

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 702

SPONSOR: Governmental Oversight & Productivity Committee and Senator Saunders

SUBJECT: Public Records Exemption

DATE: March 24, 2004 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Rhea</u>	<u>Wilson</u>	<u>GO</u>	<u>Fav/CS</u>
2.	_____	_____	<u>AGG</u>	_____
3.	_____	_____	<u>AP</u>	_____
4.	_____	_____	<u>RC</u>	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This committee substitute creates a public records exemption for information that identifies a patient that is contained in patient safety data held by the Florida Patient Safety Corporation, an entity which is created in the Committee Substitute for Senate Bill 1464 by the Senate Committee on Health, Aging and Long-Term Care. Additionally, information that identifies the person or entity that reports patient safety data or in other records held by the Florida Patient Safety Corporation and its subsidiaries, advisory committees, or contractors pursuant to s. 281.0271, F.S., is made confidential and exempt. Personal identifying information of a patient, person or entity that reports patient safety data, may be disclosed only: (a) with the express written consent of the patient or the patient’s legally authorized representative in compliance with any federal or state law or the express written consent of the person or entity reporting such information; (b) by court order upon a showing of good cause; or (c) to a health research entity under specified circumstances. The bill also exempts that portion of a meeting of the corporation, its subsidiaries, advisory committees, or contractors at which such confidential and exempt information is discussed.

The exemption is made subject to the Open Government Sunset Review Act of 1995 and will sunset on October 2, 2009, unless reviewed and saved by repeal through reenactment.

As the bill creates a new public records exemption, it must be enacted by a two-thirds vote of each house of the Legislature pursuant to the requirements of Article I, s. 24(c) of the State Constitution.

This bill creates section 381.0273 of the Florida Statutes.

II. Present Situation:

Patient Safety

As the 2003 Legislature addressed Florida's medical malpractice insurance crisis, the reduction of medical errors received renewed attention as one method of lowering the number of malpractice claims. A review of professional liability closed-claims data for the period 1990 – 2002 revealed that, in each of those years, more than 60 percent of indemnity claims paid in Florida were for injuries that occurred in the hospital setting. Any effort to reduce medical malpractice claims must respond to errors in the hospital setting.

In 1999, the Institute of Medicine reported that at least 44,000, and perhaps as many as 98,000, American hospital patients die each year as a result of medical error. The lower number is extrapolated from a study conducted in Colorado and Utah and the higher number from a study in New York. Medication errors both in and out of the hospital account for more than 7,000 deaths annually.¹

The Governor's Select Task Force on Healthcare Professional Liability Insurance made 12 recommendations to improve health care quality in its January 2003 report. The recommendations most closely related to this bill include:

Recommendation 1. The Legislature should establish a Patient Safety Authority, or an entity similar in concept, as both a short-term and long-term strategy to improve patient safety. There are two options that should be considered. The first option, which is recommended by the Institute of Medicine (IOM) is to have two systems, one for the mandatory reporting of adverse events and another system for the voluntary reporting of near misses. The second option is similar to the Patient Safety Authority established and existing in Pennsylvania, which analyzes all adverse events and near misses in that state. Experts employed by both systems would analyze data received and make recommendations about how to reduce these adverse events and near misses. Information would not be subject to discovery in lawsuits.

Recommendation 2. The Legislature should timely develop or adopt statewide electronic medical records and protocols for a physician medication ordering system. The system should be developed collaboratively with hospitals, physicians, and other health care providers. The physician medication ordering system should be implemented first. The system could be implemented initially with a web-based data exchange platform which establishes interconnectivity among providers. Another possibility is to begin with business functions, which provide an early return on investment, and then include clinical functions.

The Governor's Task Force also recommended that the Legislature consider creating a statutory public-private non-profit entity that would administer the Patient Safety Authority.

¹ Institute of Medicine, Kohn, Linda T., Corrigan, Janet M., and Donaldson, Molla S., Eds. *To Err is Human: Building a Safer Health System*, National Academy Press. 1999.

