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 2160
INTRODUCER:	Senator Saunders
SUBJECT:	Medical malpractice insurance
DATE:	March 27, 2006
REVISED:	03/30/06

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Fav/4 amendments**
2.			BI	
3.			JU	
4.			HA	
5.				
6.				

Please see last section for Summary of Amendments

- [ ] Technical amendments were recommended
- [x] Amendments were recommended
- [ ] Significant amendments were recommended

I. Summary:

The bill caps noneconomic damages in a medical malpractice case against a teaching hospital if the hospital has received certification from the Agency for Health Care Administration (agency) that the facility complies with the patient-safety measures specified in the bill. The cap is set at $500,000 in noneconomic damages, regardless of the number of claimants, number of claims, or theory of liability, including vicarious liability, arising from the same nucleus of operative fact. Teaching hospitals will also be permitted to make periodic payment of future economic damages. The bill provides legislative findings to support the public necessity for the cap.

The patient safety measures with which a teaching hospital must comply in order to have medical malpractice economic damage awards capped include, but are not limited to: implementation of a system for the early detection of potential errors; conducting simulation-based skills assessment, training and retraining; developing a web-based patient safety curriculum; and implementing a mandatory near-miss reporting system. The bill specifies the conditions that must be met for the agency to certify the hospital as a patient-safety facility.

The bill authorizes all hospitals and verified trauma centers to extend insurance and self-insurance coverage to members of their medical staff, including physicians' practices, individually or through a professional association, and other health care practitioners, including students preparing for licensure. The bill authorizes insurers issuing professional liability

coverage for medical malpractice to physicians, dentists, and nurses to have an appropriate exclusion for acts of medical negligence occurring within the premises of a hospital that has agreed to indemnify covered persons for legal liability.

This bill amends sections 766.110 and 766.118, Florida Statutes.

This bill creates ss. 627.41485, 766.401, 766.402, 766.403, 766.404, 766.405, and 766.406, F.S., and five unnumbered sections of law.

II. Present Situation:

Medical Malpractice Caps on Noneconomic Damages

In 2003, the Legislature adopted several medical malpractice reforms, including caps on noneconomic damages in an action for personal injury or wrongful death arising from medical negligence by a practitioner or nonpractitioner.

- 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.
- The law allows for setoff against noneconomic damages exceeding the statutory caps, provided a reduction is made first for comparative fault.
- The law requires reduction of any award for noneconomic damages by any settlement amount received in order to preclude recovery in excess of the statutory cap.

- 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.
- The law caps recovery of noneconomic damages in voluntary binding medical negligence arbitration involving wrongful death.[1]

Access to Courts

Section 21, Art. I of the State Constitution provide that the courts shall be open to all for redress for an injury. Florida's Medical Malpractice Reform Act has been subject to constitutional challenges regarding the infringement on a party's right of access to courts in civil actions by the imposition of caps on noneconomic damages.[2] The test for assuring the right of access to the courts was declared in *Kluger v. White* in which the Florida Supreme Court held that:

> Where a right of access to the courts for redress for a particular injury has been provided by statutory law predating the adoption of the Declaration of Rights of the Constitution of the State of Florida, or where such right has become a part of the common law of the State pursuant to Fla. Stat. s. 201, F.S.A., the Legislature is without power to abolish such a right without providing a reasonable alternative to protect the rights of the people of the State to redress for injuries, unless the Legislature can show an overpowering public necessity for the abolishment of such right, and no alternative method of meeting such public necessity can be shown.[3]

In 1986, the Legislature imposed a $450,000 cap on non-economic damages for all negligence actions[4]. In *Smith v. Department of Insurance*, the Florida Supreme Court held that an absolute $450,000 cap on noneconomic damages for losses suffered by a victim of negligence violated the tort victim's right of access to the courts.[5]

The rationale underlying the court's decision was based on the test announced in *Kluger*, regarding the right of access to courts. To impose a cap on noneconomic damages 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.[6]

The Florida Legislature revised the Act again in 1988 following the recommendations made by the Academic Task Force for Review of Insurance and Tort Systems. The 1988 legislation allows either party to a malpractice action to request voluntary binding arbitration of damages and precludes other remedies by the claimant against the defendant.[7] In addition, the claimant's

