SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL: SB 2470

SPONSOR: Senator Lynn

SUBJECT: Detection of Breast Cancer in Women Through the Use of Screening Mammograms

DATE: April 24, 2005 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Pre-meeting**
2.			BI	
3.			JU	
4.			HA	
5.				
6.				

I. Summary:

The bill implements several of the recommendations of the Workgroup on Mammography Accessibility. The bill creates the "Carole Green Breast Cancer Steering Committee" staffed by the Department of Health. The 15-member committee must promote and enhance the use of annual mammograms and provide annual reports to the Legislature and Governor.

The bill authorizes the Board of Medicine and the Board of Osteopathic Medicine to issue a citation in lieu of disciplinary action for the first allegation against a physician alleging a failure to diagnose breast cancer through the interpretation of a mammogram.

The bill imposes a cap on noneconomic damages in a cause of action for personal injury or wrongful death arising from medical negligence of a practitioner providing mammography under specified circumstances. The bill requires the Department of Health to create a pilot medical review panel as part of the presuit process with medical malpractice litigation involving the failure to diagnose breast cancer through the interpretation of a mammogram. The bill revises the burden of proof from a preponderance of evidence to a clear and convincing evidence standard in medical malpractice litigation involving a medical or osteopathic physician's acts or omissions relating to mammograms. A subsequent mammogram may not be used as evidence in a medical malpractice case if performed more than 6 months after the mammogram that is alleged to have been incorrectly interpreted.

This bill amends sections 456.077 and 766.118, Florida Statutes. The bill creates s. 766.119, F.S., and five undesignated sections of law.

II. Present Situation:

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 have graduated from an accredited medical school, passed a national licensing examination, and completed a residency of at least 4 years of graduate medical education. Such 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, chapter 468, F.S., by the Department of Health.

Mammography

Mammography is an imaging technique that uses an x-ray to give a picture of the internal structure of the breast. Mammograms are used to screen for, and to diagnose, breast problems including cancer. In Florida, 66.3 percent of women 40 years of age and older have had a mammogram within the past year.[1]

According to the American Cancer Society (ACS), mammography will detect 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. For 2004, the ACS estimated that 215,990 new cases of invasive breast cancer would be diagnosed among women, 59,390 additional cases of in situ breast cancer would be diagnosed in women and approximately 1,450 cases of breast cancer would be diagnosed in men in the United States. About 40,110 women and 470 men were expected to die from breast cancer in 2004.

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 that any woman who is age 40 or older receive an annual mammogram.

The U.S. Congress enacted the Mammography Quality Standards Act of 1992[2] with the objective of ensuring that mammography is safe and reliable and that breast cancer is detected in its most

[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.

treatable stages. The Mammography Quality Standards Act program requires that all mammography facilities in the United States meet stringent quality standards and to be inspected annually. Under the Act, each mammography facility must be accredited by an accreditation body that has been approved by the U.S. Food and Drug Administration.

Recently, there has been debate over the efficacy of mammogram screening following the publication of an article in The Lancet in 2000, in which researchers Peter Gotzsche and Ole Olsen reported that their review of eight mammography trials found bias in six of the trials and determined that the two unbiased trials showed no effect of screening on breast cancer mortality.[3] The publication of the article prompted much comment from researchers and policy leaders—some supporting the implication that recommendations for mammography screening should be questioned, others emphatically stating that mammography save lives. Both the U.S. Department of Health and Human Services and the American Cancer Society repeated their support of routine mammography screening for women over age 40. U. S. Health and Human Services Secretary Tommy Thompson said, "While developing technology certainly holds the promise for new detection and treatment methods, mammography remains a strong and important tool in the early detection of breast cancer. The early detection of breast cancer can save lives."[4]

Access to mammogram screening has been an issue for several years. There is a dispute over which specific factors cause decreased access to such screening. It has been alleged that fluctuations in access to mammogram screening may be linked to the reimbursement rates from insurers and other third party payors, changes in the supply of health care practitioners performing mammograms or reading mammograms, increasing costs of malpractice insurance and fear of lawsuits on the part of radiologists, and education of individuals in the need for such screening.

