HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1885 (PCB HC 04-06) Florida Patient Safety Corporation
SPONSOR(S): Committee on Health Care and Farkas
TIED BILLS: HB 1887 (PCB HC 04-09) **IDEN./SIM. BILLS:** CS/SB 1464 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	22 Y, 0 N	Mitchell	Collins
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

The bill is a result of the 2003 medical malpractice legislation (SB 2-D, ch. 2003-416, L.O.F.), that provided an interrelated approach to the factors contributing to the medical liability insurance crisis that included: improved health care quality; tort reform; and insurance reform. SB 2-D required AHCA to conduct a study of how best to implement a patient safety authority to coordinate improvements in patient safety and health care quality in Florida. The report was delivered to the Legislature February 1, 2004.

HB 1885 creates s. 381.0271, F.S., to establish the not-for-profit, Florida Patient Safety Corporation to provide coordination 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.

The bill establishes the corporation with a board made up of representatives of a broad cross section of health care interests with patient safety experience, who are appointed by their respective organizations. The bill also provides for 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.

The bill provides an effective date of upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[X]	N/A[]
2. Lower taxes?	Yes[]	No[]	N/A[X]
3. Expand individual freedom?	Yes[]	No[]	N/A[X]
4. Increase personal responsibility?	Yes[]	No[]	N/A[X]
5. Empower families?	Yes[]	No[]	N/A[X]

For any principle that received a "no" above, please explain:

The bill provides for establishment of a private, not-for-profit, corporation to provide coordination and direction to patient safety improvement efforts in the state.

B. EFFECT OF PROPOSED CHANGES:

HB 1885 creates s. 381.0271, F.S., to establish the Florida Patient Safety Corporation, as a not-for-profit corporation that will provide coordination and direction to efforts in the state to assist health care providers to improve the quality and safety of health care, and to reduce harm to patients. The corporation is not a state agency and shall not regulate health care providers in the state.

The corporation shall be governed by a board of directors with representation of:

- The Florida Council of Medical School Deans;
- A large health insurer;
- An authorized medical malpractice insurer;
- The Central Florida Health Care Coalition;
- A hospital in the state that is implementing innovative patient safety initiatives, appointed by the Florida Hospital Association;
- Physicians with expertise in patient safety, appointed by the Florida Medical Association, the Florida Osteopathic Medical Association, the Florida Podiatric Medical Association, and the Florida Chiropractic Association;
- A dentist with expertise in patient safety, appointed by the Florida Dental 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; and
- A representative of Florida AARP, appointed by the state director of Florida AARP.
- A consultant on health care information technology appointed by Florida chapters of the Health Care Information and Management Systems Society.

The corporation may establish the following advisory committees:

- A scientific research advisory committee with duties that include analysis of existing data and research to improve patient safety and encourage evidence-based medicine.
- A technology advisory committee with duties that include implementation of new technologies, including electronic medical records.
- A health care provider advisory committee with duties that include promotion of a culture of patient safety that reduces errors.
- A health care consumer advisory committee with duties that include incentives to encourage patient safety and the efficiency and quality of care.
- A litigation alternatives advisory committee with duties that include alternative systems to compensate for injuries.
- An education advisory committee with duties that include development of core competencies in patient safety for colleges and universities in the state.

The bill specifies the powers and duties of the corporation to include:

- Collect and analyze patient safety data, medical malpractice closed claims, and adverse incidents reported to the Agency for Health Care Administration (AHCA) and the Department of Health (DOH) and recommend changes in practices and procedures of health care practitioners and health care facilities to improve health care quality and to prevent future adverse incidents.
- Establish a three year pilot project of a "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. The near miss reporting system shall be voluntary and anonymous, and independent of mandatory reporting systems used for regulatory purposes, and data submitted to the authority shall be de-identified and shall not be discoverable or admissible in any civil or administrative action.
- Foster the development of a statewide electronic infrastructure, including implementation of statewide electronic medical records systems that may be implemented in phases over a multiyear period, to improve patient care. Support for implementation of electronic medical records systems shall include a report on current options, by January 1, 2005, and an implementation plan reported by September 1, 2005.
- Provide for access to an active library of evidence based medicine and patient safety practices, and make this information available to health care practitioners, health care facilities, and the public. Support for implementation of evidence-based medicine shall include a report by January 1, 2005, on current options, and an implementation plan reported by September 1, 2005.
- Develop and recommend core competencies in patient safety that can be incorporated into the curriculums in schools of medicine, nursing, and allied health in the state.
- Develop and recommend programs to educate the public about the role of health care consumers in promoting patient safety.
- Provide recommendations for interagency coordination of patient safety efforts in the state.