[1] See s. 766.118, F.S.
[2] Noneconomic damages are defined as "nonfinancial losses which would not have occurred but for the injury giving rise to the cause of action, including pain and suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of capacity for enjoyment of life, and other nonfinancial losses." See §766.202(7), Florida Statutes.
[3] See *Kluger v. White*, 281 So.2d 1 (1973), at 4.
[4] See section 59, chapter 86-160, Laws of Florida.
[5] *Smith v. Department of Insurance*, 507 So.2d 1080 (Fla. 1987).
[6] See *Smith v. Dep't of Ins.*, 507 So.2d 1080 at 1088 (Fla. 1987).
[7] See ss. 766.207 and 766.209, Florida Statutes.

noneconomic damages are capped at $250,000 per incident and are calculated on a percentage basis with respect to capacity to enjoy life.

In *University of Miami v. Echarte*, the Florida Supreme Court held that statutes providing a monetary cap on noneconomic damages in medical malpractice claims when a party requests binding arbitration are not unconstitutional and do not violate the access to courts provision of the Florida Constitution.[8] In *Echarte*, the court upheld the cap on noneconomic damages despite arguments that the statutes failed to provide a reasonable alternative to protect the rights of medical malpractice plaintiffs to redress injuries because the court found that the statutes at issue provide a commensurate benefit to the plaintiff in exchange for the monetary cap, the Legislature was found to have demonstrated the requisite overpowering public necessity for restricting claimant's noneconomic damages by showing an overpowering public necessity existed with regard to the control of medical malpractice premiums, and no alternative or less onerous method of meeting the crisis had been shown.[9] The court's conclusion that no alternative or less onerous method of meeting the public necessity is supported by the Legislature's actions in adopting both the Task Force's recommendations to enact arbitration statutes and to strengthen regulation of the medical profession.[10]

In 1988, a proposed constitutional amendment petition to place a $100,000 cap on non-economic damages was defeated at the polls.

Claimants may also challenge the imposition of caps on noneconomic damages under other constitutional claims such as the violation of the right to trial by jury, equal protection guarantees, substantive or procedural due process rights, the taking clause, the single subject requirement or the non-delegation doctrine.

Statutory Teaching Hospitals

Section 408.07(45), F.S., defines "teaching hospital" to mean any Florida hospital officially affiliated with an accredited Florida medical school which exhibits activity in the area of graduate medical education as reflected by at least seven different graduate medical education programs accredited by the Accreditation Council for Graduate Medical Education or the Council on Postdoctoral Training of the American Osteopathic Association and the presence of 100 or more full-time equivalent resident physicians. The Secretary of Health Care Administration is responsible for determining which hospitals meet this definition.

There are currently six statutory teaching hospitals. These include Jackson Memorial Hospital, Mount Sinai Medical Center, Orlando Regional Medical Center, Tampa General Hospital, Shands-Jacksonville, and Shands University of Florida. According to the Teaching Hospital Council of Florida, these hospitals provide 80 percent of all medical residencies, 50 percent of all indigent care, and at least 30 percent of all Medicaid treatment in Florida.

[8] *University of Miami v. Echarte*, 585 So.2d 293 (Fla. 3rd DCA 1991), rev'd, 618 So.2d 189 (Fla.), cert. denied, 114 S.Ct. 304 (1993).
[9] Id. at 194, and 196-197.
[10] Id. at 197.

Patient Safety in General

The current focus on patient safety in the U.S. health care system is generally attributed to the 1999 publication of *To Err is Human* by the Institute of Medicine, which found that as many as 44,000 to 98,000 people die in U.S. hospitals each year as the result of lapses in patient safety. Patient safety can be defined as freedom from accidental or preventable injuries produced by medical care. Some of the medically induced injuries are the result of missed or incorrect diagnoses, mistakes in surgery, mistakes with the administration of medications, and infections caused by inadequate infection control procedures.

One approach to reducing medical errors that has received considerable attention in the past several years is reporting of near misses. Taking a lesson from the aviation industry, patient safety advocates recommend that hospitals participate in near-miss reporting systems, which focus on identifying events where a medical error almost occurred, but was prevented. By studying these events and learning from what almost went wrong, hospitals can fix systemic problems in order to avoid future adverse incidents.

Specific Patient Safety Requirements for Hospitals

Although the general purpose of all licensure requirements for hospitals is to ensure a basic level of quality that safeguards patients, there are various specific patient safety requirements established for hospitals as a condition of licensure, as a condition of accreditation by private accrediting organizations, and as a condition of participating in the Medicare program.

