HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1087 w/ CS Radiologists Performing Mammograms
SPONSOR(S): Green and others
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2306 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	16 Y, 6 N w/CS	Rawlins	Collins
2) Judiciary			
3)			
4)			
5)			

SUMMARY ANALYSIS

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.

Mammography machines use low doses of X-rays to produce an image of the breast and breast tissue. The image is processed using either film screen or digital techniques. The image is examined by a radiologist who looks for changes or inconsistencies in the breast tissue. Recently, there has been debate as to the efficacy of mammogram screenings following the publications of an article in The Lancet in 2000. Researchers Peter Gøtzsche and Ole Olsen received enormous attention from the national media, scientists, breast cancer survivors, and the general public for their publication.

Chapter 2003-416, Laws of Florida, was adopted last year as part of a comprehensive medical malpractice tort reform. The law revised provisions 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). However, special immunity for radiologists was not granted within this comprehensive reform.

This bill creates an undesignated section of law and provides that a Florida-licensed radiologist is immune from liability in tort for any actions arising out of his or her duties relating to mammograms when meeting specified requirements with an exception for instances in which the radiologist is found to be grossly negligent. The bill provides for repeal effective July 1, 2006, unless reviewed and reenacted by the Legislature.

The bill creates the “Workgroup on Mammography Accessibility” within the Department of Health. The workgroup is charged with studying the availability, quality of care, and accessibility of mammography in this state.

The bill provides for an effective date upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[x]	No[]	N/A[]
2. Lower taxes?	Yes[]	No[]	N/A[x]
3. Expand individual freedom?	Yes[x]	No[]	N/A[]
4. Increase personal responsibility?	Yes[]	No[x]	N/A[]
5. Empower families?	Yes[]	No[]	N/A[x]

For any principle that received a "no" above, please explain:

This bill may have the effect of decreasing the personal responsibility of radiologist to provide quality service.

B. EFFECT OF PROPOSED CHANGES:

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 machines use low doses of X-rays to produce an image of the breast and breast tissue. The image is processed using either film screen or digital techniques. The image is examined by a radiologist who looks for changes or inconsistencies in the breast tissue. Mammograms are used to screen for, and to diagnosis, breast disease including cancer. In Florida, 66.3 percent of women 40 years of age and older have had a mammogram within the past year.

Although breast cancer can strike both men and women, routine mammography screenings are recommended only for women and are based on the age of a woman. For women in the age group of 40 to 49 a mammogram is recommended every 1 to 2 years, with or without clinical breast exam and may reduce the risk of dying from breast cancer by 17 percent. For women in the age group of 50 to 74, a mammogram is recommended every 1 to 2 years, with or without clinical breast exam and may reduce risk of dying from breast cancer by 30 percent.

According to the American Cancer Society (ACS), mammography will detect approximately 90 percent of the breast cancers in women without symptoms. Breast cancer accounts fro nearly one of every three cancers diagnosed in women in the United States. In 2004, the ACS estimates that 215,990 new cases of invasive breast cancer will be diagnosed among women and approximately 1,450 cases of breast cancer will be diagnosed in men. About 40,110 women and 470 men are expected to die from breast cancer in 2004.

The U.S. Congress enacted the Mammography Quality Standards Act of 1992 (MQSA) to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. In the fall of 1998, Congress reauthorized MQSA, extending the program to 2002. The program requires that all mammography facilities in the United States meet stringent quality of 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 as to the efficacy of mammogram screenings following the publications of an article in *The Lancet* in 2000. Researchers Peter Gøtzsche and Ole Olsen received enormous attention from the national media, scientists, breast cancer survivors, and the general public for their publication.[1]

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 (a meta-analysis). They also performed a meta-analysis themselves.

The authors reported a systematic review of eight randomized trials of screening mammography. The following trials were included in this study: New York, Edinburgh, Canada, Malmo, Stockholm, Goteborg, Kopparberg, and Ostergotland. The authors judged that six of the eight trials were inadequate for the meta-analyses 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.

One of The Lancet editors, Horton, published a commentary on the controversial political aspects of the Gøtzsche and Olsen publication (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."

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 (Henderson IC, Regular Mammograms Remain a Crucial Tool, NY Times, Feb. 9, 2002). According to committee member Dr. I. Craig Henderson, they 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 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."[2]

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).