During the 2003 Legislative Session and several subsequent special sessions, the Legislature addressed the issue of medical malpractice insurance and called for initiatives to improve patient safety as an essential part of reducing incidents of medical malpractice. In SB 2-D, the Legislature required AHCA, in consultation with DOH and existing patient safety centers in the state universities, to study the implementation requirements of establishing a statewide Patient Safety Authority. The authority would be responsible for performing activities and functions designed to improve patient safety and the quality of care delivered by health care facilities and health care practitioners. In undertaking the study, the agency was directed to examine and evaluate a Patient Safety Authority that would, either directly, by contract, or through a consortium of university-based patient safety centers:

- Analyze patient safety data and quality and patient safety indicators, including information concerning adverse incidents reported to AHCA.
- Collect, analyze, and evaluate patient safety data submitted voluntarily by a health care practitioner or health care facility.
- Foster the development of a statewide electronic infrastructure that may be implemented in phases over a multiyear period and that is designed to improve patient care and the delivery and quality of health care services by health care facilities and practitioners.
- As a statewide goal of reducing the occurrence of medication errors, inventory hospitals to determine the current status of implementation of computerized physician order entry systems, barcode point of care systems, or other technological patient safety systems and recommend a plan for expediting implementation statewide or, in hospitals where the agency determines that implementation of such systems is not practicable, alternative methods to reduce medication errors.
- Identify best practices and share this information with health care providers.
- Assess the patient safety culture at volunteering hospitals and recommend methods to improve the working environment as it relates to patient safety at these hospitals.
- Develop core competencies in patient safety that can be incorporated into the curriculums in Florida's schools of medicine, nursing, and allied health.
- Provide continuing medical education regarding patient safety to practicing physicians, nurses, and other health care providers.
- Engage in other activities that improve health care quality, improve the diagnosis and treatment of diseases and medical conditions, increase the efficiency of the delivery of health care services, increase administrative efficiency, and increase access to quality health care services.

The bill required that AHCA, in evaluating the operation of a Patient Safety Authority, must determine the costs of implementing and administering an authority and suggest funding sources and mechanisms. The bill required that at a minimum, the entity should:

- Be designed and operated by an individual or entity with demonstrated expertise in health care quality data and systems analysis, health information management, systems thinking and analysis, human factors analysis, and identification of latent and active errors.
- Include procedures for ensuring its confidentiality, timeliness, and independence.

The report was produced by AHCA through a contract with the University of Miami Center for Patient Safety. The report contained the following recommendations:

- The Florida state legislature should establish and endow “A Learning Institute” to advise and foster improvements in patient safety, to be called the Florida Patient Safety Authority (PSA).
- The PSA should be a public-private partnership organized as a nonprofit corporation registered, incorporated, organized, and operated in compliance with ch. 617, F.S., and shall have all powers necessary to carry out the purposes of this section, including, but not limited to, the power to receive and accept from any source contributions of money, property, labor, or any other thing of value.
- The PSA should be given access to closed claims data from all insurance companies, self-insurance companies, professional liability carriers, as well as similar information from the trial bar. It should also be given the ability to seek to obtain access to expert witness reports, post litigation, as well as public and secured private records in the possession of regulators in order to allow full and effective usage of all adverse patient data collected in the state of Florida.
- The Florida state legislature should create a Patient Safety Advisory Board which will include representatives of all Florida academic medical centers, insurers (both indemnity plans such as Blue Cross, and HMOs), and consumer representatives in order to assure the Patient Safety Authority remains adherent to the highest standards of “evidence based” practice and emerging science. The report recommended 11 members.
- The PSA should collect patient safety data submitted voluntarily by a health care practitioner or health care facility, as well as data submitted to the state regulatory agencies, for learning purposes.
- The PSA should analyze the data and determine changes in practices and procedures that may be implemented for the purpose of improving patient safety and preventing patient harm events.
- The PSA should maintain and share a clearinghouse of “best practices” in the areas of quality improvement and patient safety and provide technical assistance to hospitals and other health care providers in the areas of health care quality improvement and patient safety.
- The PSA should disseminate all knowledge acquired via website, newsletter and email blasts.
- The PSA mandate will include procedures that ensure privacy and confidentiality of data in full accordance with the Health Insurance Portability and Accountability Act and consistent with other state and federal laws.
- The PSA should receive state funding and coordinate contracts with providers to increase access to various simulation resources for use by hospitals, universities and other providers.
- The PSA will hold an annual Patient Safety Conference, as an opportunity for stakeholders to share lessons learned on patient safety issues.

Computerized Physician Order Entry

Computerized physician order entry systems are a tool that can be used to reduce medical errors and improve patient care by permitting the direct entry into a computer of orders for diagnostic tests, medications, patient care and referrals by physicians. The basic CPOE system is a computer application that accepts physician orders electronically, replacing hand-written orders

on an order sheet or prescription pad. Most CPOE systems communicate the orders entered into the system electronically to the hospital departments and personnel responsible for their execution. The departments or personnel can send back notification of the status of the order or the results, such as laboratory or x-ray results.