In Florida, hospitals are licensed and regulated by the Agency for Health Care Administration under ch. 395, F.S. Section 395.0161, F.S., requires the agency to conduct inspections and investigations, as it deems necessary for specified purposes. However, this section requires the agency to accept, in lieu of its own periodic inspections for licensure, the survey or inspection of an accrediting organization, provided the accreditation of the licensed facility is not provisional and provided the licensed facility authorizes release of, and the agency receives the report of, the accrediting organization. Most hospitals are accredited and therefore do not receive regular licensure inspections by the agency.

Chapter 395, F.S., does provide certain specific patient safety requirements for hospitals. Section 395.0197, F.S., requires every hospital to establish an internal risk management program that includes:

- The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.
- The development of appropriate measures to minimize the risk of adverse incidents to patients, including: risk management and risk prevention education and training of all nonphysician personnel; restrictions on staff members attending a patient in the recovery room; restrictions on unlicensed persons assisting or participating in any surgical procedure; and development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, and the correct site of the planned procedure.

- The analysis of patient grievances that relate to patient care and the quality of medical services.
- A system for informing a patient or an individual that the patient was the subject of an adverse incident.
- The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the hospital to report adverse incidents to the risk manager.

Hospitals must report adverse incidents to the agency. For purposes of reporting to the agency, the term "adverse incident" means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:

- Results in one of the following injuries:
  - Death;
  - Brain or spinal damage;
  - Permanent disfigurement;
  - Fracture or dislocation of bones or joints;
  - A resulting limitation of neurological, physical, or sensory function which continues after discharge from the hospital;
  - Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or
  - Any condition that required the transfer of the patient, within or outside the hospital, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- Was a procedure to remove unplanned foreign objects remaining from a surgical procedure?

Section 395.1012, F.S., requires each hospital to adopt a patient safety plan. A plan adopted to implement Medicare requirements is deemed to comply with this requirement. Each hospital must also appoint a patient safety officer and a patient safety committee, which must include at least one person who is neither employed by nor practicing in the hospital. The purpose of the committee is to promote the health and safety of patients, to review and evaluate the quality of patient safety measures used by the facility, and to assist in the implementation of the facility patient safety plan.

Section 395.1051, F.S., requires an appropriately trained person designated by each hospital to inform each patient, or an individual identified in the list of proxies under the health care advance directives law, in person about adverse incidents that result in serious harm to the

patient. Notifications of outcomes of care that result in harm to the patient do not constitute an acknowledgment or admission of liability, nor can it be introduced as evidence.

The Florida Patient Safety Corporation

Calls for the creation of a Florida patient safety organization began in 2000. The 2000 Legislature passed and the Governor signed into law CS/HB 2339 (Chapter 2000-256, Laws of Florida), the Patient Protection Act of 2000. This act created the Commission on Excellence in Health Care, co-chaired by the Secretary of Health Care Administration and the Secretary of Health. Among the recommendations in the Commission's February 1, 2001, report was a call for the creation of a separate, freestanding Center for Patient Safety and Excellence in Health Care.

In August 2002, the Governor appointed the Select Task Force on Health Care Professional Liability Insurance. The Task Force's mission was to address the impact of skyrocketing liability insurance premiums on health care in Florida and report to the Governor and Legislature with recommendations on how to improve the situation. The report of the Task Force included a recommendation that the Legislature create a patient safety authority. As part of the legislation passed by the Legislature in 2003 to address the medical malpractice problem (SB 2-D, Chapter 2003-416, Laws of Florida), the Legislature included a study of implementation requirements for a statewide patient safety authority. On February 1, 2004, the study report was delivered to the Governor and the Legislature.

The 2004 Legislature enacted HB 1629 (Chapter 2004-297, Laws of Florida), which established the Florida Patient Safety Corporation. Section 381.0271, F.S., creates the Florida Patient Safety Corporation as a not-for-profit corporation, whose purpose is to serve as a learning organization dedicated to assisting health care providers in the state to improve the quality and safety of health care rendered and to reduce harm to patients. The corporation is required to promote the development of a culture of patient safety in the health care system and may not regulate health care providers in the state.