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

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

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 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.[3]

Malpractice Reform

Chapter 2003-416, Laws of Florida, was adopted last year as part of a comprehensive medical malpractice tort reform. The law revised provisions 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 specifies that in the presuit process involved with medical malpractice that:

- Redefines "health care provider" for those subject to presuit procedural requirements.
- Revises and enhances statutory criteria for who may be qualified to offer presuit corroborating medical expert opinions and expert witness testimony.
- Makes presuit medical expert opinions discoverable.
- Prohibits contingency fee agreements for expert witnesses.
- Requires attorneys to certify that expert witnesses are not guilty of fraud or perjury.
- Requires a claimant to execute a medical information release to authorize a defendant to take unsworn statements from a claimant's physician and prescribes the conditions and scope for the taking of these statements.
- Specifies potential sanctions if parties fail to cooperate with presuit investigations.
- Requires 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:

- Requires claimants to provide AHCA with a copy of a complaint against a hospital or ambulatory surgical center licensed under ch. 395, F.S.
- Requires settlement forms to include boilerplate language regarding the implication of a decision to settle.
- Requires specific itemization of damages, as part of a verdict for medical malpractice actions, to include 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.

[3] See http://www.emedicine.com/radio/byname/mammography---computer-aided-detection.htm.

- 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.
- Allows for setoff against noneconomic damages exceeding the statutory caps, provided a reduction is made first for comparative fault.
- Requires reduction of any award for noneconomic damages by any settlement amount received in order to preclude recovery in excess of the statutory cap.
- Clarifies 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.
- Caps recovery of noneconomic damages in voluntary binding medical negligence arbitration involving wrongful death.

Provisions for bad faith actions against insurers were revised to:

- Provides 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.
- Provides 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.
- Provides 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.

Provisions for immunity were revised to:

- Provide immunity from injunctive or civil relief against any licensed facility or its board, board members, or staff arising out of or relating to carrying out activities relating to staff membership or clinical privileges at a hospital, ambulatory surgical center, or mobile surgical facility, absent intentional fraud.
- Provide immunity from vicarious liability to insurers, prepaid limited health service organizations, and health maintenance organizations for the negligent acts of their employees or persons with whom they contract.
- Specify the circumstances under which immunity from civil liability under the Good Samaritan Act applies, by extending the immunity to any health care provider providing emergency services pursuant to obligations imposed by federal and state statutes and revises the definition of "reckless disregard" for purposes of extending such immunity; and by extending the immunity

to any health care practitioner who is in a hospital and who voluntarily provides immediate emergency care or treatment to a nonpatient of his or hers.

- Extends sovereign immunity to health care practitioners who have contractually agreed to act as agents of a state university board of trustees to provide medical services to a student-athlete for participation in or as a result of intercollegiate athletics.
- Provides immunity for physicians performing high school examinations for student athletes by revising the requirements for the Florida High School Activities Association by-laws for participation in interscholastic athletics to require that an evaluation and history form incorporate recommendations of the American Heart Association for participation cardiovascular screening and removing standards by which certification is conducted.

Provisions for medical malpractice insurance 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 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 ch. 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.
- Amend 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 OPAAGA to study the feasibility and merits of authorizing the Office of the Public Counsel to represent the public in medical malpractice rate matters.
- Amend 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; (8) authorize the Financial Services Commission to adopt rules to require the reporting of data on open claims and reserves; and (9) maintain current law for provisions that apply to professional liability for attorneys so that the bill is limited to the single subject of "medical incidents."
- Authorizes a group of 10 or more health care providers to establish a commercial selfinsurance fund for providing medical malpractice coverage.

- Eliminates an existing prohibition against creating new medical malpractice selfinsurance funds and authorizes 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.

HB 1087

This 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[4] and provided the licensee complies with the following criteria:

- The licensee must meet and continuously maintain the requirements governing radiologists performing mammography adopted by the Federal Government pursuant to the Mammography Quality Standards Act of 1992.
- The licensee must be certified in diagnostic radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada or have at least 3 months documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection.
- The licensee must have 60 hours documented category I continuing medical education in mammography or 40 hours if initially qualified before April 28, 1999, at least 15 hours of which shall be acquired in the 3 years immediately prior to the physician's meeting his or her

[4] Florida statue defines “gross negligence” in ss. 400.0237, 400.4297, and 768.72, F.S.; however this term is not defined within this section of law.

requirements, and earn at least 15 hours category I continuing medical education in a 36-month period, at least 6 hours of which shall be related to each mammographic modality used.

