

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 Judiciary Committee

BILL: CS/SB 1370

INTRODUCER: Judiciary Committee, Health Regulation Committee, and Senator Jones

SUBJECT: Florida Patient Safety Corporation

DATE: March 20, 2008 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	Fav/2 amendments
2.	Sumner	Maclure	JU	Fav/CS
3.			GO	
4.			HA	
5.				
6.				

Please see Section VIII. for Additional Information:

- | | | |
|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes |
| B. AMENDMENTS..... | <input type="checkbox"/> | Technical amendments were recommended |
| | <input type="checkbox"/> | Amendments were recommended |
| | <input type="checkbox"/> | Significant amendments were recommended |

I. Summary:

This bill modifies provisions affecting the Florida Patient Safety Corporation (corporation) to improve its effectiveness and to delete obsolete provisions. More specifically, the bill:

- Authorizes the Florida Council of Medical School Deans to appoint a representative to serve on the board of directors of the corporation as an alternative to the current requirement that the chair of the council be a board member;
- Deletes seven specified advisory committees assigned to the corporation and authorizes the corporation to create and dissolve advisory committees as needed;
- Requires the corporation's board of directors to meet at least quarterly;
- Requires the Agency for Health Care Administration and the Department of Health to make adverse incident reports available to the corporation's designated agents;
- Requires the corporation to evaluate the impact of electronic health records on patient safety;
- Adds a duty to the corporation to encourage the use of evidence-based medicine to improve health care quality and patient safety;
- Deletes the requirement for the corporation to develop and maintain an active library of evidence-based medicine and patient safety practices;

- Authorizes the corporation to inventory health care facilities' and practitioners' technological capabilities related to patient safety in order to recommend a plan for implementing patient safety technologies statewide;
- Deletes obsolete language related to organizational activities of the corporation and initial reporting requirements; and
- Deletes obsolete language regarding a performance audit of the corporation.

This bill substantially amends section 381.0271, Florida Statutes.

II. Present Situation:

Purpose, Structure, and Funding of the Corporation

The Florida Patient Safety Corporation was created by s. 18 of ch. 2004-297, L.O.F., as a not-for-profit 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.¹ The corporation is a patient safety organization as defined in s. 766.1016, F.S.,² for purposes of establishing a privilege for patient safety data in civil and administrative actions.³ The corporation is to work with a consortium of university-based patient safety centers and other patient safety programs.⁴

The corporation has been designated as a 501(c)(3) corporation. The enabling legislation authorizes the corporation to create not-for-profit corporate subsidiaries, upon prior approval of the board of directors, as necessary, to fulfill its mission. To date, no subsidiaries have been created. The corporation is subject to the public meetings and records requirements of s. 24, Art.

¹ Section 381.0271(3)(a), F.S.

² Section 766.1016, F.S., defines a patient safety organization as any organization, group, or other entity that collects and analyzes patient safety data for improving patient safety and health care outcomes and that is independent and not under the control of the entity that reports patient safety data. Under this statute, patient safety data is not subject to discovery or introduction into evidence in any civil or administrative action.

³ Two cases recently decided by the Florida Supreme Court relate to Amendment 7, the "Patients' Right to Know About Adverse Medical Incidents" (Article X, section 25 of the Florida Constitution). See *Florida Hospital Waterman, Inc., d/b/a Florida Hospital Waterman v. Teresa M. Buster, as Personal Representative of the Estate of Larry Buster, deceased; Jeffrey B. Keeler, M.D., and Keller & Goodman, M.D., P.A.*, Case No. SC06-688 and *Notami Hospital of Florida, Inc., d/b/a Lake City Medical Center v. Evelyn Bowen and Don Bowen; John C. Nicely, as Personal Representative of the Estate of Christine Nicely; etc., et. al.*, Case No. SC06-912 (Fla. March 6, 2008). One of the issues on appeal concerned whether Amendment 7 preempts statutory self-policing procedures to the extent that information (or records) obtained through those procedures is discoverable during the course of litigation by a patient against a health care provider. The Court concurred with the holding by the First District Court in *Notami*, finding that ss. 381.028(3)(j), (5)-(7)(a), F.S. (2005), "contravene the broad rights of access to adverse medical incident records granted by Amendment 7." The Court, however, did not agree that this required the invalidation of the entire statute, concluding that the unconstitutional provisions were separable from the remainder of the statute. On August 15, 2007, the corporation submitted an initial certification application to the federal Agency for Healthcare Research and Quality to be listed as a Patient Safety Organization under the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). Final regulations relating to criteria and procedures for initial certification have not been promulgated yet; nonetheless, the corporation has submitted an application for initial certification in accordance with the provisions in this Act. The corporation believes this Act overrides any state constitutional or statutory provisions that would make patient safety work product discoverable or otherwise available to a patient or any other person.

⁴ Section 381.0271(3)(b), F.S.

I of the State Constitution, ch. 119, F.S., and s. 286.011, F.S. The corporation is not subject to the procurement provisions of ch. 287, F.S.

