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 2294

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Brown-Waite

SUBJECT: Patient Safety Improvement Act

DATE: March 6, 2002 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.			ED	
3.			JU	
4.			AED	
5.			AP	
6.				

I. Summary:

The bill creates the "Patient Safety Improvement Act" and specifies legislative intent to establish a statewide, academically based center that will serve as the designated resource for research, education, and policy concerning patient safety and for providing information to the public and to institutions. The bill creates the Florida Center for Patient Safety in the Health Sciences Center at the University of South Florida in Tampa and the College of Medicine at the Florida State University in Tallahassee and specifies duties and requirements for the center. The bill provides that if any patient-safety data received by the Florida Center for Patient Safety contains data that is confidential and exempt from the Public Records Law, such data must remain confidential as otherwise provided by law.

This bill creates one designated section of law.

II. Present Situation:

Florida Commission on Excellence in Health Care

In 2000, the Legislature created the Florida Commission on Excellence in Health Care to facilitate the development of a comprehensive statewide strategy for improving the health care delivery system through meaningful reporting standards, data collection and review, and quality measurement. The commission presented its report to the Governor and Legislature on February 1, 2001. As part of its report, the commission recommended the formation of a Center for Patient Safety and Excellence in Health Care to be empowered to:

- Collect and establish a statewide database on health care errors, adverse incidents, and near misses, maximizing the use of existing data;

- Analyze statewide data on health care errors in procedures, products and systems, and prepare an aggregate report for dissemination;
- Convene multi-disciplinary work groups of representatives from professional organizations, regulatory boards and agencies, accrediting and licensing bodies, educational institutions, health care practitioners and providers, and private industry to review and discuss the information on health care errors and patient safety practices that can be used in developing practice guidelines and standards;
- Disseminate research information on health care errors and patient safety practices to professional societies, hospitals, health plans, and ambulatory surgical centers and encourage them to incorporate patient safety practices into their clinical practice guidelines;
- Serve as a clearinghouse, in conjunction with the regulatory bodies, to disseminate information on patient safety;
- Conduct meetings with professional organizations and regulatory bodies to discuss information on health care errors to determine the types of information and methods for disseminating information on patient safety;
- Conduct meetings with consumer and patient organizations through grassroots informational meetings to determine the types of patient safety information and the most effective methods for disseminating the information to enable consumers to become involved in their care and to be more active participants in the decision-making surrounding their care;
- Develop material on preventing health care errors, patient safety and quality improvement that state regulatory bodies, purchasers, professional associations and societies, health plans, hospitals, and ambulatory surgical centers can disseminate, reprint, or adapt;
- Develop a packet of information to educate consumers on health care errors, improve patient safety, and assist them in taking an active role in making decisions concerning their health care which should be distributed by various entities including health plans, insurance companies, hospitals, health care practitioners, community leaders, and retirement centers;
- Determine the type and most effective way to present information on patient safety, health care errors and quality improvement to health care practitioners, providers, purchasers and consumers and determine the impact of providing such information;
- Analyze data on health care errors and adverse incidents and other sources to develop a model patient-safety education and training program;
- Encourage medical schools, teaching hospitals, and health care educational programs to incorporate the patient-safety training program into their curriculum; and
- Encourage medical and health care teaching facilities to use patient simulators to train and maintain health care practitioner skills.

The report contained a summary of the commission's recommendations. Copies of the commission’s report are available online at http://www.floridahealthstat.com.

National Center for Patient Safety

One entity in Florida has been designated as a national center for patient safety. A partnership between the University of South Florida Health Sciences Center and the Veteran's Health Administration has resulted in the formal designation of the University of South Florida as the State's only National Center for Patient Safety Research and Evaluation by the Federal Agency for Healthcare Research and Quality, and of the partnership as a National Patient Safety Center of Inquiry by the Veteran's Administration.

Public Records Law

The Public Records Law, ch. 119, F.S., and the Public Meetings Law, s. 286.011, F.S., specify the conditions under which public access must be provided to governmental records and meetings of the executive branch and other governmental agencies. While the state constitution provides that records and meetings of public bodies are to be open to the public, it also provides that the Legislature may create exemptions to these requirements by general law if a public need exists and certain procedural requirements are met. Article I, s. 24, Fla. Const. governs the creation and expansion of exemptions to provide, in effect, that any legislation that creates a new exemption or that substantially amends an existing exemption must also contain a statement of the public necessity that justifies the exemption. Article I, s. 24, Fla. Const. provides that any bill that contains an exemption may not contain other substantive provisions, although it may contain multiple exemptions.

