HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1621 CS Medical Malpractice Insurance
SPONSOR(S): Garcia and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1916

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	9 Y, 0 N, w/CS	Bell	Mitchell
2) Judiciary Committee			
3) Health & Families Council			
4)			
5)			

SUMMARY ANALYSIS

HB 1621 with CS addresses the issue of high liability premiums for physicians employed by Florida teaching hospitals and patient safety.

The bill encourages Florida teaching hospitals to implement an array of patient protection measures that are prescribed in statute in order to allow them to assume enterprise liability. Upon determination by AHCA that the hospital meets compliance with enterprise-wide patient safety measures and requirements – the hospitals may assume legal liability for all acts of medical negligence committed in the premises. Under this arrangement the hospital becomes the only named defendant to any medical malpractice lawsuit. All other statutory provisions pertaining to medical malpractice actions against licensed health care facilities remain intact, including the pre-suit arbitration process, the $750,000 limitation on non-economic damages, and sovereign immunity where applicable.

If ninety percent of staff are employees or agents of a public university medical school, approval by AHCA of an enterprise plan for patient protection and provider liability extends sovereign immunity to an affected hospital. (This provision potentially impacts Tampa General Hospital and the two Shands Hospitals.) Statutory limits on recovery are increased from $100,000 to $150,000 per person, and from $200,000 to $300,000 per incident, in medical malpractice actions against any “enterprise liability hospital” that is subject to sovereign immunity.

The bill also provides authority for affected hospitals and medical staffs to enter into enterprise agreements to share relevant expenses (insurance premiums) and to assure accountability of individual physicians. Enterprise insurance policies can be experience rated. An eligible hospital that obtains certification from AHCA that it meets the enhanced patient safety requirements may opt for a $500,000 limit on non-economic damages in medical malpractice actions and periodic payment of economic damages, as an alternative to enterprise liability. (A hospital subject to sovereign immunity is not eligible for this provision.) These hospitals may also indemnify staff physicians for damages from medical malpractice claims within the hospital premises, subject to certain conditions to assure solvency of any hospital self-insurance fund.

HB 1621 with CS applies to eight hospitals in the state. The hospitals include: the six statutorily defined “teaching hospitals” (Jackson Memorial Hospital, Mount Sinai Medical Center, Orlando Regional Medical Center, Tampa General Hospital, Shands Jacksonville, and Shands at the University of Florida) and two hospitals that are wholly owned by a university medical school (Anne Bates Leach Eye Hospital and Sylvester Comprehensive Cancer Clinic at the University of Miami). These hospitals are defined as “eligible hospitals.” Provisions in the bill are voluntary and not mandatory for these healthcare facilities.

The bill requires the Agency for Health Care Administration (AHCA) to certify “patient safety facilities.” According to AHCA, this will cost $64,452 in the first year and $61,842 in the second year.

The effective date of the bill is upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government/Ensure lower taxes – The bill requires the Agency for Health Care Administration (AHCA) to certify "patient safety facilities." According to AHCA, this will cost $64,452 in the first year and $61,842 in the second year.

B. EFFECT OF PROPOSED CHANGES:

Overview:

HB 1621 creates ss. 766.401-766.409, F.S., to allow eligible hospitals the opportunity to establish enterprise liability plans and patient protection initiatives.

HB 1621 creates an unnumbered section for popular title designation and legislative findings. The popular title is, "Enterprise Act for Patient Protection and Provider Liability."

HB 1621 applies to eight hospitals in the state. The hospitals include: the six statutorily defined "teaching hospitals" (Jackson Memorial Hospital, Mount Sinai Medical Center, Orlando Regional Medical Center, Tampa General Hospital, Shands Jacksonville, and Shands at the University of Florida) and two hospitals that are wholly owned by a university medical school (Anne Bates Leach Eye Hospital and Sylvester Comprehensive Cancer Clinic at the University of Miami). These hospitals are defined as "eligible hospitals." Provisions in the bill are voluntary and not mandatory for these healthcare facilities.

The bill encourages the affected hospitals to implement an array of patient protection measures that are prescribed in statute.

Upon determination by AHCA that the hospital meets patient safety measures and requirements – the hospitals may assume legal liability for all acts of medical negligence committed in the premises. Under this arrangement the hospital becomes the only named defendant to any medical malpractice lawsuit. All other statutory provisions pertaining to medical malpractice actions against licensed health care facilities remain intact, including the pre-suit arbitration process, the $750,000 limitation on non-economic damages, and sovereign immunity where applicable.

If ninety percent of staff are employees or agents of a public university medical school, approval by AHCA of an enterprise plan for patient protection and provider liability extends sovereign immunity to an affected hospital. (This provision potentially impacts Tampa General Hospital and the two Shands Hospitals.) Statutory limits on recovery are increased from $100,000 to $150,000 per person, and from $200,000 to $300,000 per incident, in medical malpractice actions against any "enterprise liability hospital" that is subject to sovereign immunity.

The affected hospitals are required to provide notice to patients about participation in an enterprise plan and the potential affects of sovereign immunity where applicable.

This is not a "strict liability" or "no-fault" plan, because the plaintiff must affirmatively prove that medical negligence occurred in the hospital. The mere occurrence of an unfavorable medical outcome does not give rise to liability or compensation, absent a departure from the prevailing standards of care.

The bill also provides authority for affected hospitals and medical staffs to enter into enterprise agreements to share relevant expenses (insurance premiums) and to assure accountability of individual physicians. Enterprise insurance policies can be experience rated.