The corporation is governed by a 15-member board of directors. The law authorizes the corporation to establish committees as needed, but requires a minimum of seven specific advisory committees. These advisory committees and duties include:⁵

- Scientific research – analysis of existing data and research to improve patient safety and encourage evidence-based medicine;
- Technology – implementation of new technologies, including electronic medical records;
- Health care provider – promotion of a culture of patient safety that reduces errors;
- Health care consumer – identify incentives to encourage patient safety and the efficiency and quality of care;
- State agency – interagency coordination of patient safety efforts;
- Litigation alternatives – identify alternative systems to compensate for injuries; and
- Education – provide advice on the development, implementation, and measurement of core competencies for patient safety to be considered for incorporation in the educational programs of the universities and colleges of this state.

The corporation indicates that the advisory committee structure in s. 381.0271, F.S., has presented some challenges for the corporation.⁶ The seven advisory committees created in law have prescribed membership, which creates problems for the corporation when the prescribed members are reluctant to serve on the committee. In addition, some of the duties of the advisory committees are duplicative of other patient safety efforts in the state.

The Legislature has appropriated a total of \$2.9 million for the corporation, which is provided annually through contract between the Agency for Health Care Administration (AHCA) and the corporation (\$650,000 in FY 2004-05 and \$750,000 for each of the subsequent three fiscal years).

Duties and Responsibilities

The Legislature assigned the following powers and duties to the corporation:

- Secure staff necessary to properly administer the corporation;
- 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 Department of Health for the purpose of recommending changes in practices and procedures for health care practitioners and facilities;
- Establish a “near-miss”⁷ patient safety reporting system;
- Work collaboratively with state agencies in the development of electronic health records;

⁵ Section 381.0271(5), F.S.

⁶ *Florida Patient Safety Corporation Progress Report*, December 1, 2006, page 28.

⁷ 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.”

- Provide access to an active library of evidence-based medicine and patient safety practices, together with the emerging evidence supporting their retention or modification;
- 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;
- Provide recommendations for interagency coordination of patient safety efforts in the state; and
- Seek private sector funding and apply for grants.

Additionally, the Legislature authorized the corporation to:

- Assess the patient safety culture at volunteering hospitals and recommend methods to improve the working environment related to patient safety;
- Inventory the information technology capabilities related to patient safety of health care facilities and practitioners and recommend a plan for expediting the implementation of patient safety technologies statewide;
- Recommend continuing medical education regarding patient safety to 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; and
- Conduct other activities identified by the board of directors to promote patient safety in this state.

The corporation is required to report annually, by December 1 of each year, to the Governor and the Legislature the following:

- A description of the activities of the corporation;
- Progress made in improving patient safety and reducing medical errors;
- Policies and programs that have been implemented and their outcomes;
- A compliance and financial audit;
- Recommendations for legislative action needed to improve patient safety in the state; and
- An assessment of the ability of the corporation to fulfill the statutory duties and the appropriateness of those duties for the corporation.

Senate Interim Project 2008-136

In November 2007, professional staff of the Senate Committee on Health Regulation reviewed, among other things, the corporation's statutory authority. This bill addresses the recommendations in the Interim Project Report 2008-136, *Florida Patient Safety Corporation*.⁸

⁸ Interim Project Report 2008-136, *Florida Patient Safety Corporation* is available at http://www.flsenate.gov/data/Publications/2008/Senate/reports/interim_reports/pdf/2008-136hr.pdf (last visited on February 29, 2008).

III. Effect of Proposed Changes:

This bill modifies provisions affecting the Florida Patient Safety Corporation (corporation) to improve its effectiveness and to delete obsolete provisions.

Section 1. Amends s. 381.0271, F.S., which establishes the corporation.

- *Subsection (4).* The bill authorizes authorizes the Florida Council of Medical School Deans to appoint a representative to serve on the board of directors of the corporation as an alternative to the current requirement that the chair of the council be a board member.
- *Subsection (5).* The bill deletes the seven specified advisory committees and authorizes the corporation to establish and dissolve advisory committees, pursuant to a majority vote by the board of directors, to assist the corporation in carrying out its duties and responsibilities.
- *Subsection (6).* The bill deletes obsolete language requiring the Agency for Health Care Administration (AHCA) to assist the corporation in its organizational activities. The bill requires the corporation to meet at least quarterly.
- *Subsection (7).* The bill requires the AHCA and the Department of Health to make adverse incident reports available to the corporation's designated agents and requires the corporation to evaluate the effects of the adoption and sharing of electronic health records on patient safety. It adds a duty to the corporation to encourage the use of evidence-based medicine to improve health care quality and patient safety. It also deletes the corporation's responsibility to provide for access to an active library of evidence-based medicine and patient safety practices. The bill expands an optional board activity involving inventorying health care facilities' and practitioners' technological capabilities related to patient safety and issuing recommendations.
- *Subsection (8).* The bill deletes obsolete language related to organizational activities of the corporation and initial reporting mandates.
- *Subsection (9).* A grammatical change is made.
- *Subsection (10).* The bill deletes obsolete language related to an outdated evaluation and reporting requirement.

Section 2. Provides an effective date of July 1, 2008.

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 this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 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 Article III, Subsection 19(f) of the Florida Constitution.

V. **Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

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.)

CS by Judiciary on March 18, 2008:

The committee substitute:

- Authorizes the Florida Council of Medical School Deans to appoint a representative to serve on the board of directors of the corporation as an alternative to the current requirement that the chair of the council be a board member.
- Adds a duty to the corporation to encourage the use of evidence-based medicine to improve health care quality and patient safety.

B. Amendments:

None.