The Leapfrog Group, comprised of 145 public and private organizations that provide health care benefits, is a leader in establishing a national emphasis on patient safety. The group identifies problems and proposes to hospitals solutions that have the potential to save lives. The Leapfrog Group has recently focused on three practices that likely would improve patient safety: computerized physician order entry (CPOE) for filling prescriptions, evidenced-based hospital referral, and intensive care unit physician staffing. The Leapfrog Group recommends using CPOE for medication orders because a computerized prescription system “can reduce serious medication mistakes by up to 86 percent”.²

Some of the potential benefits of the electronic communication of physician orders include the following efficiencies:

- Improved process turnaround times – for example, reduced time from ordering to arrival of the medication;
- Improved documentation received by ancillary departments, such as pharmacy and radiology, thereby reducing the chance of misinterpretation of an order and improving documentation needed for payment; and
- Reduced need in ancillary departments for re-entry of data into the ancillary computer system.³

More advanced CPOE systems also provide physician decision supports at the point of ordering. Examples of physician decision supports that can be provided by a CPOE system include:

- Alerts to possible patient allergic reactions and contraindications to prescribed medications and recommendation of alternative medications;
- Alerts to possible dosage errors;
- Notifications that new orders for tests duplicate tests that have recently been ordered and that a result is pending;
- Pre-programmed institutionally reviewed and approved sets of orders to facilitate the process and help physicians follow accepted protocols for ordering tests and medications for common diagnoses;
- Programmed protocols for complex order types involving calculations and multiple-day orders dependent on test results; and
- Costs and a list of possible alternatives or a list of restricted indications for orders for a particularly expensive test or medication.⁴

² Leapfrog Group. “Survey Results”. http://www.leapfroggroup.org/consumer_intro2.htm

³ “First Consulting Group for Advancing Health in America and Federation of American Hospitals. “Computerized Physician Order Entry: Costs, Benefits and Challenges – A Case Study Approach”. 2003.

⁴ Ibid.

Any organization attempting to implement CPOE faces four principle categories of challenges: affording the initial investment and ongoing costs; changing the way physicians work; redesigning inpatient care processes that affect physicians, pharmacists, nurses, and ancillary personnel; and implementing a highly reliable, responsive, and user-friendly CPOE system.⁵

Data from Florida Hospitals

The Patient Safety Center at the Florida State University College of Medicine is conducting a study of the Information Technology (IT) capabilities of Florida Hospitals. Preliminary results from a survey conducted during the summer and fall of 2003, with 40 percent of hospitals responding, indicate the following:

- When asked to indicate their hospitals' current top information technology priorities, the highest response from all the hospitals (50.6 percent of respondent hospitals) was to implement technology to reduce medical errors and promote patient safety. Implementation of technology to reduce medical errors and promote patient safety was also the highest response from hospitals for the next two years (55.4 percent of respondent hospitals).
- 12 percent of the hospitals have a fully operational CPOE system in place in at least one part of the hospital.
- 5 percent of the hospitals have begun to install CPOE hardware and software in at least one part of the hospital.
- 28 percent of the hospitals have developed a plan to implement a CPOE system in at least one part of the hospital.
- 54 percent of the hospitals have not yet begun to plan for the use of a CPOE system.
- 13.3 percent of the hospitals currently use bar coded medication management, and 57.8 percent plan to do so within the next 2 years.
- 84.3 percent of the hospitals currently use IT applications in their pharmacy, and 9.6 percent plan to do so within the next 2 years.
- 62.7 percent of the hospitals use IT capability for pharmacy dispensing, and 24.1 percent plan to do so within the next 2 years.

Patient Safety Officers

The 2003 Legislature created s. 395.1012, F.S., to require each licensed hospital, ambulatory surgical center, and mobile surgical facility to adopt a patient safety plan and appoint a patient safety officer and a patient safety committee. The purpose of the patient safety officer and the patient safety committee is to promote the health and safety of patients, review and evaluate the quality of patient safety measures used by the facility, and assist in the implementation of the facility's patient safety plan.

Patient Safety Organizations/Patient Safety Data Privilege

Section 766.1016, F.S., which was created as section 10 of CS/SB 2-D (2003), provides that patient safety data, as defined in this section, shall not be subject to discovery or introduction into evidence in any civil or administrative action. However, information, documents, or records

⁵ Ibid.

otherwise available from original sources are not immune from discovery or use in any civil or administrative action merely because they were also collected, analyzed, or presented to a patient safety organization.