Among the various functions assigned to the corporation in s. 381.0271(7), F.S., is a requirement for the corporation to establish a "near-miss" patient safety reporting system. "Near-miss" means any potentially harmful event that could have had an adverse result but, through chance or intervention in which, harm was prevented. The purpose of the near-miss reporting system is to: identify potential systemic problems that could lead to adverse incidents; enable publication of systemwide alerts of potential harm; and facilitate development of both facility-specific and statewide options to avoid adverse incidents and improve patient safety.

In June 2005, the corporation contracted with the University of Miami Patient Safety Center to develop the near-miss reporting system. The university, in collaboration with its subcontractors Marsh/STARS and CRG Medical, has developed the near-miss reporting system and is currently testing the system with a focus group of institutions that have volunteered to participate in near miss reporting. The corporation solicited volunteer institutions for near miss reporting and set an initial target of 20 hospitals, 2 birth centers, and 2 ambulatory surgical centers. As of February 16, 2006, 12 hospitals/systems, 13 ambulatory surgical centers, and 3 birth centers had applied for participation in the near-miss reporting system. None of the six statutory teaching

hospitals applied. The corporation is on target for implementation of the near-miss reporting system for selected volunteer institutions at the beginning of April 2006.

Physician Reporting of Adverse Incidents

Sections 458.351 and 459.026, F.S., require allopathic and osteopathic physicians, respectively, to report to the Department of Health any adverse incident that occurs in any office maintained by a physician for the practice of medicine or osteopathic medicine. For purposes of notification to the department, the term "adverse incident" means an event over which the physician or licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

- The death of a patient.
- Brain or spinal damage to a patient.
- The performance of a surgical procedure on the wrong patient.
- The performance of a wrong-site surgical procedure, a wrong surgical procedure, or the surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process, if any of these procedures results in death, brain or spinal damage, permanent disfigurement not to include the incision scar, fracture or dislocation of bones or joints, a limitation of neurological, physical, or sensory function, or any condition that required the transfer of the patient.
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.
- Any condition that required the transfer of a patient to a hospital licensed under ch. 395, F.S. from an ambulatory surgical center licensed under ch. 395, F.S., or any facility or any office maintained by a physician for the practice of medicine, which is not licensed under ch. 395, F.S.

Liability Insurance

The Financial Services Commission has rulemaking authority for the Office of Insurance Regulation that administers statutes regulating insurance companies. A Florida-licensed hospital is authorized under s. 766.110(2), F.S., to carry liability insurance or to adequately insure itself in an amount of not less than $1.5 million per claim or annually $5 million in the aggregate to cover all medical injuries to patients resulting from negligent acts or omissions on the part of those members of its medical staff who are covered thereby in furtherance of the requirements of ss. 458.320 and 459.0085, F.S. Sections 458.320 and 459.0085, F.S., require Florida-licensed allopathic physicians and osteopathic physicians to maintain malpractice insurance or other special financial responsibility to cover potential claims for medical malpractice as a condition of licensure, with specified exemptions.

Self-insurance coverage extended by a hospital under s. 766.110(2), F.S., to a member of a hospital's medical staff meets the financial responsibility requirements of ss. 458.320 and 459.0085, F.S., if the physician's coverage limits are not less than the minimum limits established in ss. 458.320 and 459.0085, F.S., and the hospital is a verified trauma center that has extended self-insurance coverage continuously to members of its medical staff for activities both

inside and outside of the hospital. Any insurer authorized to write casualty insurance may make available, but is not required to write such coverage. The hospital may assess certain licensed physicians, nurses and dentists on an equitable and pro rata basis for a portion of the total hospital insurance cost for this coverage.

Section 626.901, F.S., prohibits any person from representing or aiding any insurer, which is not then authorized to transact insurance in Florida.

III. Effect of Proposed Changes:

Section 1. Provides a title – the "Patient Safety and Provider Liability Act."