An eligible hospital that obtains certification from AHCA that it meets the enhanced patient safety requirements may opt for a $500,000 limit on non-economic damages in medical malpractice actions and periodic payment of economic damages, as an alternative to enterprise liability. (A hospital subject to sovereign immunity is not eligible for this provision.) These hospitals may also indemnify staff physicians for damages from medical malpractice claims within the hospital premises, subject to certain conditions to assure solvency of any hospital self-insurance fund.

Legislative Findings & Intent

The bill provides legislative findings and intent related to medical malpractice insurance that identify the relationships between hospital care, medical incidents, patient safety, malpractice insurance, and teaching hospitals. The bill makes the following Legislative findings:

(1) The Legislature finds that this state is in the midst of a prolonged medical malpractice insurance crisis that has serious adverse effects on patients, practitioners, licensed healthcare facilities, and all residents of this state.
(2) The Legislature finds that hospitals are central components of the modern health care delivery system.
(3) The Legislature finds that many of the most serious incidents of medical negligence occur in hospitals, where the most seriously ill patients are treated, and where surgical procedures are performed.
(4) The Legislature finds that modern hospitals are complex organizations, that medical care and treatment in hospitals is a complex process, and that, increasingly, medical care and treatment in hospital is a common enterprise involving an array of responsible employees, agents, and other persons, such as physicians, who are authorized to exercise clinical privileges within the premises.
(5) The Legislature finds that an increasing number of medical incidents in hospitals involve a combination of acts and omissions by employees, agents, and other persons, such as physicians, who are authorized to exercise clinical privileges within the premises.
(6) The Legislature finds that the medical malpractice insurance crisis in this state can be alleviated by the adoption of innovative approaches for patient protection in hospitals which can lead to a reduction in medical errors.
(7) The Legislature finds statutory incentives are necessary to facilitate innovative approaches for patient protection in hospitals.
(8) The Legislature finds that an enterprise approach to patient protection and provider liability in hospitals will lead to a reduction in the frequency and severity of incidents of medical malpractice in hospitals.
(9) The Legislature finds that a reduction in the frequency and severity of incidents of medical malpractice in hospitals will reduce attorney's fees and other expenses inherent in the medical liability system.
(10) The Legislature finds that making high-quality health care available to the residents of this state is an overwhelming public necessity.
(11) The Legislature finds that medical education in this state is an overwhelming public necessity.
(12) The Legislature finds that statutory teaching hospitals and hospitals owned by and operated by universities that maintain accredited medical schools are essential for high-quality medical care and medical education for this state.
(13) The Legislature finds that the critical mission of statutory teaching hospitals and hospitals owned and operated by universities that maintain accredited medical schools is severely undermined by the ongoing medical malpractice crisis.
(14) The Legislature finds that statutory teaching hospitals and hospitals owned and operated by universities that maintain accredited medical schools are appropriate health care facilities for the implementation of innovative approaches to patient protection and provider liability.
(15) The Legislature finds an overwhelming public necessity to impose reasonable limitations on actions for medical malpractice against statutory teaching hospitals and hospitals that are

owned and operated by universities that maintain accredited medical schools, in furtherance of the critical public interest in promoting access to high-quality medical care, medical education, and innovative approaches to patient protection.

(16)The Legislature finds an overwhelming public necessity for statutory teaching hospitals and hospitals owned and operated by universities that maintain accredited medical schools to implement innovative measures for patient protection and provider liability in order to generate empirical data for state policymakers on the effectiveness of these measures. Such data may lead to broader application of these measures in a wider array of hospitals after a reasonable period of evaluation and review.

(17)The Legislature finds an overwhelming public necessity to promote the academic mission of statutory teaching hospitals and hospitals owned and operated by universities that maintain accredited medical schools. Furthermore, the Legislature finds that the academic mission of these medical facilities is materially enhanced by statutory authority for the implementation of innovative approaches to patient protection and provider liability. Such approaches can be carefully studies and learned by medical student, medical student faculty, and affiliated physicians in appropriate clinical settings, thereby enlarging the body of knowledge concerning patient protection and provider liability which is essential for advancement of patient safety, reduction of expenses inherent in the medical liability system, and curtailment of medical malpractice insurance crisis in this state.

PATIENT SAFETY CERTIFICATION

HB 1621 authorizes statutory teaching hospitals and university-owned hospitals to seek designation as a certified patient safety facility by submitting a petition to the Agency for Health Care Administration (AHCA). The petition would seek an AHCA order approving the facility's enterprise plan for patient protection and provider liability. That order would remain in effect until revoked by the Agency. The Florida Patient Safety Corporation (FPSC), created by the 2004 Session of the Florida Legislature, would be authorized to intervene in administrative actions related to this act. Annual reporting requirements would be established for hospitals receiving this designation and for the Agency. AHCA would be required to adopt rules governing criteria contained in the Medical Malpractice and Related Matters of Florida Statutes

Patient Safety Requirements

In order for a hospital to qualify for any of the three options for enterprise liability coverage discussed below eligible hospitals must meet several comprehensive safety measures and procedures. Hospitals are required to:

- Have in place a process for coordinating the quality control, risk management, and patient relations functions of the facility;
- Establish within the facility a system for reporting near misses and agree to submit information collected to the Florida Patient Safety Corporation (FPSC);
- 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 communication skills training, team performance assessment and training, risk prevention strategies, and best practices and evidence based medicine. The licensed facility shall report annually to AHCA;
- Implement a program to identify health care providers on the facility's staff who may be eligible for an early intervention program providing 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 those tasks and activities that the agency identifies by rule;
- Designate a patient advocate that reports to the facility's risk manager who coordinates with members of the medical staff and the facility's chief medical officer regarding disclosure of medical incidents to patients. In addition, the patient advocate shall establish an advisory panel, consisting of providers, patients or their families, and other health care consumers or consumer groups to review general patient safety concerns and other issues related to relations among

and between patients and providers and to identify areas where additional education and program development may be appropriate;
- Establish a procedure for a semiannual review of the facility's patient safety program and its compliance with the requirements of this section. Such review shall be conducted by an independent patient safety program and its compliance with the requirements of this section. Such review shall be conducted by an independent safety organization as defined in s. 766.1016(1), F.S., or other professional organization approved by the agency;
- Establish a system for the trending and tracking of quality and patient safety indicators that the agency may identify by rule, and a method for review of data at least semiannually by the facility's patient safety committee;
- Provide assistance to affected physicians, upon request, in their establishment, implementation, and evaluation of individual risk-management, patient-safety, and incident-reporting systems in clinical settings outside the premises of the licensed facility.

