

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SPB 7046

INTRODUCER: For consideration by the Health Regulation Committee

SUBJECT: Florida Patient Safety Corporation

DATE: February 14, 2009

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson		Pre-meeting
2.				
3.				
4.				
5.				
6.				

I. Summary:

This proposed committee bill repeals the statutes creating the Florida Patient Safety Corporation (corporation) and the public records and public meetings exemptions for certain information in patient safety data held by the corporation.

This bill repeals the following sections of the Florida Statutes: 381.0271 and 381.0273.

II. Present Situation:

The Corporation

The corporation was created by s. 18 of ch. 2004-297, Laws of Florida, as a not-for-profit corporation. The genesis of the corporation was in 2000, when the Legislature passed and the Governor signed into law, the Patient Protection Act of 2000, which created a Commission on Excellence in Health Care.¹ This commission, co-chaired by the Secretaries of the Agency for Health Care Administration (AHCA) and the Department of Health (DOH), included representatives of health care agencies and organizations, the medical malpractice professional liability insurance industry, the health insurance industry, attorneys and legislators. Among this commission's recommendations was the creation of a separate, freestanding Center for Patient Safety and Excellence in Health Care.

In August 2002, Governor Bush created the Select Task Force on Healthcare Professional Liability Insurance to examine the availability and affordability of medical malpractice insurance

¹ Chapter 2000-256, Laws of Florida.

and to make recommendations for protecting Floridians' access to high-quality and affordable health care.² This task force held numerous meetings across the state spanning a 5-month period and proposed over 60 legislative recommendations.³ During the fourth Special Session of 2003, the Legislature passed and the Governor signed into law, legislation that included some of the Task Force's recommendations aimed at improving patient safety including, but not limited to: requiring each health care facility to have a patient safety system and plan, including a patient safety officer and committee; mandating that patients be notified in person by the facility or licensed health care practitioner in the event of harm to the patient; and requiring patient safety continuing education for licensed health care practitioners. This legislation also authorized the AHCA, the DOH, and patient safety centers in the state's universities to study implementation requirements for a statewide patient safety authority.⁴ The report from this study formed the basis for the 2004 legislation establishing the corporation.

The purpose of the corporation is to serve as a learning organization dedicated to assisting health care providers in this state to improve the quality and safety of health care rendered and to reduce harm to patients. Furthermore, the corporation is to promote the development of a culture of patient safety in the health care system in this state, but it is not to regulate health care providers.⁵

The Legislature assigned several powers and duties to the corporation. The corporation is required to:

- Collect, analyze, and evaluate patient safety data and quality and patient safety indicators, medical malpractice closed claims, and adverse incidents reported to the AHCA and the DOH for the purpose of recommending changes in practices and procedures for health care practitioners and facilities;
- Establish a "near-miss"⁶ patient safety reporting system;
- Develop and recommend core competencies in patient safety that can be incorporated into undergraduate and graduate health care curricula;
- Develop and recommend programs to educate the public about the role of health care consumers in promoting patient safety; and
- Provide recommendations for interagency coordination of patient safety efforts in the state.

The Legislature has appropriated a total of \$2.9 million for the corporation, which was provided annually through contract between the AHCA and the corporation. In state fiscal year 2004-2005, the corporation received \$650,000, and \$750,000 for state fiscal years 2005-2006, 2006-2007, and 2007-2008. The state did not appropriate funds to the corporation in state fiscal year 2008-2009.

² Executive Order No. 02-041, issued August 28, 2002.

³ The full text of the report is available at: <<http://www.doh.state.fl.us/myflorida/DOH-Large-Final%20Book.pdf>> (Last visited on February 14, 2009).

⁴ Chapter 2003-416, Laws of Florida.

⁵ s. 381.0271(3)(a), F.S.

⁶ Section 381.0271(7)(a)3.a., F.S., defines "near-miss" as any potentially harmful event that could have had an adverse result, but through chance or intervention in which, harm was prevented.

The Board of Directors of the corporation voted in January of 2009 to seek repeal of the statutes establishing the corporation, for among other reasons, the absence of state funding for the activities of the corporation.

The corporation is subject to the public records and meetings requirements of s. 24, Art. I of the State Constitution, ch. 119, F.S., and s. 286.011, F.S.;⁷ however, the Legislature established certain exemptions as provided in s. 381.0273, F.S.

Public Records and Public Meetings Exemptions for Patient Safety Data

Section 381.0273, F.S., also enacted in 2004,⁸ specifies that information that identifies a patient or the person or entity that reports patient safety data, as defined in s. 766.1016, F.S.,⁹ and that is contained in patient safety data or other records held by the corporation and its subsidiaries, advisory committees, or contractors is confidential and exempt from the Public Records Act and s. 24(a), Art. I of the State Constitution. Additionally, s. 381.0273, F.S., specifies that information that identifies a health care practitioner or health care facility which is held by the corporation and its subsidiaries, advisory committees, or contractors is confidential and exempt from the Public Records Act and s. 24(a), Art. I of the State Constitution. Patient identifying information, information that identifies the person or entity that reports patient safety data or information that identifies a health care practitioner or health care facility made confidential and exempt from disclosure under s. 381.0273, F.S., may be disclosed only:

- With the express written consent of the patient or the patient's legally authorized representative in compliance with any federal or state law, for the patient identifying information;
- With the express written consent of the person or entity reporting the patient safety data to the corporation, with respect to the information that identifies the person or entity that reports patient safety data;
- With the express written consent of the health care practitioner or health care facility, with respect to the information that identifies a health care practitioner or health care facility;
- By court order upon a showing of good cause; or
- To a health research entity if the 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 corporation is authorized to deny a request for records or data that identifies the patient, or the person or entity reporting 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 patient or persons or entities that report patient safety data, must limit the use of records or data in conformance with the approved research

⁷ s. 381.0271(2)(c), F.S.