Section 2. Provides legislative findings to support the provisions of the bill. The Legislature finds that:

- The state is in the midst of a prolonged medical malpractice insurance crisis that can be alleviated by the adoption of innovate approaches for patient safety in teaching hospitals, which can lead to a reduction in medical errors coupled with a limitation on noneconomic damages that can be awarded against a teaching hospital that implements such innovative approaches.
- Coupling patient safety measures and a limitation on provider liability in teaching hospitals will lead to a reduction in the frequency and severity of incidents of medical malpractice in hospitals.
- There is no alternative method that addresses the overwhelming public necessity to implement patient-safety measures and limit provider liability.
- Making high-quality health care available and providing medical education are overwhelming public necessities and statutory teaching hospitals are essential for meeting these needs.
- The critical mission of statutory teaching hospitals is severely undermined by the ongoing medical malpractice crisis.
- There is an overwhelming public necessity to promote the academic mission of teaching hospitals, which is enhanced by statutory authority for the implementation of innovative approaches to promoting patient safety and limiting provider liability.

Section 3. Creates s. 627.41485, F.S., to authorize insurers issuing policies of professional liability coverage for medical malpractice claims to make available to allopathic physicians, osteopathic physicians, podiatric physicians, dentists, and nurses coverage having an appropriate exclusion for acts of medical negligence occurring within the premises of a hospital that has agreed to indemnify covered persons for legal liability under the medical malpractice law, s. 766.110(2), F.S. The bill authorizes the Department of Financial Services to adopt rules to administer this provision.

Section 4. Amends s. 766.110, F.S., to authorize a licensed hospital and verified trauma center to extend insurance and self-insurance coverage to members of the medical staff, including physicians' practices, individually or through a professional association, and other health care practitioners, including students preparing for licensure. The coverage may be limited to legal liability arising out of medical negligence within the hospital premises. The bill deletes the

current statutory provision that states that self-insurance extended to a member of a hospital's medical staff meets the financial responsibility requirements for physicians only if the hospital is a verified trauma center that has extended self-insurance coverage continuously to members of its medical staff for activities both inside and outside of the hospital. The bill specifies that any authorized insurer, risk retention group, or joint underwriting association authorized to write casualty insurance may make available such coverage.

Section 5. Amends s. 766.118, F.S., to specify that, with respect to medical malpractice claims, a hospital that has received an order from the agency which certifies that the facility complies with patient-safety measures specified in s. 766.403, F.S., as created in this bill, shall be liable for no more than $500,000 in noneconomic damages, regardless of the number of claimants, number of claims, or theory of liability, including vicarious liability, arising from the same nucleus of operative fact.

Section 6. Creates s. 766.401, F.S., to provide definitions relating to the patient safety requirements of the bill. The terms defined include: affected patient, affected practitioner, agency, certified patient-safety facility, clinical privileges, eligible hospital or licensed facility, health care provider or provider, health care practitioner or practitioner, medical incident or adverse incident, medical negligence, person, premises, and statutory teaching hospital or teaching hospital. "Certified patient-safety facility," means any statutory teaching hospital that, in accordance with an order from the agency, has adopted a patient-safety plan.

Section 7. Creates s. 766.402, F.S., to establish requirements for approval by the agency of a patient-safety plan of a teaching hospital. A teaching hospital that has adopted a patient-safety plan may petition the agency to enter an order certifying approval of the hospital as a certified patient-safety facility. In accordance with ch. 120, F.S., the agency must enter an order certifying approval of the certified patient-safety facility upon a showing that, in furtherance of an approach to patient safety:

- The hospital has established safety measures for the care and treatment of patients.
- The hospital satisfies the patient safety requirements specified in s. 766.403, F.S., as created by this bill, which requires the hospital to have a patient-safety plan that commits the hospital to certain actions. (See next section of this analysis.)
- The hospital satisfies all other requirements of ss. 766.401-766.405, F.S., as created by this bill.

After certifying a hospital as a patient-safety facility, the agency may conduct onsite examinations to assure continued compliance with the terms and conditions of the order. The order certifying a hospital remains in effect until revoked. The agency is authorized to revoke an order upon reasonable notice to the hospital that it fails to comply with material requirements of s. 766.403, F.S., and that the hospital has failed to cure stated deficiencies upon reasonable notice. Revocation of an agency order applies prospectively to any cause of action for medical negligence, which arises on or after the effective date of the revocation order.

An order certifying a teaching hospital as a patient-safety facility is, as a matter of law, conclusive evidence that the hospital complies with the applicable patient-safety requirements of s. 766.403, F.S. A hospital's noncompliance with the requirements of s. 766.403, F.S., however,

does not affect the limitations on damages conferred by this section and is not admissible for any purpose in any action for medical malpractice. This section may not give rise to an independent cause of action for damages against any hospital.