ENTERPRISE LIABILITY PLANS

In order to eligible for an "enterprise plan" a hospital must be certified by the Agency for Health Care Administration (AHCA) as a "certified patient safety facility." Once certified eligible hospitals may choose one of the options below (hospitals may choose both option 2. and option 3.).

Option 1: Enterprise Plan
Eligible hospitals and medical staff may voluntarily agree to establish an enterprise plan. The enterprise would become the sole defendant in any malpractice action and would be solely liable for all damages caused by medical malpractice in the hospital setting, regardless of whether the error was committed by the hospital or the physician. Any of the eligible hospitals could participate in the enterprise plan.

For a public hospital or a hospital with public medical staff electing this option in conjunction with its medical staff, the liability limits would be those of public entities. The "seeds of sovereign immunity would be shared among the enterprise" if either the hospital or a clear majority of medical staff (90%) is currently protected by the sovereign immunity law. Statutory limits on recovery are increased from $100,000/$200,000 to $150,000/$300,000, applicable to per person/per incident.

Option 2: Non-Economic Damage Cap/Periodic payments
An eligible hospital that is not public may elect an aggregate cap on non-economic damages of $500,000 and the ability to pay future economic damages caused by medical malpractice on a periodic basis. Currently the cap for hospitals is $750,000 per claimant, with an aggregate cap of $1.5 million. This option would not alter the current $500,000 non-economic damage cap applicable to physicians.

Option 3: Indemnification
A teaching hospital may agree to indemnify (insure) members of its medical staff for medical malpractice caused by the staff member in the hospital. Hospitals electing this option must meet appropriate actuarial requirements when undertaking to indemnify medical staff members. Medical staff members could voluntarily participate and pay an actuarially determined premium. This option applies only to teaching hospitals without sovereign immunity.

Eligible hospitals may choose any one of the options above. The "enterprise plan" is mutually exclusive. However eligible hospitals may elect both option 3 (non-economic damage cap/period payments) and option 2 (indemnification).

OTHER EFFECTS OF THE BILL

Florida Patient Safety Corporation Intervention in Administrative Actions
HB 1621 amends s. 381.0271, relating to the Florida Patient Safety Corporation (FPSC), to allow the FPSC to intervene in administrative actions related to patient safety in hospitals or other licensed health care facilities.

Optional Risk Management for Hospitals
The bill amends s. 395.0197(3), F.S., to add the Enterprise Act for Patient Protection and Liability as an optional risk management program for hospitals.

Florida Birth-Related Neurological Injury Compensation Plan
Additionally, the bill amends s. 766.316, F.S., to require hospitals to assume liability for their physicians under the Enterprise Act for Patient Protection and Provider Liability who participate in the Florida Birth-Related Neurological Injury Compensation Plan. The Florida Birth-Related Neurological Injury Compensation Plan is administered by the Florida Birth-Related Neurological Injury Compensation Association (NICA). NICA provides compensation for birth-related neurological injury claims, regardless of fault. Participating Florida physicians pay to participate in NICA.

Financial Responsibility for Physicians Employed by an "Enterprise Plan" Hospital
The bill amends ss. 458.320 and 459.0085, F.S., to create an exemption from financial responsibility for allopathic and osteopathic physicians who only work for "certified patient safety facilities" that assume legal liability for medical negligence of affected practitioners. These physicians are required to post notice to their patients.

To accommodate this change in physician financial responsibility the bill amends s. 627.41485, F.S., to allow insurance carriers to provide professional liability coverage that specifically excludes coverage for claims related to acts of medical negligence occurring within a "certified patient safety facility" that bears sole and exclusive responsibility for acts of medical negligence.

The bill amends s. 766.110(2), F.S., to require hospitals that assume liability under the Enterprise Act to carry liability insurance in the amounts of $2.5 million per claim, $7.5 million annual aggregate to cover all medical injuries to patients resulting from negligent acts or omissions by staff covered by an enterprise plan. The hospitals insurance or self-insurance must meet the financial responsibility requirements of Chapters 458 and 459.

CURRENT SITUATION

Currently, statutory teaching hospitals and university-owned hospitals do not have authority to assume liability for malpractice claims against physicians practicing in those facilities.

Physician Financial Responsibility
Currently, the Department of Health (DOH) requires allopathic physicians and osteopathic physician to have financial responsibility as a requisite for licensure and licensure renewal. Physicians may meet this requirement by purchasing malpractice insurance, opening an escrow account, getting a letter or credit, or through self-insurance. If a physician is a governmental employee, holds a limited license, practices as part of a teaching post at a teaching hospital, does not practice in the state of Florida, or meets a list long list of requirements they are exempt from financial responsibility requirements. Physicians who are exempt from financial responsibility or choose to self-insure, must post notice in their waiting room to alert their patients that they have decided not to carry medical malpractice insurance. DOH audits approximately 3 percent of physician licensure renewals yearly in order to verify financial responsibility.

Under HB 1621 physicians who work solely for an "enterprise liability plan" hospital would not have to directly meet the financial responsibility requirements listed above. Hospitals would be held liable for the physicians they employ. Physicians are required to post notice in their patients.

