarding mammography services including "that it is of the utmost public importance that quality mammography services and other diagnostic tools remain available to detect and treat breast cancer." Other findings relate to the availability of services and the existence of a medical malpractice crisis in the State.

Citations for Health Care Practitioners

Present Situation

Section 456.077, F.S., provides a professional regulatory board, or the department if there is no board, authority to issue citations as an alternative form of discipline, and in lieu of disciplinary proceedings under s. 456.073, F.S., for violations that do not involve a substantial threat to the public health and safety. Such violations include failure to meet continuing education requirements, or failure to pay required fees or update practitioner profiles on time. If the practitioner challenges the citation, then disciplinary proceedings under s. 456.073, F.S., are initiated. A citation does not constitute discipline for a first offense, but does constitute discipline for a second or subsequent offense.

[10] Access to Mammography Services in Florida Is More Limited for Low-Income Women, OPPAGA Report No. 04-79 (December 2004).

Effect of Proposed Changes

The bill authorizes the issuance of citations and additional continuing education in lieu of disciplinary action for a first offense against a physician alleging failure to diagnose breast cancer through the interpretation of a mammogram.

Presumption of Informed Consent

Present Situation

The Florida Medical Consent Law[11] provides:

> No recovery shall be allowed in any court in this state against any physician … in an action brought for treating, examining, or operating on a patient without his or her informed consent when:
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> - The action of the physician…. in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community; and
>
> o A reasonable individual, from the information provided by the physician… under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, which are recognized among other physicians… in the same or similar community who perform similar treatments or procedures; or
>
> o The patient would reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician…
>
> A consent which is evidenced in writing and meets the requirements of subsection (3) shall, if validly signed by the patient or another authorized person, raise a rebuttable presumption of a valid consent.

Effect of Proposed Changes

The bill provides for a specific statutory mechanism of patient informed consent for mammograms. A physician or entity using the statutory form of informed consent is presumed to have acted within the appropriate standard of care in the interpretation of a mammogram unless the physician or entity fails to detect an abnormality that is clear and obvious to a reasonable physician under specified conditions.

Admissibility of Evidence

Present Situation

Chapter 766, F.S., provides for standards of recovery in medical negligence cases. Those standards are found in s. 766.102, F.S. In any action for recovery of damages based on the death or personal injury of any person in which it is alleged that such death or injury resulted from the negligence of a health care provider, the claimant has the burden of proving by the "greater weight of the evidence" (preponderance of the evidence) the alleged actions of the health care provider represented a breach of the prevailing standard of care for that "health care provider" as defined in s. 766.202(4), F.S.[12] The

[11] Section 766.103, F.S.

[12] Section 766.202(4), F.S., provides that the term "health care provider" means "any hospital, ambulatory surgical center, or mobile surgical facility as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, or chapter 486; a clinical lab licensed under chapter 483; a health maintenance

prevailing professional standard of care for a given health care provider is that level of care, skill, and treatment which, in light of all relevant, surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.

Effect of Proposed Changes

The bill provides that a subsequent mammogram performed more than six months after the alleged incorrectly read mammogram may not be used as the sole evidence by an expert witness or the finder of fact in determining the failure to diagnose breast cancer.

Retroactivity

The bill provides that it is the intent of the Legislature to apply its provisions to prior medical incidents, except that the changes made to ch. 766, F.S., are intended to apply to any medical incident for which a notice of intent to sue is mailed on or after the effective date of the act.

C. SECTION DIRECTORY:

Section 1. Provides legislative findings regarding mammography services.

Section 2. Amends s. 456.077, F.S., relating to the issuance of citations against healthcare practitioners.

Section 3. Creates s. 766.119, F.S., regarding civil actions relating to mammograms.

Section 4. Provides a severability clause.

Section 5. Provides legislative intent regarding retroactive application of the bill.

Section 6. Provides an effective date of July 1, 2005.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill does not appear to have any impact on state revenues.

2. Expenditures:

   The bill does not appear to have any impact on state expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   The bill does not appear to have any impact on local government revenues.

2. Expenditures:

   The bill does not appear to have any impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill revises provisions relating to liability and limits the admissibility of certain evidence in malpractice litigation involving radiologists and the interpretation of mammograms.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable because this joint resolution does not appear to require counties or cities to: spend funds or take action requiring the expenditure of funds; reduce the authority of counties or cities to raises revenues in the aggregate; or reduce the percentage of a state tax shared with counties or cities.