Section 8. Creates s. 766.403, F.S., to establish requirements related to patient-safety plans. In order to meet the certification requirements specified in s. 766.402, F.S., the teaching hospital must have a patient-safety plan, which provides that the hospital will:

- Have in place a process, through either the hospital's patient-safety committee or a similar body, for coordinating the quality control, risk management, and patient-relations functions of the hospital and for reporting to the hospital's governing board at least quarterly.
- Establish within the facility a system for reporting near misses and agree to submit any information collected to the Florida Patient Safety Corporation.
- Design and make available to facility staff a patient safety curriculum that provides lecture and web-based training on recognized patient-safety principles, which may include training in communication skills, team-performance assessment and training, risk-prevention strategies, and best practices and evidence-based medicine.
- Implement a program to identify health care providers on the hospital's staff who may be eligible for an early-intervention program that provides additional skills assessment and training and offer such training to the staff on a voluntary and confidential basis with established mechanisms to assess program performance and results.
- Implement a simulation-based program for skills assessment, training, and retraining of a facility's staff in tasks and activities identified by the agency by rule.
- Designate a patient advocate who coordinates with members of the medical staff and the hospital's chief medical officer regarding the disclosure of adverse medical incidents to patients. The patient advocate must establish an advisory panel to review general patient-safety concerns and issues related to relations among and between patients and providers.
- Establish a procedure to biennially review the hospital's patient-safety program. The review must be conducted by an independent patient-safety organization or other professional organization approved by the agency. The organization performing the review must issue a report to the hospital and, after review by the hospital's governing board, the report must be submitted to the agency. The report is confidential and exempt from production or discovery in any civil action and the information in the report is not admissible as evidence for any purpose in any action for medical negligence.
- Establish a system for the trending and tracking of quality and patient-safety indicators that the agency identifies by rule and a method for review of the data at least semiannually by the hospital's patient-safety committee.

This section does not constitute an applicable standard of care or create a private right of action. Evidence of noncompliance is not admissible for any purpose in any action for medical negligence against any health care provider. This section does not prohibit the hospital from implementing other measures for promoting patient safety and does not relieve the hospital from the duty to implement any other patient-safety measures that are required by state law.

Section 9. Creates s. 766.404, F.S., to require each certified patient-safety facility to submit an annual report to the agency containing information and data reasonably required by the agency to evaluate performance and effectiveness of its patient-safety plan. The bill requires the agency to aggregate information and data submitted by all certified patient-safety facilities and annually submit a report to the Legislature. This section specifies certain data that, at a minimum, must be included in the report. The report may also include information and data concerning the availability and affordability of enterprise-wide medical liability insurance coverage for affected facilities and the availability and affordability of insurance policies for individual practitioners, which contain coverage exclusions for acts of medical negligence in hospitals that indemnify health care practitioners. The bill requires the Office of Insurance Regulation to cooperate with the agency in reporting this information. Reports submitted to the agency by certified patient-safety facilities are public records, but the information contained in the reports are not admissible as evidence in a court of law in any action.

Section 10. Creates s. 766.405, F.S., to establish the limits of liability for medical malpractice arising out of the rendering of, or the failure to render, medical care by all teaching hospitals. Once a teaching hospital is certified as a patient-safety facility, the damages recoverable from the hospital and from its employees and agents in actions arising from medical negligence must be determined in accordance with the following provisions:

- Noneconomic damages shall be limited to a maximum of $500,000, regardless of the number of claimants, number of claims, or the theory of liability pursuant to s. 766.118(6), F.S.
- Awards of economic damages shall be offset by payments from collateral sources and any set-offs available. Awards for future economic losses shall be offset by future collateral source payments.
- After being offset by collateral sources, awards of future economic damages shall, at the option of the hospital, be reduced by the court to present value or paid through periodic payments in the form of an annuity or a reversionary trust.

The limitations on damages apply prospectively to causes of action for medical negligence, which arise on or after the effective date of the order certifying a hospital as a certified patient-safety facility.

Section 11. Creates s. 766.406, F.S., to authorize the agency to adopt rules to administer ss. 766.401-766.405, F.S., as created in this bill.

Section 12. Provides for severability of the provisions of the act if any provision of the act or its application is held invalid.