Workgroup on Mammography Accessibility

In 2004, the Florida Legislature, created the Workgroup on Mammography Accessibility, and directed the workgroup and the Office of Program Policy Analysis and Government Accountability (OPPAGA) to study, report, and make recommendations concerning the availability, utilization, quality of care, and cost of mammography services.[5] The workgroup heard presentations from the Department of Health, OPPAGA, the Office of Insurance Regulation, the American Cancer Society and other experts. Based on the workgroup's examination of this information, the workgroup 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. The workgroup also concluded that although Florida's mammography utilization rate compares favorably to the national rate, women enrolled in the fee-for-service part of Medicaid have only a

[3] Gotzsche, Peter, and Olsen, Ole. "Is screening for breast cancer with mammography justifiable?" *Lancet*, Vol. 355, Issue 9198. 2000.
4 See<http://www.emedicine.com/radio/byname/mammography---computer-aided-detection.htm>
5 See ch. 2004-57, L.O.F.

four percent utilization rate. It is important to determine the reasons why this utilization rate is drastically low. The utilization rate among black women is lower than the statewide utilization rate.

The workgroup requested that the 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.[6] The workgroup made the following recommendations:

- A limitation on non-economic damages for allegations of negligence in providing interpretations of mammograms of:
    - Regardless of the number of such practitioner defendants, non-economic damages shall not exceed $150,000 per claimant;
    - Notwithstanding the previous recommendation, that 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 Constitutional Amendment 8;[7]
- 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 health care agencies from the U.S. Food and Drug Administration, and other federal entities, for the purpose of 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; and
- Require the Department of Health's Bureau of Radiation Control, to maintain an electronic database that tracks the annual number of mammograms performed per machine.

OPPAGA Report 04-79

The following are the relevant findings and conclusions from OPPAGA Report 04-79 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

[6] See "Report of the Workgroup on Mammography Accessibility," December 15, 2004.
[7] Codified as s. 26, Art. X of the State Constitution

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, the report was unable to substantiate this concern because the necessary information is 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.[8]

Standard of Evidence

The "burden of proof" is the necessity or duty of affirmatively proving a fact or facts in dispute on an issue raised between the parties in a cause.[9] The state agency prosecuting a licensure disciplinary complaint has the burden of proof to establish that a violation of the applicable licensing regulations has occurred. Clear and convincing evidence is an intermediate standard of proof, which is more than a preponderance of evidence required in civil litigation and less than the beyond the reasonable doubt required in criminal prosecutions.[10]

Medical Malpractice Tort Reform

Chapter 2003-416, Laws of Florida, was adopted as part of comprehensive medical malpractice tort reform. The law revised laws affecting medical incidents in the areas of patient safety and improved quality of health care, insurance regulation, litigation, and the Florida Birth-Related Neurological Injury Compensation Association (NICA). Specifically, the law revised the presuit process involved with medical malpractice to:

- Redefine "health care provider" for those subject to presuit procedural requirements.
- Revise and enhance statutory criteria for those who may be qualified to offer presuit corroborating medical expert opinions and expert witness testimony.
- Make presuit medical expert opinions discoverable.
- Prohibit contingency fee agreements for expert witnesses.
- Require attorneys to certify that expert witnesses are not guilty of fraud or perjury.
- Require a claimant to execute a medical information release to authorize a defendant to take unsworn statements from a claimant's physician and prescribe the conditions and scope for taking these statements.
- Specify potential sanctions if parties fails to cooperate with presuit investigations.

[8] Access to Mammography Services in Florida Is More Limited for Low-Income Women, OPPAGA Report No. 04-79 (December 2004).
[9] See *Black's Law Dictionary, Abridged Fifth Edition* (1983).
[10] See *Smith v. Department of Health & Rehabilitative Services*, 522 So.2d 956 (Fla 1st DCA 1988). See also *Black's Law Dictionary, Abridged Fifth Edition*.

- Require DOH to study and report by December 31, 2003, on whether medical review panels should be created for use during the presuit process. If DOH recommends that such panels should be created, then the report must include draft legislation to implement that recommendation.

Requirements for medical malpractice suits were revised to:

- Require claimants to provide the Agency for Health Care Administration with a copy of a complaint against a hospital or ambulatory surgical center licensed under chapter 395, F.S.
- Require settlement forms to include boilerplate language regarding the implication of a decision to settle.
- Require specific itemization of damages, as part of a verdict for medical malpractice actions, to include a break-out for future losses.