Patient safety data is defined to mean reports made to patient safety organizations, including all health care data, interviews, memoranda, analyses, root cause analyses, products of quality assurance or quality improvement processes, corrective action plans information collected or created by a health care facility licensed under ch. 395, F.S., or a health care practitioner as defined in s. 456.001(4), F.S., as a result of an occurrence related to the provision of health care services which exacerbates an existing medical condition or could result in injury, illness, or death.

Patient safety organization is defined to mean any organization, group, or other entity that collects and analyzes patient safety data for the purpose of improving patient safety and health care outcomes and that is independent and not under the control of the entity that reports patient safety data.

Section 766.1016(3), F.S., requires that, unless otherwise provided by law, a patient safety organization must promptly remove all patient-identifying information after receipt of a complete patient safety data report unless such organization is otherwise permitted by state or federal law to maintain such information. Patient safety organizations must maintain the confidentiality of all patient-identifying information and may not disseminate such information, except as permitted by stat or federal law.

Centers for Patient Safety

Florida has three university-based patient safety centers, all created in the past two years:

- In 2001, the Suncoast Developmental Center for Patient Safety Evaluation and Research, a national patient safety center, was created at the University of South Florida with funding from the Federal Agency for Healthcare Research and Quality. The Suncoast center works in partnership with the Veteran's Administration Patient Safety Center of Inquiry at James A. Haley V.A. Hospital, with other local and regional health care providers, with the patient safety centers at Florida State University and the University of Miami and with the college of Pharmacy at Florida Agricultural and Mechanical University.
- In 2002, the Florida State University College of Medicine established the Center on Patient Safety to promote and conduct research and education designed to reduce medical errors and increase healthcare quality. In 2003, the center conducted a survey of the information technology capabilities of Florida's hospitals relating to patient safety.
- In 2003, the Center for Patient Safety was established at the University of Miami. As the recipient of a grant from the Agency for Health Care Administration to conduct patient safety studies mandated by the 2003 Legislature in CS/SB 2-D, the center provided reports to the Legislature in February 2004, on the establishment of a statewide patient safety authority and on the most feasible information to provide to consumers comparing in-patient quality indicators for state licensed hospitals.

Senate Interim Project Report 2004-143

Senate Interim Project 2004-143 analyzed the use of CPOE systems in hospitals as a tool for reducing medical errors. The report concluded that:

- The history of the use of information technology in clinical practice by physicians and hospitals does not indicate that progress can be mandated.
- The implementation of CPOE has been successful where administrators and practitioners supported the change.
- The best way to bring about further use of CPOE in Florida would be for the Legislature to encourage the state's existing patient safety centers at universities to work with hospitals to improve their use of information technology to improve patient safety.
- Florida's university-based patient safety centers should analyze the return on investment that could be realized from implementing CPOE in large and small hospitals in both urban and rural settings.

Each hospital's patient safety officer, required under s. 395.1012, F.S., should identify ways that inpatient care processes that affect physicians, pharmacists, nurses, and ancillary personnel could be redesigned for implementation of CPOE.

The Committee Substitute for Senate Bill 1464

Creates s. 381.0271, F.S., which establishes the Florida Patient Safety Corporation.

Subsection (1) defines the following terms:

- *Adverse incident* has the meanings given to the term in s. 395.0197, F.S., s. 458.351, F.S., and s. 459.026, F.S. (Section 395.0197, F.S., requires hospitals, ambulatory surgical centers, and mobile surgical facilities to report adverse incidents, as defined in that section, to AHCA. Sections 458.351 and 459.026, F.S., require medical physicians and osteopathic physicians, respectively, to report office surgery adverse incidents, as defined in those sections, to DOH.)
- *Corporation* means the Florida Patient Safety Corporation created in this section.
- *Patient safety data* has the meaning given to the term in s. 766.1016, F.S. (Section 766.1016, F.S., defines "patient safety data" for purposes of establishing a privilege in administrative or civil actions for such data held by a patient safety organization.)

Subsection (2) creates the Florida Patient Safety Corporation as a not-for-profit corporation which must be registered, incorporated, organized, and operated in compliance with ch. 617, F.S. The corporation is authorized to create not-for-profit corporate subsidiaries that are organized under the provisions of ch. 617, F.S., as necessary to fulfill its mission and upon the prior approval of the Board of Directors.