In carrying out its powers and duties the corporation may also:

- 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 the implementation of patient safety technologies statewide.
- Recommend continuing medical education regarding patient safety to practicing health care practitioners.
- Study and facilitate the testing of alternative systems of compensating injured patients as a means of reducing and preventing medical errors and promoting patient safety.

The bill requires the Agency for Health Care Administration to provide assistance in establishing the corporation. The corporation and certain subsidiaries are subject to public meetings and records requirements. The bill requires annual reports. The bill requires the corporation, in consultation with the Office of Program Policy Analysis and Government Accountability (OPPAGA), AHCA and DOH, to develop performance measures for the corporation and requires OPPAGA to complete a performance audit of the corporation

The bill provides an effective date of upon becoming law.

CURRENT SITUATION

Prevention of Medical Errors

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.

According to the Institute of Medicine, the focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. People must be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

Health care 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.

History of Legislative Initiatives

In 2000, the Legislature created the Florida Commission on Excellence in Health Care (HB 2339, ch. 2000-256, L.O.F.), 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.

In 2001, the Legislature adopted many of the recommendations of the Commission relating to reporting and discipline requirements as part of CS/SB 1558 (ch. 2001-277, L.O.F.) including: specifying acts such as wrong site surgery for which a physician may be disciplined; requiring hospitals and ambulatory surgical centers to implement risk management programs; establishing practitioner profiles for consumers with information related to professional competence; and continuing education in patient safety. A proposed Center for Patient Safety to analyze data on adverse incidents and “near misses,” and to develop practice guidelines with stakeholders was not implemented.

In 2003, the House Select Committee on Medical Liability Insurance and the Governor’s Select Task Force on Healthcare Professional Liability Insurance heard information from stakeholders and experts regarding the need to address rising medical liability rates, the reasons for rising costs, and actions the Legislature may take. The committee was presented research findings which show that improvements in patient safety can reduce medical errors that drive malpractice insurance rates.

While most discussions of medical malpractice focused on changes in the tort law or changes in insurance law, the committees also heard information that if we can reduce the incidence of medical errors, we can reduce the number of cases where tort litigation is possible and limit the exposure faced by practitioners and insurance companies.

Methods suggested to decrease the number of errors included increased reporting and analysis of errors. This would permit the study of why an error occurred and allow the determination of how to prevent the error in the future. Other proposals included computer entry of drug information and

medical history so that such information can both be easily retrieved by all medical providers and have a heightened degree of accuracy.

The medical malpractice legislation that passed during the 2003 Special Session (SB 2-D, ch. 2003-416, L.O.F.), provided an interrelated approach to the complex factors contributing to the current medical liability insurance crisis through improved health care quality, tort reform and insurance reform. It included continued steps by the Legislature to improve patient safety.
Provisions of SB 2-D included the requirement for the Agency for Health Care Administration (AHCA) to conduct a study of how best to implement a patient safety authority that would among other responsibilities:

- Analyze adverse incident data reported to AHCA by practitioners and facilities, to identify patterns of errors and recommend ways to prevent bad outcomes;
- Foster development of statewide electronic infrastructure to share data;
- Inventory hospitals regarding implementation of computerized physician medication ordering systems; and
- Explore alternatives to current malpractice litigation procedures.

The bill also required the study to include an inventory of hospital implementation of computerized physician medication ordering systems. The report was released on February 1, 2004.