Caps on noneconomic damages in an action for personal injury or wrongful death arising from medical negligence by a practitioner or nonpractitioner were revised to provide that:

- For an injury other than a permanent vegetative state or death, noneconomic damages are capped at $500,000 from each practitioner defendant and $750,000 from a nonpractitioner defendant. However, no more than $1 million and $1.5 million can be recovered from all practitioner defendants and all nonpractitioner defendants, respectively, regardless of the number of claimants. Alternatively, the $500,000 cap and $750,000 cap can be "pierced" to allow an injured patient to recover up to $1 million and $1.5 million aggregated from all practitioner defendants and all nonpractitioner defendants, respectively, if the injury qualifies as a catastrophic injury and manifest injustice would occur if the cap was not pierced.
- For an injury that is a permanent vegetative state or death, noneconomic damages are capped at $1 million and $1.5 million from practitioner defendants and nonpractitioner defendants, respectively, regardless of the number of claimants.
- For any type of injury resulting when a practitioner provides emergency services in a hospital or life support services including transportation, provided there is no pre-existing health care patient-practitioner relationship, noneconomic damages are capped at $150,000 per claimant but cannot exceed $300,000, regardless of the number of claimants or practitioner defendants. This cap only applies to injuries prior to the patient being stabilized.
- For any type of injury resulting when a nonpractitioner provides emergency services in a hospital or prehospital emergency treatment pursuant to statutory obligations, provided there is no pre-existing health care patient-practitioner relationship, noneconomic damages are capped at $750,000 per claimant from all nonpractitioner defendants but cannot exceed $1.5 million, regardless of the number of claimants or nonpractitioner defendants.
- A setoff is allowed against noneconomic damages exceeding the statutory caps, if a reduction is made first for comparative fault.

The law regarding damages in a malpractice suit was revised to:

- Require a reduction of any award for noneconomic damages by any settlement amount received in order to preclude recovery in excess of the statutory cap.

- Clarify that the caps on noneconomic damages applicable in medical negligence trials are applicable to trials that take place following a defendant's refusal to accept a claimant's offer of voluntary binding arbitration.
- Cap recovery of noneconomic damages in voluntary binding medical negligence arbitration involving wrongful death.

Bad faith actions against insurers were revised to:

- Provide that a professional liability insurer, for insuring medical negligence, may not be held to have acted in bad faith for failure to timely pay policy limits if it tenders its policy limits and meets other reasonable conditions of settlement before the earlier of two events: the 210th day after service of the complaint or the 60th day after the conclusion of the deposition of parties and expert witnesses, the initial disclosure of witnesses and production of documents, and required mediation.
- Provide that the failure to tender policy limits is not presumptive of an insurer acting in bad faith and provides factors to be considered by the trier of fact in determining whether an insurer has acted in bad faith.
- Provide that when an insurer tenders policy limits and such tender is accepted by the claimant, the insurer is entitled to a release of its insured.

Medical malpractice insurance requirements were revised to:

- Require a rate freeze and mandatory rate filing to reflect the savings of the bill. Rates approved on or before July 1, 2003, for medical malpractice insurance remain in effect until the effective date of the new rate filing required by the act. Insurers must make a rate filing effective no later than January 1, 2004, to reflect the savings of the act, using the presumed factor established by the Office of Insurance Regulation (OIR), or using a different factor if the insurer contends that the presumed factor results in a rate that is excessive, inadequate, or unfairly discriminatory, subject to prior approval by OIR. The new rate would apply to policies issued or renewed on or after the effective date of the act, requiring insurers to provide a refund for policies issued between the effective date of the act and the effective date of the rate filing.
- Require medical malpractice insurers to notify insureds at least 60 days prior to the effective date of a rate increase and at least 90 days prior to cancellation or non-renewal.
- Provide that medical malpractice rate filings disapproved by OIR may not be submitted to an arbitration panel, but would be subject to administrative review pursuant to chapter 120, F.S.
- Require medical malpractice insurers to notify policyholders upon making a rate filing that would have a statewide average increase of 25 percent or greater.
- Require that medical malpractice insurers make a rate filing at least once annually, sworn to by at least two executive officers.
- Revise the rating standards for medical malpractice insurance to prohibit the inclusion of payments made by insurers for bad faith or punitive damages in the insurer's rate base. Such payments shall not be used to justify a rate or rate change.
- Require the Office of Program Policy and Government Accountability to study the feasibility and merits of authorizing the Office of the Public Counsel to represent the public in medical malpractice rate matters.