The bill allows insurance carriers to issue professional liability coverage the excludes coverage for claims related to medical negligence occurring within a "certified patient safety facility" that bears sole and exclusive liability for acts of medical negligence.

Enterprise Liability

At the general level, the theory of tort law is both to provide compensation for person injured by the avoidable accidents of others and provide deterrence/incentives to potential defendants to take more care to avoid accidents. The theory of enterprise liability has developed to make tort law more effective for both concerns: the enterprise would absorb the costs of those avoidable accidents that still occurr and ensure that those costs were internalized and built into the cost of the service or product the enterprise produces. The enterprise approach is most appropriate in situations where the enterprise is better situated than the individual defendant to take measures to minimize accidents.

In the context of hospital-based incidents of medical malpractice, enterprise liability means that individuals (such a physicians) do not directly bear liability to third persons for the costs associated with an injury. Instead, the enterprise – in this case the hospital – assumes sole legal liability by meeting the costs of liability premiums for all affiliated medical staff. The hospital and covered physicians can split liability insurance costs, pursuant to reasonable actuarial criteria. Premium levels for hospitals – or in other words liability costs for the entire hospital-based medical enterprise – can be experience rated. Therefore, a hospital (and affected medical staff) would pay more in a given year if there was a rash of avoidable injuries and less if quality improvement initiatives curtails the incidence of such events. Enterprise liability can effectively target financial incentives at institutions, even specific processes within institutions, according to medical-legal researchers.

Sovereign Immunity

Sovereign immunity is derived from a medieval English doctrine that "one could not sue the king in his own court;" hence the phrase "the king can do no wrong."[1] "A sovereign is exempt from suit, not because of any formal conception or obsolete theory, but on the logical and practical ground that there can be no legal right as against authority that makes that law which right depends."[2] The doctrine of sovereign immunity as applied by the Florida courts is based on two public policy considerations: "the protection of the public against profligate encroachments on the public treasury[3] and the need for the orderly administration of government, which, in the absence of immunity, would be disrupted if the state could be sued at the instance of every citizen."[4] The state, its agencies, and counties have always been fully covered by sovereign immunity. Municipalities and quasi-governmental entities have been found by the courts to have limited immunity depending on whether the activity performed is considered a governmental function covered by sovereign immunity or a propriety function for which the entity could be held liable.

Article X, s. 13, Fla.Const., recognizes that the concept of sovereign immunity applies to the state, although the state may waive its immunity through an enactment of general law.[5] Sovereign immunity extends to all subdivisions of the state, including counties and school boards.

In 1973, the Legislature enacted s. 768.28, F.S., a partial waiver of sovereign immunity allowing individuals to sue state government, subdivisions of the state, and municipalities. According to subsection (1), individuals may sue the government under circumstances where a private person "would be liable to the claimant, in accordance with the general laws of th[e] state . . . . " Section 768.28, F.S., imposes a $100,000 limit on the government's liability to a single person. Furthermore, it imposes a $200,000 limit on the government's liability for claims arising out of a single incident. These limits do not preclude plaintiffs from obtaining judgments in excess of the recovery cap. However, plaintiffs cannot force the government to pay damages which exceed the recovery cap. The limits are constitutional.[6] In *Gerard v. Department of Transportation*, 472 So.2d 1170 (Fla. 1985), the Florida

[1] *Cauley v. City of Jacksonville,* 403 So. 2d 379 (Fla. 1981).
[2] *Kawananakaoa v. Polyblank,* 205 U.S. 349.
[3] *Cauley v. City of Jacksonville*, 403 So.2d 379 (Fla.1981).
[4] *Spangler v. Florida State Turnpike Authority*, 106 So.2d 421 (Fla. 1958).
[5] See generally Gerald t. Wetherington and Donald I. Pollack, Tort Suits Against Government Entities in Florida, 44 U.Fla.LRev. 1 (1992).
[6] *Berek v. Metropolitan Dade County*, 422 So.2d 838 (Fla. 1982); *Cauley v. City of Jacksonville*, 403 So.2d 379 (Fla. 1981).

Supreme Court held that the recovery caps within s. 768.28(5), F.S., did not prevent a plaintiff from seeking a judgment exceeding the recovery caps. However, the court noted: "Even if he is able to obtain a judgment against the Department of Transportation in excess of the settlement amount and goes to the legislature to seek a claims bill with the judgment in hand, this does not mean that the liability of the Department has been conclusively established. The legislature will still conduct its own independent hearing to determine whether public funds would be expended, much like a non jury trial. After all this, the legislature, in its discretion, may still decline to grant him any relief."[7]

Chapter 766, F.S., provides current law on medical malpractice. Section 766.1115, F.S., provides that certain health care providers who contract with the state are considered agents of the state, and thus entitled to the protection of sovereign immunity. The protection only applies should the contract contain specific conditions.

Section 768.28(9)(b)2., F.S., defines the term "officer, employee, or agent" (which are the persons to whom sovereign immunity applies). Several identified groups are included in the definition, including health care providers when providing services pursuant to s. 766.1115, F.S.