Report on Patient Safety

To prepare the required study on implementation of a Patient Safety Authority, the Agency for Health Care Administration (AHCA) contracted with the University of Miami and the Florida Patient Safety Network. The Florida Patient Safety Network, which prepared the report, is a multi-institutional group including the Universities of Florida, Central Florida, Miami and South Florida, Florida State University, and Nova Southeastern College of Medicine. Participants in the project included experts in health care safety, representatives of aviation safety, health care administrators, health care practitioners and educators from the U.S. and other countries.

Recommendations of the Report on Implementation of a Patient Safety Authority (PSA)

Recommendation 1: Create and Endow a Florida Patient Safety Authority that Would:

- Create a Patient Safety Advisory Board which will include representatives of all Florida academic Medical Centers, insurers (both indemnity plans such as Blue Cross Blue Shield, and HMOs); and consumer representatives in order to ensure that the Patient Safety Authority remains adherent to the highest standards of "evidence based" practice and emerging science. The report suggests a maximum of 11 members.
- Be created as a nonprofit corporation registered, incorporated, organized, and operated in compliance with chapter 617, and should 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, to be held, used, and applied for the purpose of this section.
- Provide timely feedback of findings from reported incidents to the health care community to encourage change.
- Utilize conclusions from analysis of existing Florida reporting systems to make recommendations for more efficient and effective collection, analysis and use of the data.
- Explore partnerships at the national level for funding research and development of standard patient safety definitions.
- Develop and maintain a relationship with various health related associations in order to incorporate concerns and suggestions of potential reporters.
- Be totally disengaged from any regulatory action related to incident reporting.
- Begin implementation with teaching hospitals by collecting incident data related to high-risk topics, such as cardiac surgery cases.

- Disseminate evidence-based information to guide the development and continuous improvement of best practices.
- Provide technical assistance to state agencies and health care organizations on standards and best practices.
- Provide and ensure appropriate confidentiality of data, confidentiality protections against discovery and disclosure of incidents reported.

Organizational Structure of the Patient Safety Authority--The report recommended that the PSA not be housed in any one hospital, medical school, or university but work intimately with the state universities and their established patient safety centers. Academic Health Centers are sites where care is delivered, so having the PSA appear to be part of the university, raises both apparent and real conflicts of interest, especially in the public's mind-- doctors investigating themselves, etc. The National Transportation Safety Board (NTSB) is not hosted by Delta or United Airlines. This sets the PSA up for failure, since its workings might be perceived as uninformed by or irrelevant to the realities of day-to-day practice in community settings, where the majority of care is delivered.

Recommendation 2: Pilot a Near Miss Voluntary Incident Reporting System

- Implement a voluntary near miss reporting system to capture near miss data, which will be analyzed, aggregated and trended to facilitate the development of action plans to improve processes/systems, implement change, and foster a culture of safety, at the local facility level.
- Review and revise existing statutory and regulatory reporting requirements to enable the establishment of a single-entry-source reporting system which can be electronically segmented for security and distribution to appropriate user organizations.

Recommendation 3: Support implementation of IT infrastructure as it relates to:

- Electronic Health Records
- Computerized Physician Order Entry (CPOEs)
- Quality Monitoring
- Pilot Projects

Other Recommendations include:

- The PSA should collate, organize, stratify, and promulgate “best practice” information from all specialties in all health care areas to promote quality information and patient safety.
- The PSA should design and define the core competencies--essential knowledge, skills and attitudes regarding safety and quality in health care.
- The PSA should study alternatives to the current medical liability and accountability including evaluating no-fault medico-legal systems while adhering to reasonable and ethical medico-legal standards and practices.
- The PSA should formulate and encourage wide-ranging and applied research approaches to both methodology for enhancing safe medical practices and developing the metrics for assessing patient safety.
- Identification of Federal Funding Opportunities--The Florida Patient Safety Authority should be given the expressed right to seek out and gain funding through sources such as grants from the state, federal and private sectors and from philanthropic gifts and foundations.