Managed Care Ombudsman Confidentiality

The medical records of a subscriber and the identity of a complainant involved in a managed care ombudsman review are exempt from public records disclosure under s. 641.67, F.S. That portion of any meeting of an ombudsman committee addressing medical records or complainant identity is exempt from public meeting requirements under s. 641.68, F.S. As well, "any problem identified by the ombudsman committee as a result of an investigation" is made exempt under s. 641.67(1)(b), F.S. Similar provisions are contained in s. 400.0077, F.S., for the long-term care ombudsman program.

The public purpose or goal of maintaining the disclosure exemptions for medical records and complainant identity is primarily to protect information of a sensitive personal nature concerning individuals, the release of which information could cause embarrassment, loss of privacy or harm to the reputation or public standing of such individuals. The principal purpose or goal of the exemption for a "problem identified" is instead to allow the state or its political subdivisions to effectively and efficiently administer the ombudsman programs, which administration would be significantly impaired without the exemption, and to protect information of a confidential nature concerning managed care entities and long-term care facilities, the disclosure of which could injure the affected entity in the marketplace.

The nature of the exemption for a "problem identified" is similar to the exemption provided for medical peer review committees and hospital risk management functions under ss. 395.0197 and 766.101, F.S. Without the exemption for a "problem identified" under ss. 641.67(1)(b) and 400.0077, F.S., there would be a significant disincentive for managed care organizations and

long-term care facilities to candidly discuss issues and cooperate in ombudsman complaint resolution.

State Center for Health Statistics and Data Collection by the Agency for Health Care Administration

Section 408.05, F.S., establishes the State Center for Health Statistics (a comprehensive health information system) to provide for the collection, compilation, coordination, analysis, indexing, dissemination, and utilization of health-related data and statistics. Under s. 408.061, F.S., the Agency for Health Care Administration (AHCA) may require the submission by health care facilities, health care providers, and health insurers of data necessary to carry out the agency's duties. Such data may include: case-mix data, patient admission or discharge data with patient and provider-specific identifiers, Medicare and Medicaid participation, type of services offered to patients, amount of revenue and expenses of the health care provider, data on utilization patterns, and specific provider reimbursement data. Any specific provider reimbursement data obtained by AHCA is confidential and exempt from the Public Records Law. Portions of patient records containing the name, residence or business address, telephone number, social security or other identifying number, or photograph of any person or the spouse, relative, or guardian of such person, or any other identifying information which is patient-specific or otherwise identifies the patient, either directly or indirectly are confidential and exempt from the Public Records Law. The identity of any health care provider, health care facility or health insurer who submits data which is proprietary business information to AHCA is confidential and exempt from the Public Records Law.

AHCA is the primary source for collection and dissemination of health care data. No other agency of state government may gather data from a health care provider licensed or regulated under ch. 408, F.S., without first determining if the data is currently being collected by the agency and affirmatively demonstrating that it would be more cost-effective for an agency of state government other than AHCA to gather the health care data. Confidential information may be released to other governmental entities or to parties contracting with AHCA to perform its duties or functions as needed in connections with the performance of the duties of the receiving entity. The receiving entity or party must retain the confidentiality of such information as provided in s. 408.061, F.S.

Hospital Adverse Incident Reporting

Ambulatory surgical centers and hospitals must be licensed under chapter 395, F.S. Chapter 395, F.S., imposes requirements on ambulatory surgical centers and hospitals that include inspection and accreditation, and reporting of adverse incidents that result in serious patient injury. Ambulatory surgical centers and hospitals, under s. 395.0197(8), F.S., must report the following incidents within 15 calendar days after they occur to AHCA: death of a patient; brain or spinal damage to a patient; performance of a surgical procedure on the wrong patient; performance of a wrong-site surgical procedure; performance of a wrong surgical procedure; performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition; surgical repair of damage resulting to the patient from a planned surgical procedure where damage is not a recognized specific risk, as disclosed to the patient and

documented through the informed consent process; or performance of procedures to remove unplanned foreign objects remaining in a patient following surgery.