Florida law confers sovereign immunity to a number of persons who perform public services, including:

- Persons or organizations providing shelter space without compensation during an emergency per, s. 252.51, F.S.
- A health care entity providing services as part of a school nurse services contract per, s. 381.0056(10), F.S.
- Members of the Florida Health Services Corps who provide medical care to indigent persons in medically underserved areas per, s. 381.0302(11), F.S.
- A person under contract to review materials, make site visits or provide expert testimony regarding complaints or applications received by the Department of Health or the Department of Business and Professional Regulation per, ss. 455.221(3) and 456.009(3), F.S.
- A business contracted with by the Department of Business and Professional Regulation under the Management Privatization Act, per s. 455.32(4), F.S.
- Physicians retained by the Florida State Boxing Commission per, s. 548.046(1), F.S.
- Health care providers under contract to provide uncompensated care to indigent state residents per, s. 768.28(9)(b), F.S.
- Health care providers or vendors under contract with the Department of Corrections to provide inmate care per, s. 768.28(10)(a), F.S.
- An operator, dispatcher, or other person or entity providing security or maintenance for rail services in the South Florida Rail Corridor, under contract with the Tri-County Commuter Rail Authority the Department of Transportation per, s. 768.28(10)(d), F.S.
- Professional firms that provide monitoring and inspection services of work required for state roadway, bridge or other transportation facility projects per, s. 768.28(10)(e), F.S.
- A provider or vendor under contract with the Department of Juvenile Justice to provide juvenile and family services per, s. 768.28(11)(a), F.S.
- Health care practitioners under contract with state universities to provide medical services to student athletes per, s. 768.28(12)(a), F.S.

Kluger Test for Limitations on Access to the Courts

The Governor's 2002 Select Task Force on Healthcare Professional Liability Insurance found that new designations of sovereign immunity must pass the Kluger test.

> In reviewing the application of sovereign immunity and the provisions of s. 768.28, F.S., the courts have examined the application to specific entities and types of actions. In these cases, it

[7] See generally D. Stephen Kahn, *Legislative Claim Bills: A Practical Guide to a Potent(ial) Remedy*, FLA.B.J. 8 (April 1988).

has been argued that by applying sovereign immunity, the Legislature has violated article I, section 21 of the Florida Constitution by denying access to the courts. In analyzing this issue the courts have applied the test set for in *Kluger v. White*.[8] That test provides that, "where a right of access to the courts for redress of a particular injury has been provided by statutory law predating the adoption of the Declaration of the 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 s. 2.01, F.S., 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.[9]"

Florida Statutory Teaching Hospitals

There are currently six major teaching hospitals in Florida. They include:

- University Medical Center (UMC) in Jacksonville, affiliated with University of Florida;
- Mount Sinai Hospital (MSH) in Dade County, affiliated with the University of Miami;
- Jackson Memorial (JM) in Dade County, affiliated with the University of Miami;
- Shands Teaching Hospital in Gainesville, affiliated with University of Florida;
- Tampa General (TG), affiliated with University of South Florida; and
- Orlando Regional Medical Center (ORMC), affiliated with the University of Florida.

One of the primary missions of the six Florida teaching hospitals is to train interning physicians and a second is to provide primary sites of care for Florida's indigent population. Each teaching facility receives public subsidies (taxes, grants, and other public revenues) to assist with financing these missions. The range of needed indigent care and therefore public subsidy support (and operational losses varies widely.[10]

The six major teaching hospitals account for 80 percent of all graduate medical education (i.e., medical residents), 50 percent of all indigent care, and 30 percent of all Medicaid treatment in Florida. Everyday, Florida's statutory teaching hospitals deliver high quality tertiary health care services to thousands of needy patients. These patients often present themselves with advanced disease and are therefore at higher risk for poor health outcomes. [11]

University of Miami Medical School & Jackson Memorial Hospital

Jackson Memorial Hospital (JMH) is an accredited, non-profit, tertiary care hospital located in Miami. It is the major teaching facility for the University of Miami School of Medicine. With 1,567 licensed beds, Jackson Memorial Hospital's many roles in South Florida include: being the only full-service provider for the indigent and medically indigent of Miami-Dade County, a regional referral center, and a magnet for medical research and innovation. Based on the number of admissions to a single facility, Jackson Memorial is one of the nation's busiest hospitals. Jackson Memorial Hospital's trauma facilities form the only adult and pediatric Level 1 Trauma Center in South Florida. This center serves as a regional trauma center resource, one of the busiest such providers in the nation.[12] Jackson Memorial is operated by the Public Health Trust for Miami-Dade County.

The University of Miami is a private university located in Miami. While Jackson Memorial, as a public hospital, currently is protected under sovereign immunity, the university and its professors are not. The result is the University of Miami becomes the proverbial "deep pocket" defendant in many medical malpractice suits filed regarding an adverse incident occurring at Jackson Memorial.[13]

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[8] 281 So. 2d 1 (Fla. 1973).

[10] *Financial Profile of Florida's Teaching Hospitals and Tallahassee Memorial Hospital*, Center for Economic Forecasting and Analysis, Florida State University, 1997.

[11] Information supplied by the University of Miami.

[12] Available online at [http://um-jmh.org/JHS/Jackson.html].

[13] Information supplied by the University of Miami.

The bill also applies to Anne Bates Leach Eye Hospital and Sylvester Comprehensive Cancer Clinic owned by the University of Miami.

Florida Patient Safety Corporation

In 1999, the National Institute of Medicine reported that medical errors are estimated to be responsible for injury in as many as 1 out of every 25 hospital patients. Medical errors are estimated to be the eighth leading cause of death in this country; higher than motor vehicle accidents. According to the Institute of Medicine, preventable health care-related injuries cost the economy from $17 to $29 billion annually, of which half are health care costs.

Examples of medical errors include: a patient inadvertently given the wrong medication; a clinician misreading the results of a test; and a person with ambiguous symptoms (shortness of breath, abdominal pain, and dizziness) whose heart attack is not diagnosed by emergency room staff.

The health care industry is estimated to be a decade or more behind other high-risk industries in its attention to ensuring basic safety. Aviation has focused extensively on building safe systems, and has been doing so since World War II. Between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century. According to the Institute report, although health care may never achieve aviation's impressive record, there is clearly room for improvement. The increase in error rates, whether in providing patient treatment or flying an airplane, creates an increase in production cost or the cost of providing service. When the rate of error in providing medical care decreases, it is generally accepted that the cost of providing services will decrease correspondingly.