Other Reports on the Use of New Technologies to Improve Care and Safety

Report by the House Select Committee on Affordable Health Care for Floridians

To address the issues of affordable and accessible employment-based insurance, Speaker Johnnie Byrd created the Select Committee on Affordable Health Care for Floridians and appointed Representative Frank Farkas, D.C., Chairman, in August, 2003. The committee held public hearings across the state from October through November, 2003. Two (2) of the committee’s recommendations relate to patient safety and quality of care:

- **Require the use of technology supporting a single medical record to promote compatible information technology within the health care delivery system.**
The report of the select committee found that the health care delivery system has failed to keep up with technological advances in at least one respect: exchange of and access to medical records. It found application of information technology has been identified by the Institute of Medicine as one of the principle ways to improve the quality of health care. A single electronic medical record system would lend itself to increased efficiency related to more rational utilization of services, and a significant drop in medical errors.

- **Promote initiatives that increase the use of evidence-based medicine to decrease over-utilization of services, while increasing quality of care and creating a more efficient health care system.**
The report also found that increased use of evidence-based medicine by physicians and health care institutions would improve the quality of health care and provide for a more efficient and effective delivery system.

Evidence-Based Medicine--Studies have indicated that historically, physicians have practiced medicine from an opinion-based system where clinicians identified the problem, used their experience to formulate an option, then asked a "trusted" colleague for advice, and finally, consulted a reference text when making a diagnosis. Recently, university teaching facilities around the world have begun to develop Centers for Evidenced-Based Medicine (EBM).

Evidence-Based Medicine programs are designed to alert clinicians to scientifically meritorious and clinically important advances in treatment, diagnosis and clinical prediction, etiology, prognosis, economics, and quality improvement. Instead of routinely reviewing the contents of dozens of journals for interesting articles, EBM offers clinicians the opportunity to target their reading to issues related to specific patient problems.

One of the underlying forces driving health care toward an EBM system is information overload. For example, in 1948, there were about 4,700 scientific journals in publication (Alphabetical List of Abbreviations of Titles of Medical Periodicals, 1948); in 1990, there were more than 100,000 scientific journals; 90 percent of all major scientific advances are in only 150 of those 100,000 publications; 80 percent of the citations noted by Science Citation Index are to fewer than 1,000 journals.

Health Care Committee Interim Project Report on Use of New Information Technologies

The Health Care Committee issued a report on the use of new information technologies in health care January, 2004, and found that sophisticated computer systems help improve patient care, reduce medical errors, and lower health care costs, by linking practitioners and providing them with more patient information that assists them in diagnosis and treatment. Such systems include built in safety checks to prevent errors, such as warnings of drug interactions and side effects.

Electronic Medical Records are a priority initiative in this area. Such systems are able to provide patients and their doctors with access to their complete medical record and help to improve care and reduce data entry costs and errors. An industry survey of health care IT executives found that nearly one in five executives report their organizations already have computer-based electronic patient records systems in place.

The report found that the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) has provided a framework to establish privacy, coding and transaction standards that supports electronic medical systems. The U.S. Department of Health and Human Services is currently licensing a common medical language and a standardized medical record to provide

further support to electronic records. It will share these tools with the health care industry at no cost.

The report found that Florida's health care industry has made huge investments in information systems that support administrative functions such as patient records and billing. Many sectors of the industry are now making large investments in innovative technologies that can improve health care itself. According to the Agency for Health Care Administration (AHCA), many of the larger hospitals in Florida are at the forefront of electronic patient record systems. Some of the hospitals that are implementing sophisticated electronic medical record systems include: Orlando Regional; Mayo Clinic--Jacksonville; Tallahassee Memorial; North Broward Hospital District; St. Vincent's—Jacksonville; and Shands--Jacksonville and Gainesville.

Barriers to Implementation of New Technologies--National studies indicate that while these new technologies can improve health care, they are not widely implemented because new information systems require large investments and carry the risk of making wrong choices in rapidly changing technologies.