The corporation and any authorized and approved subsidiary:

- Are not an agency within the meaning of s. 20.03(11), F.S., which defines organizational units within the executive branch of state government;
- Are subject to the public meetings and records requirements of s. 24, Art. I of the State Constitution, ch. 119, and s. 286.011, F.S.; and

- Are not subject to the provisions of ch. 287, F.S., which governs procurement of personal property and services.

The corporation is a patient safety organization for purposes of s. 766.1016, F.S., which establishes a privilege in civil and administrative actions for patient safety data, held by such organizations.

Subsection (3) establishes the purpose of the Florida Patient Safety Corporation, which will be to serve as a learning organization dedicated to assisting health care providers in the state to improve the quality and safety of the health care that is rendered and to reduce harm to patients. The corporation must promote the development of a culture of patient safety in Florida's health care system, but the corporation may not regulate health care providers. In the fulfillment of its purpose, the corporation must work with a consortium of patient safety centers and other patient safety programs in universities in Florida.

Subsection (4) establishes the board of directors of the corporation. The corporation must be governed by a board of directors, consisting of:

- The chairperson of the Council of Medical School Deans.
- The person responsible for patient safety issues for the authorized health insurer with the largest market share as measured by premiums written in the state for the most recent calendar year, appointed by that insurer.
- A representative of the authorized medical malpractice insurer with the largest market share as measured by premiums written in the state for the most recent calendar year, appointed by that insurer.
- The President of the Florida Health Care Coalition.
- A representative of a hospital in the state that is implementing innovative patient safety initiatives, appointed by the Florida Hospital Association.
- A physician with expertise in patient safety, appointed by the Florida Medical Association.
- A physician with expertise in patient safety, appointed by the Florida Osteopathic Medical Association.
- A nurse with expertise in patient safety, appointed by the Florida Nurses Association.
- An institutional pharmacist, appointed by the Florida Society of Health System Pharmacists, Inc.
- A representative of Florida AARP, appointed by the director of Florida AARP.
- An independent health care information systems consultant appointed jointly by the Central Florida Chapter and the South Florida Chapter of the Healthcare Information and Management Systems Society.

Subsection (5) requires the corporation to establish the following advisory committees:

- A scientific research advisory committee that includes, at a minimum, a representative from each patient safety center or other patient safety program in the universities in Florida.
- A technology advisory committee that includes, at a minimum, a representative of a hospital that has implemented a computerized physician order entry system, and a health care provider that has implemented an electronic medical records system.

- A health care provider advisory committee that includes, at a minimum, representatives of hospitals, ambulatory surgical centers, physicians, nurses, and pharmacists licensed in this state and a representative of the Veterans Integrated Service Network 8 VA Patient Safety Center.
- A health care consumer advisory committee that includes, at a minimum, representatives of businesses that provide health insurance coverage to their employees, consumer advocacy groups, and representatives of patient organizations.
- A state agency advisory committee that includes, at a minimum, a representative from each state agency that has regulatory responsibilities related to patient safety.
- A litigation alternatives advisory committee that includes, at a minimum, representatives of medical malpractice plaintiffs and defendants attorneys, and a representative of each law school in the state.
- An educational advisory committee that includes, at a minimum, the associate dean of education, or the equivalent position, as a representative from each school of medicine, nursing, public health, or allied health to provide advice on the development, implementation, and measurement of core competencies of patient safety to be considered for incorporation in the educational programs of the universities in Florida.

The corporation may establish other committees as it sees fit.

Subsection (6) requires AHCA to assist the corporation in its organizational activities required under ch. 617, F.S., including, but not limited to:

- Eliciting appointments for the initial board of directors.
- Convening the first meeting of the board of directors and assisting with other meetings of the board of directors, upon request of the board of directors, during the first year of operation of the corporation.
- Drafting articles of incorporation for the board of directors and, upon request of the board of directors, delivering articles of incorporation to the Department of State for filing.
- Drafting proposed bylaws for the corporation.
- Paying fees related to incorporation.
- Providing office space and administrative support, at the request of the board of directors, but not beyond July 1, 2005.

The board of directors must conduct its first meeting no later than August 1, 2004, and must meet thereafter as frequently as necessary to carry out the duties of the corporation.