The Legislature established the not-for-profit, Florida Patient Safety Corporation in 2003 (SB 2-D), to provide coordination to and direction to efforts in the state to improve the quality and safety of health care, and reduce harm to patients. The corporation is not a state agency and shall not regulate health care providers in the state. It works collaboratively with state agencies in the development of electronic health records.

The corporation has a board composed of representatives of a broad cross section of health care interests with patient safety experience, who are appointed by their respective organizations. It may have advisory committees to address issues including: scientific research, technology, provider patient safety culture, consumers, interagency coordination, and tort alternatives.

The powers and duties of the corporation include:

- Collecting and analyzing patient safety data, medical malpractice closed claims, and adverse incidents already reported to the Agency for Health Care Administration (AHCA) and the Department of Health (DOH);
- A three year pilot project of a voluntary and anonymous, “near-miss,” patient safety reporting system, to: identify potential systemic problems that could lead to adverse incidents; enable publication of system-wide alerts of potential harm; and facilitate development of both facility-specific and statewide options to avoid adverse incidents and improve patient safety;
- Foster development of a statewide electronic infrastructure, including electronic medical records, that may be implemented in phases over a multiyear period; and
- Provide for access to an active library of evidence-based medicine and patient safety practices, available to health care practitioners, health care facilities, and the public.

C. SECTION DIRECTORY:

Section 1. Creates the popular name “Enterprise Act for Patient Protection and Provider Liability.”

Section 2. Provides legislative findings related to medical malpractice insurance that identify the relationships between hospital care, medical incidents, patient safety, malpractice insurance, and teaching hospitals.

Section 3. Amends s. 395.0197(3), F.S., to add the Enterprise Act for Patient Protection and Liability as an optional risk management program for hospitals. The bill includes provisions of the "Enterprise Act for Patient Protection and Provider Liability" as the basis for a hospital or ambulatory surgical center to assume liability for acts or omissions of a practitioner that occurs within that licensed facility.

Section 4. Amends s. 458.320, F.S., to create an exemption from financial responsibility for allopathic physicians who only work for "certified patient safety facilities" that assume legal liability for medical negligence of affected practitioners. A "certified patient safety facility" is defined in the bill as a statutory teaching hospital or a hospital that is wholly owned by a university that maintains an accredited medical school, and that is liable for acts or omissions of medical negligence in accordance with an order by the Agency that approves the "enterprise plan for patient protection and provider liability." This designation would apply to seven hospitals in Florida. (The approval process is included in Section 11. of the bill, creating s. 766.402, F.S.)

Subsection (5) is revised to require that physicians who are exempt from financial responsibility requirements on the basis of the Enterprise Act for Patient Protection and Provider Liability, must post a sign informing patients and persons receiving services that the physicians does not carry medical malpractice insurance.

Section 5. Amends s. 459.0085, F.S., to create the same exemption from financial responsibility for osteopathic physicians who only work for "certified patient safety facilities" as provided in Section 4. of the bill, for allopathic physicians.

Section 6. Creates s. 627.41485, F.S., to authorize insurance carriers to issue professional liability coverage that specifically excludes coverage for claims related to acts of medical negligence occurring within a "certified patient safety facility" that bears sole and exclusive liability for acts of medical negligence pursuant to the Enterprise Act for Patient Protection and Provider Liability. The Department of Financial Services may adopt rules to administer this section.

Section 7. Amends s. 766.316, F.S., to require hospitals that assume liability for their physicians under the Enterprise Act for Patient Protection and Provider Liability and who participate in the Florida Birth-Related Neurological Injury Compensation Plan, to provide notice to obstetrical patients as to the limited no-fault alternative for birth-related injuries.

Section 8. Amends s. 766.110(2), F.S., relating to liability of health care facilities. The revisions require hospitals that assume liability under the Enterprise Act for Patient Protection and Provider Liability to carry liability insurance in the amounts of $2.5 million per claim, $7.5 million annual aggregate to cover all medical injuries to patients resulting from medical negligence by staff covered by an enterprise plan. The bill provides that the hospital's insurance or fund must satisfy the financial responsibility requirements of Chapters 458 and 459, F.S and requirements in the Act for Patient Protection and Provider Liability, in order to retain sovereign immunity status under s. 768.28, F.S. Any hospital that provides such malpractice coverage must submit a certified financial statement, regarding the soundness of the reserve funds to the Agency for Health Care Administration.

Section 9. Creates s. 766.401, F.S., to specify definitions used in ss. 766.401-766.409, F.S. The bill creates definitions that apply to the proposed Enterprise Act for Patient Protection and Provider Liability. Those definitions focus on "eligible hospitals" or "licensed facility", which are the facilities that will be affected by the provisions of the act. Those facilities will be designated by an Agency order approving an enterprise plan for patient protection and provider liability.

The definitions provide that an "eligible hospital" or "licensed facility" is a statutory teaching hospital or a hospital that is wholly owned by a university with an accredited medical school. Those specified hospitals may become a "certified patient safety facility" by petitioning the Agency to issue an Agency order approving the hospital's enterprise plan for patient protection and provider liability. The enterprise plan would be based on the "enterprise agreement" executed by the governing board of the eligible hospital that establishes a plan for patient protection and provider liability in that facility. The bill defines "premises" and "within the premises" to include the buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment in reasonable proximity to the facility as to appear to the public to be under the dominion and control of the facility.