Under s. 395.0197(8), F.S., the incident reports filed with AHCA may not be made available to the public under s. 119.07(1), F.S., or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the Department of Health (DOH) or the appropriate regulatory board. The incident reports may not be made available to the public as part of the records of investigation for and prosecution in disciplinary proceedings that are made available to the public. DOH or the appropriate regulatory board must make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. DOH must review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action under the provisions of s. 456.073, F.S.

Nursing Home and Assisted Living Facility Adverse Incident Reporting

Section 400.147, F.S., requires nursing homes to have an internal risk management and quality assurance program and report adverse incidents to the Agency for Health Care Administration. Each nursing facility must develop and implement an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed facility to report adverse incidents to the risk manager or his or her designee, within three business days after their occurrence. "Adverse incident" is defined as an event over which the facility staff could have exercised control and which is associated in whole or in part with the facility's intervention, rather than the condition for which the intervention occurred. Adverse incidents are those events which result in death; brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory function; any condition requiring medical attention to which the resident has not given his or her informed consent, including failure to honor advance directives; any condition that requires the transfer of the resident, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the resident's condition prior to the adverse incident; abuse, neglect, or exploitation; resident elopement; or an event that is reported to law enforcement.

The facility is required to notify AHCA within one business day after the risk manager or his or her designee receives the report of an adverse incident. AHCA may investigate any such incident, as it deems appropriate, and is allowed to prescribe measures that must or may be taken in response to the incident. AHCA must review each incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action. If this is the case, the provisions related to disciplinary proceedings of s. 456.073, F.S., apply. The notification is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by AHCA or a regulatory board.

Each facility must complete the investigation and submit an adverse incident report to AHCA for each adverse incident within 15 calendar days after its occurrence, on a form developed by the agency. AHCA must review the information, and determine whether the incident potentially involved conduct subject to the disciplinary proceedings of s. 456.073, F.S. The adverse incident report must contain the name and license number of the risk manager. The report is confidential

and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by the agency or a professional board.

Section 400.119, F.S., makes records of meetings of the risk management and quality assurance committee of a long-term care facility licensed under part II or part III of ch. 400, F.S.,[1] as well as the adverse incident reports filed with the facility's risk manager and administrator, notifications of the occurrence of an adverse incident, and adverse incident reports from the facility confidential and exempt from the Public Records Law and unavailable to the public.

Assisted living facilities, pursuant to s. 400.423, F.S., may establish a voluntary risk management program, but must report adverse incidents. Each facility is required to maintain adverse incident reports. "Adverse incident" is defined as an event over which the facility staff could have exercised control and which is associated in whole or in part with the facility's intervention, rather than the condition for which the intervention occurred. Adverse incidents are those events which result in death; brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; any condition requiring medical attention to which the resident has not given his or her informed consent, including failure to honor advance directives; any condition that requires the transfer of the resident from the facility to a unit providing a more acute level of care due to the adverse incident, rather than the resident's condition prior to the adverse incident; abuse, neglect, or exploitation; resident elopement; or an event that is reported to law enforcement.

The assisted living facility, regardless of the number of beds, is required to notify AHCA within one business day after the occurrence of an adverse incident. AHCA must review each incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action. If this is the case, the provisions related to disciplinary proceedings of s. 456.073, F.S., apply. The notification is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by AHCA or regulatory boards.

Physician Office Surgery Adverse Incident Reporting

Licensed medical physicians may perform surgery in their medical offices, ambulatory surgical centers, or hospitals. Sections 458.351 and 459.026, F.S., require any medical physician, osteopathic physician, or physician assistant to notify the Department of Health of any adverse incident that involved the physician or physician assistant which occurred on or after January 1, 2000, in any office maintained by the physician for the practice of medicine that is not licensed under chapter 395, F.S., relating to licensure for hospitals and ambulatory surgical centers. The sections require any medical physician, osteopathic physician, or physician assistant to notify the department in writing and by certified mail of the adverse incident within 15 days after the adverse incident occurred. The notice must be postmarked within 15 days after the adverse incident occurred.