Subsection (7) provides that, in addition to the powers and duties prescribed in ch. 617, F.S., and the articles and bylaws adopted under that chapter; the corporation must, either directly or through contract:

- Secure staff necessary to properly administer the corporation.
- Collect, analyze, and evaluate patient safety data, quality and patient safety indicators, medical malpractice closed claims, and adverse incidents reported to the Agency for Health Care Administration and the Department of Health, for the purpose of recommending changes in practices and procedures that may be implemented by health care practitioners

and health care facilities to improve health care quality and to prevent future adverse incidents. Notwithstanding any other law, the Agency for Health Care Administration and the Department of Health must make available to the corporation any adverse incident report submitted under ss. 395.0197, 458.351, and 459.026, F.S. To the extent that adverse incident reports submitted under s. 395.0197, F.S., are confidential and exempt, the confidential and exempt status of such reports must be maintained by the corporation.

- Maintain an active library of best practices relating to patient safety and patient safety literature along with the emerging evidence supporting the retention or modification of such practices, and make this information available to health care practitioners, health care facilities, and the public.
- Foster the development of a statewide electronic infrastructure that may be implemented in phases over a multiyear period and that is designed to improve patient care and the delivery and quality of health care services by health care facilities and health care practitioners.
- Assess the patient safety culture at volunteering hospitals and recommend methods to improve the working environment related to patient safety at these hospitals.
- Inventory the information technology capabilities related to patient safety of health care facilities and health care practitioners and recommend a plan for expediting implementation of safety technologies statewide.
- Facilitate the development of core competencies relevant to patient safety which can be made available to be considered for incorporation into the curriculums in the undergraduate and graduate curriculums in schools of medicine, nursing and allied health in Florida
- Study and facilitate the testing of alternative systems of encouraging the implementation of effective risk management strategies and clinical best practices, and of compensating injured patients as a means of reducing and preventing medical errors and promoting patient safety.
- Develop programs to educate the public about the role of health care consumers in promoting patient safety.
- Provide interagency coordination of patient safety efforts in Florida.
- Conduct other activities identified by the board of directors to promote patient safety in Florida.

Subsection (8) requires the corporation, by December 1, 2004, to prepare a report on the start-up activities of the corporation and any proposals for legislative action that are needed for the corporation to fulfill its purposes. By December 1 of each year thereafter, the corporation must prepare a report for the preceding fiscal year. The report, at a minimum, must include:

- A description of the activities of the corporation.
- Progress made in improving patient safety and reducing medical errors.
- A compliance and financial audit of the accounts and records of the corporation at the end of the preceding fiscal year conducted by an independent certified public accountant.
- An assessment of the ability of the corporation to fulfill the duties specified in the bill and the appropriateness of those duties for the corporation.
- Recommendations for legislative action needed to improve patient safety in this state.

The corporation must submit the report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

Subsection (9) requires OPPAGA, in consultation with the Agency for Health Care Administration, the Department of Health, and the corporation, to develop performance standards by which to measure the success of the corporation in organizing to fulfill and beginning to implement its purposes and duties. OPPAGA must conduct a performance audit of the corporation, using the performance standards, during 2006, and must submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2007.

Section 2. Requires the Patient Safety Center at the Florida State University College of Medicine, in collaboration with researchers at other state universities, to conduct a study to analyze the return on investment that hospitals in this state could realize from implementing computerized physician order entry and other information technologies related to patient safety. The analysis must include both financial results and benefits relating to quality of care and patient safety. The study must include a representative sample of large and small hospitals, in urban and rural settings, in the north, central and southern regions of the state. By February 1, 2005, the Patient Safety Center at the Florida State University College of Medicine must submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives concerning the results of the study.

Section 3. Amends s. 395.1012, F.S., to require each patient safety officer and patient safety committee at a licensed hospital, ambulatory surgical facility, or mobile surgical facility to recommend improvements in the patient safety measures used by the facility. Each licensed facility must adopt a plan to reduce medication errors and adverse drug events that must consider the use of computerized physician order entry and other information technologies related to patient safety.

Section 4. Repeals subsection (3) of s. 766.1016, F.S., which requires a patient safety organization to promptly remove all patient-identifying information after receipt of a complete patient safety data report, unless otherwise provided by law. The requirement for patient safety organizations to maintain the confidentiality of patient-identifying information and not disseminate such information, except as permitted by state or federal law, is also repealed.

Section 5. Appropriates the sum of \$350,000 in nonrecurring general revenue funds to AHCA for the establishment of the Florida Patient Safety Corporation during the 2004-2005 fiscal year.