Section 10. Creates s. 766.402, F.S., to create procedures for AHCA approval of enterprise plans for patient safety and liability. The bill would require the Agency, in accordance with Chapter 120, F.S., to enter an order certifying approval of the eligible hospitals as a “certified patient safety facility” on the basis of a petition by the facility that shows that the facility is in compliance with provisions of ss. 766.401-766.409, F.S., which are created by the bill.

Section 11. Creates s. 766.403, F.S., to designate additional required patient safety measures required for hospitals seeking to enter into an enterprise agreement.

This section creates the criteria for satisfying the requirement that a petitioner facility be "engaged in a common enterprise for the care and treatment of hospital patients”, as required in s. 766.402(2)(a), F.S., or in compliance with s. 766.409, F.S., describing the process for petitioning the Agency to have an order issued identifying the facility as a certified patient safety facility. Those criteria include a process for quarterly reporting by the patient safety committee, a system for reporting near misses to the Florida Patient Safety Corporation (FPSC), a patient safety curriculum, a program to identify staff eligible for an early-intervention program, assessment and training program on skills identified by Agency rules, designation of a patient advocate and advisory panel, a procedure for semi-annual review of patient safety program by an independent organization or other organization approved by the Agency with a report presented to the governing board, establish a system for trending and tracking patient safety and quality indicators that may be established by Agency rule, and assistance to affected physicians in evaluating risk-management, patient-safety, and incident-reporting systems in settings outside the premises of the licensed facility.

The proposed language states that this section does not constitute an applicable standard of care in a legal action against the facility or a health care provider; that reviews or reports related to this section are not discoverable or admissible in a legal action; and that these criteria do not prevent facilities from implementing other measures as the legislative intent is that these safety measures are in addition to all other patient safety measures required by law.

Although not discoverable in a legal action, the reports must be submitted to AHCA, so would be available under Chapter 119, as they are not specifically exempted from the Public Records Law.

Section 12. Creates s. 766.404, F.S. to allow qualified hospitals who meet the requirements of ss. 766.401-766.409, F.S., to enter into enterprise liability plans. The hospital must bear sole and exclusive liability for any and all acts of medical negligence within the licensed facility. This section requires an affected practitioner to post notice of enterprise liability and exemption of personal liability. The section lists exemptions from notice to patients. It provides that AHCA certification of an enterprise plan is conclusive evidence that the hospital complies with all applicable patient safety requirements of s. 766.403, F.S. and all other requirements of ss. 766.401-766.409, F.S. Any evidence of noncompliance may not be admissible for any action for medical malpractice. This section does not give rise to an independent cause of action.

The section also provides that the agency may revoke an enterprise plan for patient protection. An administrative order revoking approval of an enterprise plan for patient protection and provider liability

terminates the plan on January 1 of the year following entry of the order or 6 months after entry of the order, whichever is longer.

The section provides that employees and agents of a certified patient safety facility many not be joined as defendants in any action for medical negligence because the licensed facility bears sole and exclusive liability for acts of medical negligence within the premises of the licensed facility. It requires affected physicians to cooperate in good faith with the affected facility. If the physician does not cooperate the affected facility shall have a cause of action for damages against an affected provider for bad faith refusal to cooperate. It provides that in a cause of action the claimant must allege and prove that an employee or agent of the licensed facility or an affected member of the medical staff committed an act or omission within the licensed facility which constitutes medical negligence under state law.

This section provides that ss. 766.401-766.409, F.S., do not create an independent cause of action against any health care provider, does not impose enterprise liability on any health care provider, except as expressly provided, and may not be construed to support any cause of action other than an action for medical malpractice as expressly provided against any person, organization, or entity. This section provides that ss. 766.401-766.409 does not waive sovereign immunity, except as provided by s. 768.28, F.S.

Section 13. Creates s. 766.405, F.S., to establish provisions for enterprise agreements. The section provides that the enterprise plans are elective and not mandatory for eligible hospitals. An eligible hospital and its executive committee of the medical staff or affiliated medical school (whichever is applicable), must execute an enterprise plan in order to be approved by the Agency as a certified patient safety facility. At minimum, the enterprise plan must contain provisions covering: compliance with patient protection plan; internal review of medical incidents; timely reporting of medical incidents of state agencies; professional accountability of affected practitioners; and financial accountability of affected practitioners.

Section 14. Creates s. 766.406, F.S., to provide professional accountability of affected practitioners. It establishes reporting requirements for incidents, adverse findings of medical negligence, or acts of omission which adversely affect patient safety pursuant to Department of Health rules. Facilities are authorized to limit or suspend clinical privileges of practitioners. The licensed facility and its officers, directors, employees, and agents are granted immunity from liability for sanctions imposed against practitioners. Immunity from liability for peer review committee members is granted.

Section 15. Creates s. 766.407, F.S., to provide financial accountability to affected practitioners. It establishes reporting requirements for incidents, adverse findings of medical negligence, or acts of omission which adversely affect patient safety pursuant to Department of Health rules. Facilities are authorized to limit or suspend clinical privileges of practitioners. The licensed facility and its officers, directors, employees, and agents are granted immunity from liability for sanctions imposed against practitioners. Immunity from liability for peer review committee members is granted.

Section 16. Creates s. 766.408, F.S., to provide parameters for data collection and reports of certified patient safety facilities. It requires that each certified patient safety facility submit an annual report to the Agency with data sufficient to evaluate the enterprise plan. The Agency is required to aggregate the data and evaluate the performance and effectiveness of the enterprise approach in an annual report to the Legislature before March 1. The reports submitted by the certified patient safety facility must include but are not limited to data on the number and names of affected facilities; number and types of patient protection measures currently in effect; number of affected practitioners; number of affected patients; number of surgical procedures by affected practitioners on affected patients; number of medical incidents, claims of medical malpractice, and claims resulting in indemnity; average time for resolution of contested and uncontested claims of medical malpractice; percentage of claims that result in civil trials; percentage of civil trials resulting in adverse judgments against affected facilities; number and average size of an indemnity paid to claimants; number and average size of assessments imposed on

affected practitioners; estimated liability expense, inclusive of liability insurance premiums, and other information the Agency deems appropriate.