- Revise the closed claim reporting requirements of s. 627.912, F.S., to: (1) require reporting by all types of insurance and self-insurance entities, including specified health care practitioners and facilities for claims not otherwise reported by an insurer; (2) include reports of claims resulting in nonpayment; (3) include professional license numbers; (4) provide for electronic access to DOH for all closed claim data and otherwise delete separate reporting to DOH; (5) increase penalties for nonreporting; (6) provide that violations by health care providers of reporting requirements constitutes a violation of their practice act; (7) require OIR to prepare an annual report analyzing the closed claim reports, financial reports submitted by insurers, approved rate filings, and loss trends; and (8) authorize the Financial Services Commission to adopt rules to require the reporting of data on open claims and reserves.
- Authorize a group of 10 or more health care providers to establish a commercial self-insurance fund for providing medical malpractice coverage.
- Eliminate a prohibition against creating new medical malpractice self-insurance funds and authorize the Financial Services Commission to adopt rules relating to such funds.

Medical Negligence

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 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. The 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.

Section 766.104(1), F.S., provides that no action shall be filed for personal injury or wrongful death arising out of medical negligence unless the attorney filing the action has made a reasonable investigation to determine if there are grounds for a good faith belief that there has been negligence in the care or treatment of the claimant. This statute provides a safe harbor for the attorney's good faith determination, as good faith may be shown to exist if the claimant or his counsel has received a written opinion of an expert as defined in s. 766.102, F.S., that there appears to be evidence of medical negligence. The written opinion of the expert is not subject to discovery by an opposing party to the litigation. Section 766.102(2), F.S., sets forth the qualifications of the health care provider who may testify as an expert in a medical negligence action, and who, pursuant to s. 766.104(1), F.S., may provide an opinion supporting the attorney's good faith presuit belief that there has been medical negligence.

The purpose of s. 766.102(2), F.S., is to establish a relative standard of care for various categories and classifications of health care providers for the purpose of testifying in court. Accordingly, pursuant to s. 766.102(5), F.S., a person may not give expert testimony regarding the prevailing standard of care unless that person is a licensed health care provider and meets the following conditions.

If the health care provider against whom or on whose behalf the testimony is offered is a specialist, the expert witness must:

- Specialize in the same specialty as the health care provider against whom or on whose behalf the testimony is offered; or specialize in a similar specialty that includes the evaluation, diagnosis, or treatment of the medical condition that is the subject of the claim and have prior experience treating similar patients; and
- Have devoted professional time during the three years immediately preceding the date of the occurrence that is the basis for the action to:

    - The active clinical practice of, or consulting with respect to, the same or similar specialty that includes the evaluation, diagnosis, or treatment of the medical condition that is the subject of the claim and have prior experience treating similar patients;
    - Instruction of students in an accredited health professional school or accredited residency or clinical research program in the same or similar specialty; or
    - A clinical research program that is affiliated with an accredited health professional school or accredited residency or clinical research program in the same or similar specialty.

If the health care provider against whom or on whose behalf the testimony is offered is a general practitioner, the expert witness must have devoted professional time during the 5 years immediately preceding the date of the occurrence that is the basis for the action to:

- The active clinical practice or consultation as a general practitioner;
- The instruction of students in an accredited health professional school or accredited residency program in the general practice of medicine; or
- A clinical research program that is affiliated with an accredited medical school or teaching hospital and that is in the general practice of medicine.

If the health care provider against whom or on whose behalf the testimony is offered is a health care provider other than a specialist or a general practitioner, the expert witness must have devoted professional time during the 3 years immediately preceding the date of the occurrence that is the basis for the action to:

- The active clinical practice of, or consulting with respect to, the same or similar health profession as the health care provider against whom or on whose behalf the testimony is offered;
- The instruction of students in an accredited health professional school or accredited residency program in the same or similar health profession in which the health care provider against whom or on whose behalf the testimony is offered; or
- A clinical research program that is affiliated with an accredited medical school or teaching hospital and that is in the same or similar health profession as the health care provider against whom or on whose behalf the testimony is offered.

A medical physician or osteopathic physician who qualifies as an expert witness and who, by reason of active clinical practice or instruction of students, has knowledge of the applicable standard of care for nurses, nurse practitioners, certified registered nurse anesthetists, certified

registered nurse midwives, physician assistants, or other medical support staff may give expert testimony in a medical negligence action with respect to the standard of care of such medical support staff.

Notwithstanding s. 766.102(5), F.S., in a medical negligence action against a hospital, a health care facility, or medical facility, a person may give expert testimony on the appropriate standard of care as to administrative and other nonclinical issues if the person has substantial knowledge, by virtue of his or her training and experience, concerning the standard of care among hospitals, health care facilities, or medical facilities of the same type as the hospital, health care facility, or medical facility whose acts or omissions are the subject of the testimony and which are located in the same or similar communities at the time of the alleged act giving rise to the cause of action.

If a health care provider who otherwise qualifies to provide expert testimony is providing evaluation, treatment, or diagnosis for a condition that is not within his or her specialty, a specialist trained in the evaluation, treatment, or diagnosis for that condition shall be considered a similar health care provider.

Discipline of Health Care Practitioners

Chapter 456, F.S., and the various practice acts of health practitioners specify grounds to discipline a practitioner regulated by the Department of Health or the applicable board. As an alternative to discipline, under s. 456.077, F.S., the Department of Health and boards may adopt a rule to specify violations for the imposition of a citation in lieu of discipline. The citation offenses that the department or boards may designate expressly exclude those violations that constitute a substantial threat to the public health, safety, and welfare or involve the violation of a standard of care involving an injury to a patient.

III. Effect of Proposed Changes:

Section 1. Creates an undesignated section of law to specify legislative findings regarding mammography services and other diagnostic tools to detect and treat breast cancer, and malpractice actions relating to mammography.

Section 2. Creates an undesignated section, to create the “Carole Green Breast Cancer Steering Committee” to promote and enhance the use of annual mammograms, with emphasis to medically underserved women. The fifteen-member committee must work to implement the recommendations of the Workgroup on Mammography Accessibility. The committee must include the Secretary of Health or his or her designee, the Secretary of the Agency for Health Care Administration or his or her designee, a representative of the Office of Insurance Regulation, four persons appointed by the Governor, four persons appointed by the President of the Senate, one of which must be a current senator, and four persons appointed by the Speaker of the House of Representatives, one of which must be a current representative. The Governor’s appointees and the Legislature’s appointees who are not members of the Legislature must have a background in mammography by either practicing or teaching or both, or trying or defending medical malpractice as an attorney. The steering committee must provide annual reports to the Governor, President of the Senate, and Speaker of the House of Representatives recommending

necessary legislative and executive branch action relating to mammography services. The Department of Health must staff the committee.

Section 3. Amends s. 456.077, F.S., to authorize the Board of Medicine and the Board of Osteopathic Medicine to issue a citation in lieu of disciplinary action for the first allegation brought against a physician alleging failure to diagnose breast cancer through the interpretation of a mammogram. The Board of Medicine or the Board of Osteopathic Medicine, as applicable, in issuing the citation, may impose up to 10 additional hours of continuing education in interpreting mammograms.

Section 4. Amends s. 766.118, F.S., relating to determination of noneconomic damages in a personal injury or wrongful death action, to limit noneconomic damages in a cause of action for personal injury or wrongful death.

Subsection 766.118(8), F.S., is added to limit noneconomic damages in a cause of action for personal injury or wrongful death arising from *medical negligence of a practitioner providing mammography services to persons with whom the practitioner does not have a then-existing health care patient-practitioner relationship for that medical condition*. Noneconomic damages may not exceed $150,000 per claimant regardless of the number of such practitioner defendants. The total noneconomic damages recoverable by all claimants from all such practitioners may not exceed $300,000. The limitation in this subsection applies only to noneconomic damages awarded as a result of any act or omission of providing mammography interpretation.