Section 6. Appropriates the sum of \$113,500 in nonrecurring general revenue funds to the Florida State University College of Medicine for the purpose of conducting the study required in section 2 of the bill during the 2004-2005 fiscal year.

Constitutional Access to Public Records and Meetings

Article I, s. 24 of the State Constitution, provides every person with the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf. The section specifically includes the legislative, executive and judicial branches and each agency or department created under them. It also includes counties, municipalities, and districts, as well as constitutional officers, boards, and commissions or entities created pursuant to law or the State Constitution.

The term “public records” has been defined by the Legislature in s. 119.011(1), F.S., to include:

. . . all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.

This definition of public records has been interpreted by the Florida Supreme Court to include all materials made or received by an agency in connection with official business, which are used to perpetuate, communicate or formalize knowledge. *Shevin v. Byron, Harless, Schaffer, Reid and Associates, Inc.*, 379 So.2d 633, 640 (Fla. 1980). Unless these materials have been made exempt by the Legislature, they are open for public inspection, regardless of whether they are in final form. *Wait v. Florida Power & Light Company*, 372 So.2d 420 (Fla. 1979).

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

Exemptions to public records requirements are strictly construed because the general purpose of open records requirements is to allow Florida’s citizens to discover the actions of their government. *Christy v. Palm Beach County Sheriff’s Office*, 698 So.2d 1365, 1366 (Fla. 4th DCA 1997). The Public Records Act is liberally construed in favor of open government, and exemptions from disclosure are to be narrowly construed so they are limited to their stated purpose. *Krischer v. D’Amato*, 674 So.2d 909, 911 (Fla. 4th DCA 1996); *Seminole County v. Wood*, 512 So.2d 1000, 1002 (Fla. 5th DCA 1987), review denied, 520 So.2d 586 (Fla. 1988); *Tribune Company v. Public Records*, 493 So.2d 480, 483 (Fla. 2d DCA 1986), review denied sub nom., *Gillum v. Tribune Company*, 503 So.2d 327 (Fla. 1987).

There is a difference between records that the Legislature has made exempt from public inspection and those that are exempt and confidential. If the Legislature makes certain records confidential, with no provision for its release such that its confidential status will be maintained, such information may not be released by an agency to anyone other than to the persons or entities designated in the statute. Attorney General Opinion 85-625. If a record is not made confidential but is simply exempt from mandatory disclosure requirements, an agency is not prohibited from disclosing the record in all circumstances. *Williams v. City of Minneola*, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).

Under s. 119.10, F.S., any public officer violating any provision of this chapter is guilty of a noncriminal infraction, punishable by a fine not exceeding \$500. In addition, any person willfully and knowingly violating any provision of the chapter is guilty of a first degree misdemeanor, punishable by potential imprisonment not exceeding one year and a fine not exceeding \$1,000. Section 119.02, F.S., also provides a first degree misdemeanor penalty for

public officers who knowingly violate the provisions of s. 119.07(1), F.S., relating to the right to inspect public records, as well as suspension and removal or impeachment from office.

The Open Government Sunset Review Act of 1995

Section 119.15, F.S., the Open Government Sunset Review Act of 1995, establishes a review and repeal process for exemptions to public records or meetings requirements. Under s. 119.15(3)(a), F.S., a law that enacts a new exemption or substantially amends an existing exemption must state that the exemption is repealed at the end of 5 years. Further, a law that enacts or substantially amends an exemption must state that the exemption must be reviewed by the Legislature before the scheduled repeal date. An exemption is substantially amended if the amendment expands the scope of the exemption to include more records or information or to include meetings as well as records. An exemption is not substantially amended if the amendment narrows the scope of the exemption.

In the fifth year after enactment of a new exemption or the substantial amendment of an existing exemption, the exemption is repealed on October 2nd of the 5th year, unless the Legislature acts to reenact the exemption.

Under the requirements of the Open Government Sunset Review Act, an exemption is to be maintained only if:

- (a) The exempted record or meeting is of a sensitive, personal nature concerning individuals;
- (b) The exemption is necessary for the effective and efficient administration of a governmental program; or
- (c) The exemption affects confidential information concerning an entity.

As part of the review process, s. 119.15(4)(a), F.S., requires the consideration of the following specific questions:

- (a) What specific records or meetings are affected by the exemption?
- (b) Whom does the exemption uniquely affect, as opposed to the general public?
- (c) What is the identifiable public purpose or goal of the exemption?
- (d) Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?

