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: Judiciary Committee

BILL:	SB 2160
INTRODUCER:	Senator Saunders
SUBJECT:	Medical Malpractice Insurance
DATE:	April 24, 2006
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Fav/4 amendments**
2.		Deffenbaugh	BI	**Withdrawn**
3.	Cibula	Maclure	JU	**Pre-meeting**
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:

This bill limits liability for medical negligence occurring within a teaching hospital that is a certified patient-safety facility. The cumulative liability for non-economic damages of a teaching hospital certified as a patent-safety facility and all its employees and agents is limited to $500,000. The bill also permits awards of future economic damages to be paid periodically through an annuity or reversionary trust.

Additionally, the bill permits hospitals and verified trauma centers to extend liability insurance to medical staff and health care practitioners for negligence occurring within a hospital. Lastly, the bill authorizes insurers to offer liability insurance that excludes coverage for negligence occurring within a hospital that offers liability insurance.

This bill substantially amends sections 766.110 and 766.118, Florida Statutes. This bill creates the following sections of the Florida Statutes: 627.41485, 766.401, 766.402, 766.403, 766.404, 766.405, and 766.406. The bill also creates unnumbered sections of the Florida Statutes.

II. Present Situation:

Medical Malpractice Caps on Noneconomic Damages

In 2003, the Legislature adopted several medical malpractice reforms, including caps on non-economic damages in an action for personal injury or wrongful death arising from medical negligence by a practitioner or nonpractitioner.[1] Under the 2003 law, the term practitioner generally applies to human beings who are medical professionals. The term nonpractitioner appears to include entities such as hospitals.[2] The limitations on non-economic damages are described in the tables below.

Table 1 Limits on Non-economic Damages Per Injury Type

Type of Defendant	General Injuries	Permanent Vegetative State or Death	Special Circumstances (not inc. perm. veg. state or death)
Practitioners Generally[3]	$500,000	$1,000,000	$1,000,000
Nonpractitioners Generally[4]	$750,000	$1,500,000	$1,500,000

Table 2 Limits on Non-economic Damages Caused by Emergency Services and Care

Type of Defendant	Per Claimant	Per Incident
Practitioners of Emergency Services[5]	$150,000	$300,000
Nonpractioners of Emergency Services[6]	$750,000	$1,500,000

Statutory Teaching Hospitals

Section 408.07(45), F.S., defines "teaching hospital" as:

> 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.

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

[1] *See* ch. 2003-416, L.O.F.
[2] *See* s. 766.118, F.S.
[3] Section 766.118(2), F.S.
[4] Section 766.118(3), F.S.
[5] Section 766.118(4), F.S.
[6] Section 766.118(5), F.S.

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.

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 (agency) 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.
- 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 also must report adverse incidents to the agency.[7] 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

[7] Section 395.0197 (5)-(8), F.S.

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

The 2004 Legislature enacted HB 1629 (ch. 2004-297, L.O.F.), 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 certain members of its medical staff. 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.

III. Effect of Proposed Changes:

This bill limits liability for medical negligence occurring within a teaching hospital that is a certified patient-safety facility. The cumulative liability for non-economic damages of a teaching hospital certified as a patent-safety facility and all its employees and agents is limited to $500,000. Non-economic damages include damages for pain and suffering, physical impairment, disfigurement, and other non-financial losses.[8] The bill also permits certified patient-safety facilities to pay awards of future economic damages periodically through an annuity or reversionary trust. Economic damages include damages for medical expenses and lost wages and earning capacity.[9]

[8] Section 766.202(8), F.S.
[9] Section 766.202(3), F.S.

Additionally, the bill permits hospitals and verified trauma centers to extend liability insurance to medical staff and health care practitioners for negligence occurring within a hospital. Lastly, the bill authorizes insurers to offer liability insurance that excludes coverage for negligence occurring within a hospital that offers liability insurance.

Application of Limited Liability

The limitation on liability applies to all claims "arising from the same nucleus of operative fact." Case law has defined a similar phrase, "common nucleus of operative fact," as a "series of transactions closely related in time, space, and origin.[10] The limitation on liability also applies to causes of action that accrue while an order certifying a teaching hospital as a patient-safety facility is in effect.

Certification Standards

The bill establishes standards that a teaching hospital must satisfy to be a certified patient-safety facility. The bill provides that the Agency for Health Care Administration administers the certification process. To qualify as a patient-safety facility, a teaching hospital must:

- Establish safety measures for the care and treatment of patients; and
- Have a patient-safety plan meeting certain requirements.

The bill also requires that a teaching hospital satisfy the other requirements of ss. 766.401-766.405, F.S. The only other requirement in those sections is the requirement to submit annual reports to the agency. However, the requirement to submit reports does not apply until after certification.

To retain certification, a teaching hospital must comply with the "material" statutory requirements for a patient-safety plan. The Legislature may wish to define what these material requirements are. Additionally, the failure to satisfy the other requirements of ss. 766.401-766.405, F.S., which include the establishment of safety measures and the submission of annual reports, are not grounds for revocation of certification.

Patient-Safety Plan

A patient safety plan must provide for the following:

- A quality control process;
- A system for reporting near-misses;
- Patient safety training;
- An early intervention program that provides additional training to staff of a teaching hospital;
- A simulation-based assessment and training program;
- A designated patient advocate;

[10] *Ragsdale v. Rubbermaid, Inc.*, 193 F.3d 1235, 1240 (11th Cir. 1999).

- A biennial review of the patient safety program conducted by an independent organization; and
- A system to track patient-safety indicators;

Annual Report

Certified patient-safety facilities must submit annual reports to the agency. The reports must include the information reasonably required by the agency to evaluate the performance and effectiveness of a patient-safety plan. The information from the reports must be aggregated by the agency and reported to the Legislature.