Florida stakeholders identified several issues that prevent the full use of these new technologies, including:

- Financial barriers—due to limited resources in a tight health care economy.
- Lack of data standards—which limit the ability to link data among applications.
- Practice barriers—from clinicians who are resistant to new technologies and changes in their practices.
- HIPAA costs and weaknesses—as an unfunded mandate when newer standards are needed for web based systems.
- Patient privacy—clinicians are reluctant to share extremely sensitive patient medical data without strong security measures.
- Lack of participation—in the use of new systems leads to incomplete records that are not useful.
- Need for national direction—to establish industry standards that encourage provider investment.

Recommendations--The report recommended that the Legislature might consider possible options to encourage coordination, integration, and investment, including:

- Address any relevant findings and recommendations in the report on options for a statewide infrastructure to support improved patient safety and quality of care that was mandated as part of the medical incident legislation adopted during Special Session D (SB 2-D, ch. 2003-416, L.O.F.).
- Encourage joint industry and state agency development of standards and protocols for new technologies to enable easier communication among providers and increase security of information.
- Encourage investment in health care information technologies through private sector market reinforcements and state economic development initiatives that target the health care industry.

C. SECTION DIRECTORY:

Section 1. Creates s. 381.0271, F.S., to establish the Florida Patient Safety Corporation with definitions, organization, purpose, board of directors, advisory committees, powers and duties, which include a near miss reporting system, electronic medical records and evidence-based medicine, and reports and performance expectations.

Section 2. Provides the act shall take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   There may be reduced costs of health care and malpractice litigation from the reduction of medical errors and improvement in care and quality as a result of provisions of the bill.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The Agency for Health Care Administration (AHCA) and the Department of Health (DOH) were not able to complete a detailed analysis of the fiscal impact of the bill. They initially identified the following fiscal issues:

AHCA has provided an estimate of approximately $1,637,000 in Year 1 to cover establishing the corporation and board, contracting for required reports and establishing the “near miss” reporting system.

This estimate is based on:

1. Travel costs for the 11 board members and all members of the 6 committees to be established. Travel costs generally average about $500 per trip, depending upon where the people and the meetings are located.
2. Costs to incorporate a non-profit entity of $170, per the Department of State website.
3. Anticipated staff of an executive director, secretary, probably 5 to 7 analyst type staff and an office manager/bookkeeper. At state rates, this would require roughly $500,000 for the staff salaries and benefits, plus an annual expense package of about $11,000 per person, to cover supplies, rent, utilities, etc. In addition, there is the non-recurring expense of desks, chairs, computers, etc., that generally runs about $2,700 per person.
4. Three reports due in the first year while the corporation is just getting established which would require some contract arrangement estimated to be at least $100,000 per report--or about $300,000.
5. The first year of a 3-year pilot project on a near miss patient safety reporting system, which will require a computerized system to collect near miss data from volunteers. The best way to do this will likely be over the Internet that will require hardware and software. There will likely be an option to buy an already created software package or to have one developed.

The Department of Health has expressed concern about the requirement to report evidence-based medicine by the health regulatory boards under the Division of Medical Quality Assurance (MQA). The

department reports that it could participate in the publication or dissemination of pertinent findings made by other entities to health care licensees. However, given the number of diseases and the many methods of treating them, DOH is concerned that identifying evidence-based practices involves a large research effort far beyond the staffing and funding capabilities of the self-funded health regulatory boards. DOH recommends that federal funding or a partnership through medical institutions such as university medical schools or hospital corporations be used to meet this corporation responsibility.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No rulemaking authority is required by the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Health, s. 381.0271(7)(b), F.S., in the bill would require the department to give copies of any adverse incident reports collected under s. 458.351 or s. 459.026, F.S., to the corporation. The bill also requires AHCA to give copies of facility adverse incident reports collected under s. 395.0197, F.S., to the corporation. However, while the section states that the AHCA reports must by maintained as confidential by the corporation, it is silent on the confidentiality of the reports obtained from DOH.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES