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.)

BILL: SB 2306

SPONSOR: Senator Lynn

SUBJECT: Radiologists Performing Mammograms

DATE: April 8, 2004 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable
2.			JU	
3.				
4.				
5.				
6.				

I. Summary:

The bill makes a Florida-licensed radiologist immune from liability in tort for any actions arising out of his or her duties relating to mammograms, except for instances in which the radiologist is found to be grossly negligent. The section is repealed July 1, 2006, unless reviewed and reenacted by the Legislature.

This bill creates an undesignated section 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 (DOH).

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 will be diagnosed among women, 59,390 additional cases of *in situ* breast cancer will be diagnosed in women and approximately 1,450 cases of breast cancer will be diagnosed in men in the United States. About 40,110 women and 470 men are 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 to ensure that mammography is safe and reliable and that breast cancer is detected in its most 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

[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.
[3] Gotzsche, Peter, and Olsen, Ole. "Is screening for breast cancer with mammography justifiable?" *Lancet*, Vol. 355, Issue 9198. 2000.

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. Arguments have 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 need of such screening.

Medical Malpractice Tort Reform

Chapter 2003-416, Laws of Florida, was adopted last year 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.
- 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.

[4] http://www.cancer.org/docroot/NWS/content/NWS_1_1x_Federal_Officials_Announce_Support_of_Mammography.asp.>

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 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 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.

III. Effect of Proposed Changes:

The bill creates an undesignated section of law to make a Florida-licensed radiologist immune from liability in tort for any actions arising out of his or her duties relating to mammograms, except for instances in which the radiologist is found to be grossly negligent.[5] The section is repealed July 1, 2006, unless reviewed and reenacted by the Legislature.

The effective date of the bill is upon becoming a law.

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, s. 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, s. 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. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

It may be more difficult for plaintiffs to successfully bring a medical malpractice lawsuit against a Florida-licensed radiologist for her or his duties relating to mammograms under a gross negligence standard of care. Radiologists who perform mammograms may have a lower risk of negligence that may result in lower malpractice insurance costs.

C. Government Sector Impact:

None.

[5] Black's Law Dictionary defines "gross negligence" as the intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another.

VI. Technical Deficiencies:

None.

VII. Related Issues:

According to the Florida OIR, the malpractice insurance carriers who represent a large majority of the medical malpractice underwriting in Florida do not surcharge radiologists for reading mammograms. A 1997 survey which was published by the Physicians Insurers Association of America and the American College of Radiology found that mammography is the most prevalent patient condition for which claims are generated against physicians. "Furthermore, an error in the diagnosis of breast cancer is the most prevalent patient condition for which claims are generated against physicians."[6]

VIII. Amendments:

None.

[6] Physician Insurers Association of America, American College of Radiology. Practice Standards Claims Survey. Rockville, MD: Physician Insurers Association of America, 1997 as cited at <http://www.acr.org/departments/pub_rel/press_releases/jama_coments.html.>.