Evidence

The bill provides that reports, reviews, or other documents created as the result of the bill are not discoverable or admissible in trials.

Effective Date

The bill takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

This bill caps the liability of certain teaching hospitals for non-economic damages caused by medical negligence. Courts have found some caps on non-economic damages unconstitutional for restricting access to courts under s. 21, Art. I, State Const. The caps on liability established by the bill are not clearly constitutional under existing case law.

The access to courts provision, s. 21, Art. I, State Const., states: “The courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial or delay.”

Caps on non-economic damages violate s. 21, Art. I, State Const., unless, the Legislature satisfies one of the two components of the test from *Kluger v. White.*[11] That test requires the Legislature to: (1) provide a reasonable alternative remedy or commensurate benefit; or (2) show an overpowering public necessity for the abolishment of the right and that no alternative method of meeting such public necessity exists.[12]

This bill may contain a commensurate benefit in terms of improved patient care and health care provider training. On the other hand, those provisions providing for commensurate benefits likely could be adopted without adopting the caps on damages. This bill also contains extensive findings that the bill satisfies and "overwhelming public necessity." However, the bill does not contain statements regarding the availability of alternatives to the caps imposed by the bill. It's possible that the findings may satisfy the *Kluger* test. Nevertheless, courts are not bound always to legislative findings.[13]

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 adopt rules, to review petitions for certification and reports of patient-safety facilities, and to evaluate the performance and effectiveness of each facility's patient-safety plan.

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.

Section 1. of the bill provides the following short title for the bill: "Patient Safety and Provider Liability Act." The Florida Senate *Manual for Drafting General Bills* advises against using short

[11] *Kluger v. White*, 281 So. 2d 1, 4 (Fla. 1973

[12] *See Smith v. Dep't of Ins.*, 507 So. 2d 1080, 1088, (Fla. 1987).

[13] In *North Florida Women's Health and Counseling Services*, 866 So. 2d 612, 627 (Fla. 2003), the Court stated:

> While courts may defer to legislative statements of policy and fact, courts may do so only when those statements are based on actual findings of fact, and even then courts must conduct their own inquiry: The general rule is that findings of fact made by the legislature are presumptively correct. However, it is well-recognized that the findings of fact made by the legislature must actually be findings of fact. They are not entitled to the presumption of correctness if they are nothing more than recitations amounting only to conclusions and they are always subject to judicial inquiry.

titles "that name an act that amends existing law."[14] The bill drafting manual also advises against using a short title to "name an act that amends sections scattered throughout various chapters of the Florida Statutes."[15] This bill amends existing law and includes sections from multiple chapters. As such, the Legislature may wish to remove the short title from the bill. Alternatively, the Legislature may wish to create a new section 766.401, F.S., to state: Sections 766.401-766.406 may be cited as the "Patient Safety and Provider Liability Act."

Section 2. of the bill creates extensive legislative findings. These findings may be better placed in the preamble to the bill as whereas clauses because they are not substantive law. A preamble is not codified in the statutes, but is codified in the Laws of Florida. Additionally, practitioners, except those involved in an access to courts challenge, will have no need to read these findings. Similarly, s. 766.405(1), F.S., contains statements of legislative intent that might be more appropriate for inclusion in the preamble to the bill. Accordingly, the Legislature may wish to place section 2. and s. 766.405(1), F.S., in the preamble of the bill as whereas clauses.

Section 4. of the bill refers to a professional association as defined in ch. 621, F.S. The chapter does not define the term "professional association." However, s. 621.03, F.S., defines the terms "professional corporation" and "professional limited liability company." The Legislature may wish to consider whether to replace "professional association" with the terms in s. 621.03, F.S.

Section 6. of the bill provides a definition for the term "clinical privileges." The term, however, is not used in the substantive provisions of the bill. The Legislature may wish to remove from the bill s. 766.401(5), F.S., which creates a definition of "clinical privileges."

Section 6. of the bill states that the terms "'Medical incident" or "adverse incident" ha[ve] the same meaning as provided in ss. 381.0271, 395.0197, 458.351, and 459.026." The term "medical incident" is not defined in any statute. Further, s. 381.0271, F.S., does not directly define the term "adverse incident." Section 381.0271, F.S., refers to other statutes that define the term adverse incident. As a result, the reference to s. 381.0271, F.S., as the definition of "adverse incident" is unnecessary. Lastly, the term "adverse incident" is not used in the bill. The Legislature may wish to revise the bill to replace references to "medical incident" with "adverse incident." The Legislature also may wish to replace s. 766.401(9), F.S., with the following: "Adverse incident" has the same meaning as provided in ss. 385.0197, 458.351, and 459.026.

Section 13. of the bill states that the provisions of the bill prevail in the event of a conflict with certain specified statutes. The statutes specified in section 13., however, do not appear to have any relationship to the bill. As such, the Legislature may wish to revise section 13. to reflect its intent. Alternatively, the Legislature may wish to remove section 13. from the bill.

Section 14. of the bill states that the provisions of the bill are self-executing. The intent or effect of section 14. is unclear. As such, the Legislature may wish to revise section 14. or remove it from the bill.

[14] The Florida Senate, *Manual for Drafting General Bills*, p. 33 (1999).
[15] *Id.*

VII. Related Issues:

None.

VIII. Summary of Amendments:

Barcode 555754 by Health Care:
Deletes provisions 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:
Removes a requirement that a hospital have a verified trauma center to be authorized to extend insurance and self-insurance coverage for professional liability to members of its medical staff.

Barcode 093910 by Health Care:
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:
Authorizes certain insurers, risk retention groups, and joint underwriting associations to make casualty insurance available.