Further, under the Open Government Sunset Review Act, an exemption may be created or maintained only if it serves an identifiable public purpose. An identifiable public purpose is served if the exemption:

1. Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, the administration of which would be significantly impaired without the exemption;
2. Protects information of a sensitive personal nature concerning individuals, the release of which information would be defamatory to such individuals or cause unwarranted damage to the good name or reputation of such individuals or would jeopardize the safety of such individuals; or

3. Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information which is used to protect or further a business advantage over those who do not know or use it, the disclosure of which information would injure the affected entity in the marketplace.

Further, the exemption must be no broader than is necessary to meet the public purpose it serves. The Legislature must find that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption.

III. Effect of Proposed Changes:

The committee substitute creates an exemption from public records requirements. Information that identifies a patient and that is contained in patient safety data, as defined in s. 766.1016, F.S., or in other records held by the Florida Patient Safety Corporation and its subsidiaries, advisory committees, or contractors pursuant to s. 381.0271, F.S., is made confidential and exempt by the committee substitute.

Exceptions to the exemption are provided. Specifically, personal identifying information may be disclosed only:

1. With the express written consent of the patient or the patient's legally authorized representative in compliance with any federal or state law.
2. By court order upon a showing of good cause.
3. To a health research entity if that entity seeks the records or data pursuant to a research protocol approved by the corporation, maintains the records or data in accordance with the approved protocol, and enters into a purchase and data-use agreement with the corporation, the fee provisions of which are consistent with s. 119.07(1)(a), F.S.

The committee substitute permits the Florida Patient Safety Corporation to deny a request for data or records that identify a patient if the protocol provides for intrusive follow-back contacts, has not been approved by a human studies institutional review board, does not plan for the destruction of confidential records after the research is concluded, or does not have scientific merit. The agreement must prohibit the release of any information that would permit the identification of any patient, must limit the use of records or data in conformance with the approved research protocol, and must prohibit any other use of the records or data. Copies of the records or data issued pursuant to the paragraph remain the property of the corporation.

Additionally, information that identifies a person or entity that reports patient safety data as defined in s. 766.1016, F.S., to the corporation and that is contained in patient safety data, as defined in s. 766.1016, F.S., or in other records held by the Florida Patient Safety Corporation and its subsidiaries, advisory committees, or contractors pursuant to s. 381.0271, F.S., is made confidential and exempt by the committee substitute.

Exceptions to the exemption are provided. Specifically, personal identifying information may be disclosed only:

1. With the express written consent of the person or entity reporting the patient safety data to the corporation.
2. By court order upon a showing of good cause; or
3. To a health research entity if that entity seeks the records or data pursuant to a research protocol approved by the corporation, maintains the records or data in accordance with the approved protocol, and enters into a purchase and data-use agreement with the corporation, the fee provisions of which are consistent with s. 119.07(1)(a), F.S.

The committee substitute permits the Florida Patient Safety Corporation to deny a request for data or records that identify a person or entity that reports patient safety data if the protocol provides for intrusive follow-back contacts, has not been approved by a human studies institutional review board, does not plan for the destruction of confidential records after the research is concluded, or does not have scientific merit. The agreement must prohibit the release of any information that would permit the identification of any person or entity who reports patient safety data, must limit the use of records or data in conformance with the approved research protocol, and must prohibit any other use of the records or data. Copies of the records or data issued pursuant to the paragraph remain the property of the corporation.

The bill also exempts that portion of a meeting of the corporation, its subsidiaries, advisory committees, or contractors at which such confidential and exempt information is discussed.

The exemption is made subject to the Open Government Sunset Review Act of 1995 and will repeal October 2, 2009, unless reviewed and saved from repeal through reenactment by the Legislature.

The statement of public necessity bases the need for the exemptions created by the committee substitute on the sensitive and personal nature of the records that are held by the corporation. Release of the information could be defamatory to the patient and cause unwarranted damage to the name or reputation of the patient. The same public necessity supports the protecting the identity of persons or entities reporting patient safety data, as well as the likelihood that these persons or entities might not provide this voluntary information if it could be made public. Further, the committee substitute also notes that these exemptions are necessary in order for the Florida Patient Safety Corporation to perform its delegated functions and without these exemptions, its effectiveness would be seriously impaired and jeopardized.

The effective date of the committee substitute is contingent upon passage of the Committee Substitute for Senate Bill 1464 or similar legislation.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

See supra.

C. Trust Funds Restrictions:

None.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