Subsection 766.118(9), F.S., is added to limit noneconomic damages in a cause of action for personal injury or wrongful death arising from *medical negligence of defendants other than a practitioner providing mammography services to persons with whom the practitioner does not have a then-existing health care patient-practitioner relationship for that medical condition*. Noneconomic damages may not exceed $750,000 per claimant regardless of the number of such nonpractitioner defendants. The total noneconomic damages recoverable by all claimants from all such nonpractitioner defendants may not exceed $1.5 million. The limitation in this subsection applies only to noneconomic damages awarded as a result of any act or omission of providing mammography interpretation.

Section 5. Creates an undesignated section of law, to require the Department of Health, in consultation with the Board of Medicine and the American College of Radiology, to create a pilot medical review panel as part of the presuit process in medical malpractice litigation involving the failure to diagnose breast cancer through the interpretation of a mammogram. The panel must consist of three Florida-licensed medical or osteopathic physicians who are board certified in radiology and who have experience in the past 3 years in reading and interpreting mammograms.

The medical review panel must review all medical malpractice cases involving mammography during the presuit process and make judgments on the merits of the case based on established standards of care. The panel’s report may be used as admissible evidence at trial and in disciplinary proceedings.

The Department of Health must report to the Governor and Legislature on or before December 31, 2006, whether medical review panels or similar panels should be created for use during the presuit process for other medical services. The section specifies requirements for the report.

Section 6. Creates s. 766.119, F.S., to provide that the burden of proof is clear and convincing evidence, in a civil action brought under ch. 766, F.S., against a radiologist licensed in Florida as a medical or osteopathic physician for any actions or omissions arising from the performance of his or her duties relating to mammograms. A subsequent mammogram may not be used as the sole evidence relied upon by an expert witness or a finder of fact in determining the failure to diagnose breast cancer when the subsequent mammogram was performed more than 6 months after the mammogram that is alleged to have been incorrectly interpreted.

Section 7. Creates an undesignated section, to provide a severability clause.

Section 8. Creates an undesignated section, to provide legislative intent to apply the provisions of this bill to prior medical incidents to the extent such application is not prohibited by the State or federal Constitution, except that changes to ch. 766, F.S., must apply only to any medical incident for which a notice of intent to initiate litigation is mailed on or after the effective date of this bill.

Section 9. Provides an effective date of July 1, 2005.

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.

B. Public Records/Open Meetings Issues:

The provisions of this 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.

D. Other Constitutional Issues:

The bill limits the noneconmic damages that claimants may get in an action for personal injury or wrongful death arising from medical negligence of certain practitioners providing mammography services as specified in the bill. The bill's revision to the requirements to bring a cause of action to allege such a medical malpractice claim and its limitation on noneconomic damages raises questions about possible infringements on the right of access to the courts. Section 21, Article I of the State Constitution provides that

the courts shall be open to all for redress for an injury. To impose a barrier or limitation on litigants' right to file certain actions it would have to meet the test announced by the Florida Supreme Court in Kluger v. White[11]. Under the constitutional test established by the Florida Supreme Court in *Kluger v. White*, the Legislature would have to: (1) provide a reasonable alternative remedy or commensurate benefit, or (2) make a legislative showing of overpowering public necessity for the abolishment of the right and no alternative method of meeting such public necessity.

In addition, the substantive provisions of the bill apply to cases pending but that have not yet gone to trial as of the effective date of the bill. A bill may provide that its provisions apply retroactively if there is no constitutional proscription against making them retroactive; the act overcomes the presumption that it applies only prospectively by explicitly providing for retroactive application; and its title conveys notice of this retroactive application.[12] There is no express constitutional prohibition against retroactive noncriminal statutes; however, retroactive application of statutes that impair the obligations of contracts or vested rights is invalid.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

If the tort reforms in the bill are implemented, radiologists may experience fewer claims, may pay less for malpractice insurance costs, and associated risk management of such claims.

C. Government Sector Impact:

The Department of Health will incur costs to implement the bill, indicates that the fiscal impact of the bill is approximately $800,000 annually, and notes that there is insufficient detail to provide specific estimates.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[11] See *Kluger v. White*, 281 So.2d 1 (Fla. 1973).
[12] See *Dewberry v. Auto-Owners Ins. Co*., 363 So.2d 1077 (Fla. 1978) and *Chiapetta v. Jordan*, 16 So.2d 241 (Fla.1943) as cited in The Florida Senate Manual for Drafting General Bills, Fifth Edition, 1999

VIII. Summary of Amendments:

None.