[1] The exemption to the Public Records Law in s. 400.119, F.S., also applies to adverse incidents reported in assisted living facilities that are regulated under part III, ch. 400, F.S.

"Adverse incident" is defined under ss. 458.351 and 459.026, F.S., to mean an event over which the physician or physician assistant could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries: death of a patient; brain or spinal damage to a patient; performance of a surgical procedure on the wrong patient; any condition that required the transfer of a patient to a hospital licensed under ch. 395, F.S., from an ambulatory surgical center licensed under ch. 395, F.S., or from any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.; or performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure. Under the definition of adverse incident, a medical physician, osteopathic physician, or physician assistant must provide notice of patient injuries only if they result in death, brain or spinal damage, permanent disfigurement, fracture or dislocation of bones or joints, a limitation of neurological, physical or sensory function, or any condition that required the transfer of the patient. The Department of Health must review each adverse incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action, and provides that the procedures for handling disciplinary complaints under s. 456.073, F.S., apply.

There is no exemption to the Public Records Law for physician office surgery adverse incidents filed with the Department of Health. Senate Bill 1600 has been filed to create an exemption for information contained in the notification of adverse incidents involving physician office surgery and makes such information confidential. Under Senate Bill 1600 such information may not be made available to the public as part of the record of investigation or prosecution in disciplinary proceedings by the Department of Health or a regulatory board.

Disciplinary Procedures for Health Care Practitioners

Section 456.073, F.S., sets forth procedures the Department of Health must follow in conducting disciplinary proceedings against practitioners under its jurisdiction. The department, for the boards under its jurisdiction, must investigate all written complaints filed with it that are legally sufficient. Complaints are legally sufficient if they contain facts, which, if true, show that a licensee has violated any applicable regulations governing the licensee's profession or occupation.

When investigations of licensees within the department's jurisdiction are determined to be complete and legally sufficient, the department is required to prepare, and submit to a probable cause panel of the appropriate board, if there is a board, an investigative report along with a recommendation of the department regarding the existence of probable cause. A board has discretion over whether to delegate the responsibility of determining probable cause to the department or to retain the responsibility to do so by appointing a probable cause panel for the board. The determination as to whether probable cause exists must be made by majority vote of a probable cause panel of the appropriate board or by the department, if there is no board or if the board has delegated the probable cause determination to the department.

If the subject of the complaint makes a written request and agrees to maintain the confidentiality of the information, the subject may review the department's complete investigative file. The licensee may respond within 20 days of the licensee's review of the investigative file to

information in the file before it is considered by the probable cause panel. Section 456.073(10), F.S., provides that complaints and information obtained by the department during its investigations are exempt from the Public Records Law until 10 days after probable cause has been found to exist by the probable cause panel or the department, or until the subject of the investigation waives confidentiality. If the case is dismissed prior to a finding of probable cause, the complaints and information remain confidential in perpetuity under s. 456.073(2), F.S. Under s. 456.073(4), F.S., all proceedings of a probable cause panel are exempt from the open meetings requirements of ch. 286, F.S., until 10 days after probable cause has been found to exist or until the subject of an investigation of a disciplinary complaint waives confidentiality.

The Department of Health contracts with the Agency for Health Care Administration to investigate and prosecute disciplinary complaints. The Department of Health's clerk is the custodian designated for orders and related information regarding the discipline of a licensed health care practitioner under s. 456.073, F.S. The Department of Health and its agents may share information with law enforcement agencies or other regulatory agencies that are investigating an individual for activity within such agency's regulatory jurisdiction which may be related to activities being investigated by the department. The information provided by the department retains its confidential status in the hands of those other agencies.

Under s. 456.057(8)(a), F.S., all patient records obtained by the Department of Health and any other documents maintained by the department that identify the patient by name are confidential and exempt from the Public Records Law and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

As used in s. 456.057, F.S., "records owner" is defined to mean any health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; or to any health care practitioner's employer, if the contract or agreement between the employer and the health care practitioner designates the employer as the records owner. The following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of s. 456.057, F.S., to maintain those documents required by regulations under which they are regulated: certified nursing assistants, *pharmacists and pharmacies*, nursing home administrators, respiratory therapists, athletic trainers, electrologists, clinical laboratory personnel, medical physicists, opticians and optical establishments, persons or entities making physical examinations for an injured person as part of personal injury protection claim, or hospitals and ambulatory surgical centers.