- The licensee must have interpreted mammograms from exams of 240 patients within the 6 months immediately prior to the physician's qualifying date or in any 6 months within the last 2 years of residency if the physician becomes board certified at his or her first possible opportunity and shall continue to interpret or multi-read at least 960 mammographic examinations over a 24-month period.
- The interpreting physician must receive at least 8 hours of training in any mammographic modality for which he or she was not previously trained before beginning to use that modality.
- The licensee must meet the most current guidelines of the American College of Radiology for mammography procedures.
- The licensee operates from a facility which has established and implemented policies and procedures to provide for the safety of patients and personnel, which shall include:
    - ⇒ Attention to the physical environment.
    - ⇒ The proper use, storage, and disposal of medications and hazardous materials and their attendant equipment.
    - ⇒ Methods for addressing medical and other emergencies.
- The licensee operates from a facility which has established and implemented policies and procedures for educating and informing patients about procedures and interventions to be performed and facility processes for such procedures and interventions, which shall include appropriate instructions for patient preparation and aftercare, if any. This information shall be provided in an appropriate form to the patient. Such communication policies shall include provisions that provide direct communication, accomplished in person or by telephone, to the referring physician or an appropriate representative. Documentation of direct communication is recommended. In those situations in which the interpreting physician feels that immediate patient treatment is indicated, which may include, but are not limited to, tension pneumothorax, the interpreting physician should communicate directly with the referring physician, other health care provider, or an appropriate representative. If that individual cannot be reached, the interpreting physician should directly communicate the need for emergency care to the patient or responsible guardian, if possible.
    - ⇒ Under some circumstances, practice constraints may dictate the necessity of a preliminary report before the final report is prepared. A significant change between the preliminary and final interpretation shall be reported directly to the referring physician.
    - ⇒ In those situations in which the interpreting physician feels that the findings do not warrant immediate treatment but constitute significant unexpected findings, the interpreting physician or his or her designee shall communicate the findings to the referring physician, other health care provider, or an appropriate individual in a manner that reasonably insures receipt of the findings.
- The licensee's patient examinations shall be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring shall include evaluation of the accuracy of interpretation as well as the appropriateness of the examination. Complications and adverse events or activities that may have the potential for sentinel events should be monitored, analyzed, and reported as required by law and periodically reviewed in order to identify opportunities to improve patient care. This data shall be collected in a manner that complies with statutory and regulatory peer-review procedures in order to ensure the confidentiality of the peer-review process.
- The licensee operates from a facility which has established and implemented policies and procedures to control the spread of infection among patients and personnel and shall include

adherence to universal precautions and the use of clean or aseptic techniques as warranted by the procedure or intervention being performed.

Immunity is not provided if all the provisions within this section are not met and for instances in which the radiologist is found to be grossly negligent.

The bill provides for repeal, effective July 1, 2007, unless reviewed and reenacted by the Legislature.

The bill creates the "Workgroup on Mammography Accessibility" within the Department of Health. The workgroup is charged with studying the availability, quality of care, and accessibility of mammography in this state. Specifically the study shall review:

- The need for research and educational facilities, including, but not limited to, facilities with institutional training programs and community training programs for doctors of radiological medicine at the student, internship, and residency training levels.
- The availability of resources, including health personnel and management personnel for mammography programs.

The workgroup will consist of 13 members and be staffed by the Department of Health and chaired by the Secretary of Health or his or her designee. The Secretary of Health shall appoint the remaining 12 members.

The bill provides for an effective date of upon becoming law.

C. SECTION DIRECTORY:

Section 1. Provides licensed radiologists with immunity from tort liability under certain circumstances; provides exceptions; and provides for future repeal unless reviewed and reenacted by the Legislature.

Section 2. Creates a 13-member "Workgroup on Mammography Accessibility," chaired by the Secretary of Heath.

Section 3. Provides for an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   Expenditures are anticipated for the study required by the Department of Health.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Florida Office of Insurance Regulation (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."