⁸ Chapter 2004-70, Laws of Florida (L.O.F.).

⁹ Section 766.1016, F.S., defines patient safety data as 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, or 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.

protocol, and must prohibit any other use of the records or data. Copies of records or data issued according to this provision remain the property of the corporation.¹⁰

In addition, any portion of a meeting held by the corporation and its subsidiaries, advisory committees, or contractors during which information that is confidential and exempt from disclosure under s. 381.0273, F.S., is discussed is exempt from the Public Meetings Law and s. 24(b), Art. I of the State Constitution.

This public records and meetings exemption is scheduled for repeal on October 2, 2009.

Certification as a Patient Safety Organization

On November 5, 2008, the corporation became certified under the federal Patient Safety and Quality Improvement Act of 2005¹¹ (PSQIA) as a Patient Safety Organization (PSO). The PSQIA establishes a structure to improve patient safety and reduce the incidence of events that adversely affect patient safety by facilitating PSOs and other entities collecting, aggregating, and analyzing confidential information reported by health care providers. The federal PSQIA also provides for legal privilege and confidentiality protections to information that is assembled and reported by providers to a PSO or developed by a PSO, which is referred to as patient safety work product,¹² for the conduct of patient safety activities notwithstanding any other provision of federal, state, or local law.

Senate Interim Project 2009-212

During the 2008-2009 interim, professional staff of the Senate Committee on Health Regulation performed an Open Government Sunset Review of s. 381.0273, F.S. The recommendation in the resulting report is that the Legislature re-enact the exemptions from the public records and meetings laws and correct a drafting error included in the exemptions currently enacted. However, subsequent to the release of the recommendation from the mandatory review to reenact the public records and meetings exemptions, the corporation became certified as a PSO and the Board of Directors voted to seek repeal of the statutes establishing the corporation. Senate professional staff reported to the committee the recommendation from the report and summarized the subsequent events affecting the corporation. Senate professional staff further advised the committee that if the statutory authority for the corporation is repealed there would be no need to re-enact the public records and meetings exemptions since the corporation would no longer be an “agency” for purposes of the public records and meetings laws. The committee instructed staff to draft a proposed committee bill repealing the statutory authority for the

¹⁰ Section 381.0273(3)(c), F.S., appears to contain a drafting error since it duplicates s. 381.0273(2)(c), F.S., and does not authorize the corporation to deny a request from a health research entity for records or data that identifies a health care practitioner or health care facility or specify that the purchase and data-use agreement must prohibit release of information that would permit the identification of a health care practitioner or health care facility.

¹¹ Public Law 109-41.

¹² Patient safety work product is defined in this act to mean any data, reports, records, memoranda, analyses (such as cause analyses), or written or oral statements which: are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization, or are developed by a patient safety organization for the conduct of patient safety activities, and which could result in improved patient safety, health care quality, or health care outcomes; or identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

corporation and the public records and meetings exemptions. This proposed committee bill implements that direction from the committee.

III. Effect of Proposed Changes:

Section 1. Repeals s. 381.0271, F.S., related to the creation and duties of the Florida Patient Safety Corporation.

Section 2. Repeals s. 381.0273, F.S., related to the public records and meetings exemptions for patient safety data held by the corporation.

Section 3. Provides an effective date of upon the bill becoming a law.

Other Potential Implications

The Florida Patient Safety Corporation was created as a component of a larger plan to address the availability and affordability of medical malpractice insurance and to protect Floridians' access to high-quality and affordable health care. Subsequent to the creation of the corporation, the voters adopted two constitutional amendments (Patient's right to know about adverse medical incidents¹³ and Prohibition of medical license after repeated medical malpractice¹⁴) that have affected the ability of the corporation to move forward with implementation of a near-miss reporting system. Also, subsequent to the creation of the corporation, Congress passed the PSQIA and the corporation became certified as a PSO under that law. If the corporation maintains certification under the PSQIA, it will be required to conduct patient safety activities similar to those specified in s. 381.0271, F.S.

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 Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no adverse impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution, since if the bill becomes law, the corporation would no longer be considered an agency to which these provisions apply.

C. Trust Funds Restrictions:

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

¹³ See Article X, Section 25 of the State Constitution.

¹⁴ See Article X, Section 26 of the State Constitution.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Although there would be no requirement in statute for the corporation to continue its mission and objectives, the corporation has indicated that it intends to continue with its patient safety activity as a certified PSO.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.