Section 13. Provides that if a conflict exists between any provision of this bill and s. 456.052, F.S. (prohibition against referral of patients to an entity in which the health care provider is an investor, unless the provider gives the patient certain disclosures), s. 456.053, F.S. (Patient Self-Referral Act of 1992), s. 456.054, F.S. (prohibition against kickbacks), s. 458.331, F.S. (grounds for disciplinary action against physicians), s. 459.015, F.S. (grounds for disciplinary action against osteopathic physicians), and s. 817.505, F.S. (patient brokering), the provisions of this act shall govern.

Section 14. States the Legislature's intent that the provisions of the act are self-executing.

Section 15. Provides that the bill will take effect 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, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The bill establishes a procedure to biennially review a teaching hospital's patient-safety program. The review must be conducted by an independent patient-safety organization or other professional organization approved by the agency. The organization performing the review must issue a report to the hospital and, after review by the hospital's governing board, the report must be submitted to the agency. The bill provides that the report is confidential and exempt from production or discovery in any civil action and the information in the report is not admissible as evidence for any purpose in any action for medical negligence. It is unclear whether this provision in the bill is an attempt to create an exemption to the Public Records Law.

The State Constitution authorizes exemptions to the open government requirements and establishes the means by which these exemptions are to be established. Under Art. I, s. 24(c) of the State Constitution, the Legislature may provide by general law for the exemption of records and meetings. The general law must state with specificity the public necessity justifying the exemption and must be no broader than necessary to accomplish its purpose. Laws creating public records and meetings exemptions must contain only exemptions and must relate to one subject.

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 recovery that medical malpractice claimants may get to the limitations as specified in the bill against a hospital that has received an order from the agency, which certifies that the facility complies with patient-safety measures specified in s. 766.403, F.S., as created in this bill. Additionally, during 2003, the Legislature adopted several medical malpractice reforms, including caps on noneconomic damages in an action for personal injury or wrongful death arising from medical negligence by a practitioner or nonpractitioner. It is unclear how the cap for recovery proposed in the bill will affect those existing limitations on recovery. The bill states that an order certifying a teaching hospital as a patient-safety facility is, as a matter of law, conclusive evidence

that the hospital complies with the applicable patient-safety requirements of s. 766.403, F.S., as created in this bill. *A hospital's noncompliance with the requirements of s. 766.403, F.S., however, does not affect the limitations on damages conferred by this section and is not admissible for any purpose in any action for medical malpractice.*

The limitation on a medical malpractice claimants rights to recovery raises questions about possible infringements on the right of access to the courts. It is unclear what commensurate benefit is extended to individuals whose rights of access to the courts are possibly infringed. Section 21, Art. I of the State Constitution provide that the courts shall be open to all for redress for an injury. To impose a barrier or limitation on litigant's 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.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Teaching hospitals that are certified by the agency as patient-safety facilities will have a reduced liability for any medical claims at those facilities.

C. Government Sector Impact:

The agency will incur costs to implement the bill's requirements to adopt rules and to review petitions and reports of patient-safety facilities, and to evaluate the performance and effectiveness of each facility's patient-safety plan to determine compliance.

VI. Technical Deficiencies:

On page 6, line 3 of the bill, "Department of Financial Services" should be replaced with "Financial Services Commission." The Financial Services Commission has rulemaking authority for the Office of Insurance Regulation that administers statutes regulating insurance companies

VII. Related Issues:

None.

[11] See *Kluger v. White*, 281 So.2d 1 (Fla. 1973).

VIII. Summary of Amendments:

Barcode 555754 by Health Care:
This amendment deletes provisions in the bill that authorize insurers to issue policies of professional liability coverage for medical malpractice claims to allopathic physicians, osteopathic physicians, podiatric physicians, dentists, and nurses having an appropriate exclusion for acts of medical negligence occurring within the premises of a hospital that has agreed to indemnify covered persons for legal liability. (WITH TITLE AMENDMENT)

Barcode 062446 by Health Care:
No longer requires a hospital to have a verified trauma center to extend insurance and self-insurance coverage for professional liability to members of its medical staff.

Barcode 093910 by Health Care:
This amendment requires the insurance and self-insurance coverage extended by a hospital to members of its medical staff to be limited to legal liability arising out of medical negligence within the hospital premises.

Barcode 960792 by Health Care:
The amendment provides that any authorized or approved insurer, risk retention group, or joint underwriting association authorized to write casualty insurance may make available such insurance coverage.