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 13, 2004, the Committee on Health considered HB 1087 with a strike-all amendment and reported the bill favorably with a committee substitute.

The strike-all amendment differs from the original bill in that the strike all requires immunity only if the licensee complies with the following criteria:

- The licensee must meet and continuously maintain the requirements governing radiologists performing mammography adopted by the Federal Government pursuant to the Mammography Quality Standards Act of 1992.
- The licensee must be certified in diagnostic radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada or have at least 3 months documented training in mammography interpretation, radiation physics, radiation effects, and radiation protection.

- The licensee must have 60 hours documented category I continuing medical education in mammography or 40 hours if initially qualified before April 28, 1999, at least 15 hours of which shall be acquired in the 3 years immediately prior to the physician's meeting his or her requirements, and earn at least 15 hours category I continuing medical education in a 36-month period, at least 6 hours of which shall be related to each mammographic modality used.
- The licensee must have interpreted mammograms from exams of 240 patients within the 6 months immediately prior to the physician's qualifying date or in any 6 months within the last 2 years of residency if the physician becomes board certified at his or her first possible opportunity and shall continue to interpret or multi-read at least 960 mammographic examinations over a 24-month period.
- The interpreting physician must receive at least 8 hours of training in any mammographic modality for which he or she was not previously trained before beginning to use that modality.
- The licensee must meet the most current guidelines of the American College of Radiology for mammography procedures.
- The licensee operates from a facility which has established and implemented policies and procedures to provide for the safety of patients and personnel, which shall include:
    - Attention to the physical environment.
    - The proper use, storage, and disposal of medications and hazardous materials and their attendant equipment.
    - Methods for addressing medical and other emergencies.
- The licensee operates from a facility which has established and implemented policies and procedures for educating and informing patients about procedures and interventions to be performed and facility processes for such procedures and interventions, which shall include appropriate instructions for patient preparation and aftercare, if any. This information shall be provided in an appropriate form to the patient. Such communication policies shall include provisions that provide direct communication, accomplished in person or by telephone, to the referring physician or an appropriate representative. Documentation of direct communication is recommended. In those situations in which the interpreting physician feels that immediate patient treatment is indicated, which may include, but are not limited to, tension pneumothorax, the interpreting physician should communicate directly with the referring physician, other health care provider, or an appropriate representative. If that individual cannot be reached, the interpreting physician should directly communicate the need for emergency care to the patient or responsible guardian, if possible.
    - ⇒ Under some circumstances, practice constraints may dictate the necessity of a preliminary report before the final report is prepared. A significant change between the preliminary and final interpretation shall be reported directly to the referring physician.
    - ⇒ In those situations in which the interpreting physician feels that the findings do not warrant immediate treatment but constitute significant unexpected findings, the interpreting physician or his or her designee shall communicate the findings to the referring physician, other health care provider, or an appropriate individual in a manner that reasonably insures receipt of the findings.
- The licensee's patient examinations shall be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring shall include evaluation of the accuracy of interpretation as well as the appropriateness of the examination. Complications and adverse events or activities that may have the potential for sentinel events should be monitored, analyzed, and reported as required by law and periodically reviewed in order to identify opportunities to improve patient care. This data shall be collected in a manner that complies with statutory and regulatory peer-review procedures in order to ensure the confidentiality of the peer-review process.
- The licensee operates from a facility which has established and implemented policies and procedures to control the spread of infection among patients and personnel and shall include adherence to

universal precautions and the use of clean or aseptic techniques as warranted by the procedure or intervention being performed.

The amendment specifies that immunity is not provided if all the provisions are not met and for instances in which the radiologist is found to be grossly negligent.

As in the original bill the amendment provides for repeal, effective July 1, 2007, unless reviewed and reenacted by the Legislature.

The amendment creates the “Workgroup on Mammography Accessibility” within the Department of Health. The workgroup is charged with studying the availability, quality of care, and accessibility of mammography in this state. Specifically the study shall review:

- The need for research and educational facilities, including, but not limited to, facilities with institutional training programs and community training programs for doctors of radiological medicine at the student, internship, and residency training levels.
- The availability of resources, including health personnel and management personnel for mammography programs.
- The workgroup will consist of 13 members and be staffed by the Department of Health and chaired by the Secretary of Health or his or her designee. The Secretary of Health shall appoint the remaining 12 members.