2. Other:

Access to Courts

Article I, section 21 of the Florida Constitution provides: "The courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial or delay."[13] In *Kluger v. White*,[14] the Florida Supreme Court considered the Legislature's power to abolish causes of action. At issue in *Kluger* was a statute that abolished causes of action to recover for property damage caused by an automobile accident unless the damage exceeded $550.[15] The court determined that the statute violated the access to courts provision of the state constitution, holding that where a right to access the courts for redress for a particular injury predates the adoption of the access to courts provision in the 1968 state constitution, the Legislature cannot abolish the right without providing a reasonable alternative unless the Legislature can show (1) an overpowering public necessity to abolish the right and (2) no alternative method of meeting such public necessity.[16] Because the right to recover for property damage caused by auto accidents predated the 1968 adoption of the declaration of rights, the court held that the restriction on that cause of action violated the access to courts provision of the state constitution.

In 1986, the Legislature passed comprehensive tort reform legislation that included a cap of $450,000 on noneconomic damages. The cap on damages was challenged on the basis that it violated the access to courts provision of the state constitution. The Florida Supreme Court held that the right to sue for unlimited economic damages existed at the time the constitution was adopted.[17] The court said that a cap on noneconomic damages must meet the Kluger test in order to pass constitutional muster.[18] The Court held that the Legislature did not provide an alternative remedy or commensurate benefit in exchange for limiting the right to recover damages and noted that the parties did not assert that an overwhelming public necessity existed.[19] Accordingly, the court held that the $450,000 cap on noneconomic damages violated the access to courts provision of the Florida Constitution.

[13] *See generally* 10A FLA. JUR. 2D CONSTITUTIONAL LAW §§ 360-69.
[14] 281 So.2d 1 (Fla. 1973).
[15] Chapter 71-252, s. 9, L.O.F.
[16] *See Kluger* at 4.
[17] *Smith v. Department of Insurance,* 507 So.2d 1080 (Fla. 1987).
[18] *Id.* at 1087-1088.
[19] *Id.* at 1089.

Separation of Powers

The Florida Constitution provides that "[t]he supreme court shall adopt rules for the practice and procedure in all courts".[20] The separation of powers provision of the state constitution prohibits one branch of government from exercising a power given to another branch.[21]

Florida courts generally protect their rulemaking power by striking down laws passed by the Legislature that they determine are "procedural" in nature. In January of 2000, the Legislature passed the Death Penalty Reform Act (DPRA) of 2000 in order to reduce the amount of time spent in litigation of capital cases. The bill advanced the start of the postconviction appeals process in capital cases to have it begin while the case was on direct appeal. The bill also imposed certain time limitations and limited certain. In 2000, the Florida Supreme Court held that the Death Penalty Reform Act of 2000 was an "unconstitutional encroachment" on the Court's "exclusive power to adopt rules for the practice and procedure in all courts."[22]

It is possible that this bill could implicate such considerations in that it limits the evidence that may be used in certain medical malpractice cases.

Retroactivity

Unless the Legislature states otherwise, legislation is presumed to operate prospectively only, especially when retrospective operation would impair existing rights.[23] Common law provides that the government, through rule or legislation, cannot adversely affect substantive rights once such rights have vested.[24]

B. RULE-MAKING AUTHORITY:

The Department of Health appears to have adequate existing rulemaking authority to implement its responsibilities under the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

This analysis is drawn to the Committee Substitute that was adopted at the April 13, 2005, meeting of the House Judiciary Committee. The Committee Substitute differs from the bill as filed in that the Committee Substitute:

- Leaves intact whereas clauses, legislative findings, citations, and limitation on subsequent mammograms.
- Removes the creation of the Carole Green Breast Cancer Steering Committee and medical review panel pilot project.
- Removes provision that caps noneconomic damages for radiologists performing mammograms and creates a new provision that:
    - provides for obtaining informed consent prior to the performance of a mammogram

[20] Art. V. Section 2(a), Fla. Const.
[21] Art. II, Section 3, Fla. Const.
[22] *Allen v. Butterworth*, 756 So.2d 52, 54 (Fla. 2000).
[23] *State Farm Mut. Auto. Ins. Co. v. Laforet*, 658 So.2d 55 (Fla. 1995); *Alamo Rent-A-Car, Inc. v. Mancusi*, 632 So.2d 1352 (Fla. 1994).
[24] *Bitterman v. Bitterman*, 714 So.2d 356 (Fla. 1998).

- creates a presumption that a physician is operating within the appropriate standard of care when obtaining such informed consent unless the physician fails to detect an abnormality that is readily apparent

- provides standards for when such a limitation on liability is appropriate

- Removes provision raising the burden of proof in mammogram negligence cases from preponderance of the evidence to clear and convincing evidence.