The report also may include information and data obtained from the Department of Financial Services (DFS) on the availability and affordability of enterprise-wide medical liability insurance coverage for affected facilities. The Office of Insurance Regulation of DFS shall cooperate with the Agency in the reporting of information specified. These records are specifically designated as public records under chapter 119, F.S.

Section 17. Creates s. 766.409, F.S., to provide damage limits in malpractice actions against certain hospitals that meet patient safety requirements and agency approval of patient safety measures. It establishes that the limits of liability for medical malpractice for care by eligible hospitals shall be determined in accordance with the requirements of this section, notwithstanding any other provision of state law. The section authorizes eligible hospitals to petition the Agency for issuance of an order showing that the hospital complies with the patient safety measures specified in s. 766.403, F.S. The limits of liability for medical malpractice for a hospital covered by an order shall be $500,000 in the aggregate for claims or judgments for non-economic damages arising out of the same incident or occurrence. It also establishes the limits and payment mechanisms for payment of other damages. The bill specifies that the agency order remains in force until revoked, constitutes conclusive evidence that the hospital complies with all applicable patient safety requirements, and does not impose enterprise liability for acts or omissions of medical negligence.

Section 18. Creates s. 766.410, F.S., to provide rule making authority to the Agency of Health Care Administration to implement ss. 766.401 – 766.409, F.S.

Section 19. Amends s. 768.28, F.S., to provide for a waiver of sovereign immunity and to cap liability limits. The section provides a waiver of sovereign immunity for “certified patient safety facilities” that bear liability pursuant to the Enterprise Act for Patient Protection and Provider Liability established in the bill. The section would limit the payment made for a claim to $150,000 for a single claim and a total of $300,000 for all claims arising out of a single incident. The bill authorizes a certified patient safety facility to secure liability protection from a self-insurance program.

Section 20. Provides that the provisions of this act are severable.

Section 21. Provides that this act shall govern in the instance of conflicts with professional licensure statutes.

Section 22. States that the Legislature intends that the provisions of this act are self-executing.

Section 23. Provides that this act shall take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

FISCAL IMPACT ON AHCA/FUNDS:

							Amount Year 1 FY 05-06	Amount Year 2 FY 06-07
Expense (Agency Standard Expense & Operating Capital Outlay Package)								
Professional Staff			1	@	$2,610		$2,610	$0
Total Non-Recurring Expense							**$2,610**	**$0**
Salaries								
Health Services & Facilities Consultant	12	5894	1.0	**PG**	24		$50,513	$50,513
Total Salary and Benefits			1.0	**FTEs**			**$50,513**	**$50,513**
Expenses								
Professional Staff			1.0	@	$10,940		$10,940	$10,940
Total Expenses							**$10,940**	**$10,940**
Human Resources Services								
FTE Positions			1.0	@	$389		$389	$389
Total Human Resources Services							**$389**	**$389**
Total Recurring Expenditures			**1.0**	**FTEs**			**$61,842**	**$61,842**
Long Run Effects Other Than Normal Growth:								
Sub-Total Non-Recurring Expenditures							$2,610	$0
Sub-Total Recurring Expenditures							$61,842	$61,842
Total Expenditures			**1.0**	**FTEs**			**$64,452**	**$61,842**
Funding of Expenditures:								
General Revenue							$64,452	$61,842
Total							**$64,452**	**$61,842**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

Indeterminate.

2. Expenditures:

Indeterminate.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Indeterminate.

D. FISCAL COMMENTS:

According to the Agency for Health Care Administration (AHCA), the set of duties and responsibilities in the bill would require an additional staff person, 1 FTE, with experience and qualifications at a level of a Health Services and Facilities Consultant.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or 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 revenue.

2. Other:

Kluger Test for Limitations on Access to the Courts
The Governor's 2002 Select Task Force on Healthcare Professional Liability Insurance found that new designations of sovereign immunity must pass the Kluger test.

> In reviewing the application of sovereign immunity and the provisions of s. 768.28, F.S., the courts have examined the application to specific entities and types of actions. In these cases, it has been argued that by applying sovereign immunity, the Legislature has violated article I, section 21 of the Florida Constitution by denying access to the courts. In analyzing this issue the courts have applied the test set for in *Kluger v. White*.[14] That test provides that, "where a right of access to the courts for redress of a particular injury has been provided by statutory law predating the adoption of the Declaration of the 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 s. 2.01, F.S., 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.[15]"

B. RULE-MAKING AUTHORITY:

The bill provides necessary rule making authority to carry-out the provisions in the Act.

C. DRAFTING ISSUES OR OTHER COMMENTS:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 13, 2005, the Health Care Regulation Committee adopted three amendments sponsored by Representative Garcia.

[14] 281 So. 2d 1 (Fla. 1973).

- **Strike-All Amendment:** The strike-all amendment addressed several technical and conforming issues – including those brought to attention by the Office of Insurance Regulation, the Department of Health, and the Agency for Health Care Administration. Two key policy issues were addressed in the strike-all. First, additional language was included to make sure the enterprise option is only available to teaching hospitals and associated outpatient facilities. Second, the bill specifies that community physicians are not benefactors of an enterprise plan.
- **Amendment 1 & 2 to the strike-all –** Theses amendments remove the ability for the Florida Patient Safety Corporation to intervene in administrative actions (per Chapter 120).

The analysis is drafted to the committee substitute.