III. Effect of Proposed Changes:

Section 1. Creates an undesignated section of law, to provide for the "Patient Safety Improvement Act" and to specify legislative intent to establish a statewide, academically based center that will serve as the designated resource for research, education, and policy concerning patient safety and for providing information to the public and to institutions. Definitions are

created for the act. *Center* means the Florida Center for Patient Safety. *Health care provider* means any physician, nurse, pharmacist, occupational therapist, physical therapist, hospital, or other person, institution, or organization that furnishes health care services and is licensed or otherwise authorized to practice in Florida. *Nonidentifiable patient-safety data* means data that are presented in a form and manner that prevents the identification of the health care provider or patient. *Patient safety data* means any data, reports, records, memoranda, analyses, or other quality improvement processes of patient-safety events which are: collected or developed by a health care provider; reported to a patient-safety organization or the State Patient Safety Database; contained in, or collected by, a patient-safety organization or the State Patient Safety Database; requested by a patient-safety organization for the purpose of monitoring, researching, or improving patient safety; reported to a health care provider by a patient-safety organization to assist with quality improvement and patient-safety effectiveness; or information concerning corrective action taken in response to patient safety events. *Patient-safety event* means an event over which health care personnel could exercise control, which is associated in whole or in part with medical intervention rather than the condition for which such intervention occurred, and which could result in the injury or death of a patient or any other adverse incident defined in s. 395.0197, F.S. *Patient-safety organization* means a public or private organization that collects and analyzes data or information concerning patient safety; reports nonidentifiable patient-safety data to the State Patient Safety Database; and provides direct feedback concerning patient-safety data to health care providers.

The Florida Center for Patient Safety is collocated in the Health Sciences Center at the University of South Florida in Tampa and the College of Medicine at the Florida State University in Tallahassee. The center's duties include: coordinating public and private resources to conduct and support research, demonstrations, and evaluations of patient safety; conducting and supporting research on effective ways to improve and enhance patient safety and participating in the dissemination of this information to health care providers, health care institutions, patients and their families, and policymakers; evaluating methods to identify and promote patient-safety programs; supporting dissemination and communication of patient safety; designing, conducting, and coordinating studies and surveys to assess aspects of patient safety; developing and testing measures and methods of evaluating and enhancing patient safety and promoting the use of such measures in practice; and providing technical assistance, gathering information concerning the use of consumer and patient information, and reporting on patient safety and the resulting effects of intervention policies.

The Florida Center for Patient Safety is authorized to consult with and develop partnerships; to establish a State Patient Safety Database to collect, support, and coordinate the analysis of nonidentifiable patient-safety data submitted voluntarily by health care providers and patient-safety organizations; and to disseminate information developed through analysis of the database concerning the existence and causes of practices that affect patient safety, findings and conclusions regarding patient-safety events, outcome measures, and evidence-based recommendations to improve patient safety.

The Florida Center for Patient Safety must establish a voluntary process, using a standardized format, to enable health care providers or patient-safety organizations to report nonidentifiable patient-safety data. The center must consult with, and solicit and consider recommendations

from, appropriate sectors of the health care community, including health care providers, patient safety-organizations, and other relevant experts.

If any patient-safety data received by the Florida Center for Patient Safety contains data that is confidential and exempt from the Public Records Law, such data must remain confidential as otherwise provided by law.

Section 2. The bill provides an effective date of July 1, 2002.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The Florida Center for Patient Safety established in the bill can substantially contribute to a reduction in liabilities and costs incurred by health care providers.

C. Government Sector Impact:

The bill does not provide an appropriation for the activities of the Florida Center for Patient Safety. The bill directs the Florida Center for Patient Safety to coordinate public and private resources to conduct and support research, demonstrations, and evaluations of patient safety. The University of South Florida Health Sciences Center reports that it has space and resources dedicated to an existing patient safety center and that additional funds for research and programmatic efforts are part of its current mission to acquire by way of grant applications to federal and private sources. The University of South Florida reports that Congress has set aside more than $200 million to be used exclusively for patient safety research by the designated National Centers for Patient Safety, including the one currently located at the university.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.