# The Florida Senate

*Interim Project Report 2008-136* *November 2007*

Committee on Health Regulation

## FLORIDA PATIENT SAFETY CORPORATION


## SUMMARY

The Florida Patient Safety Corporation (corporation) was created by the Legislature in 2004 to assist health care providers in Florida improve the quality and safety of health care rendered and thereby reduce harm to patients. The Office of Program Policy Analysis and Government Accountability (OPPAGA) reviewed the corporation's progress toward fulfilling its statutory duties and responsibilities and issued a report in December 2006. The report indicated that the corporation needed to take additional steps to develop its infrastructure to fully achieve its purpose and be recognized as a leader in promoting a culture of patient safety. This report is a follow-up to OPPAGA's report and assesses whether the corporation has complied with the OPPAGA recommendations and whether the corporation's statutory authority should be modified.

Senate professional staff found that the corporation has generally complied with the recommendations in the OPPAGA report but needs to accelerate its efforts to acquire grant and private sector funding. Staff recommends statutory modifications to improve the effectiveness of the corporation and eliminate obsolete provisions. Further, staff perceives that the corporation is in limbo and cannot fully achieve its mission until the Florida Supreme Court renders a favorable opinion regarding the effects on the corporation of the constitutional amendment titled "Patients' Right to Know About Adverse Medical Incidents" or the corporation receives federal certification as a Patient Safety Organization.


## BACKGROUND

### History of the Corporation

The corporation was created by s. 18 of ch. 2004-297, Laws of Florida, 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. The corporation is to work with a consortium of university-based patient safety centers and other patient safety programs.[3]

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.[4] 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 and to make recommendations for protecting Floridians' access to high-quality and affordable healthcare.[5] This task force

[1] Section 381.0271(3)(a), Florida Statutes.
[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 the purpose of improving patient safety and health care outcomes and that is independent and not under the control of the entity that reports patient safety data.
[3] S. 381.0271(3)(b), F.S.
[4] Chapter 2000-256, Laws of Florida.
[5] Executive Order No. 02-041, issued August 28, 2002.

held numerous meetings across the state spanning a five-month period and proposed over 60 legislative recommendations.[6] 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, DOH, and patient safety centers in the state's universities to study implementation requirements for a statewide patient safety authority[7]. The report from this study formed the basis for the 2004 legislation establishing the corporation.

**Organizational Structure and State Funding**

The corporation was incorporated in Florida on August 20, 2004, as a not-for-profit corporation. On June 16, 2005, the corporation was 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. 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 Board of Directors held its first meeting on July 29, 2004, and at the third meeting approved bylaws and elected officers. 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[8]:

- 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 Legislature has appropriated a total of $2.9 million for the corporation, which is provided annually through contract between the 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 DOH for the purpose of recommending changes in practices and procedures for health care practitioners and facilities;
- Establish a "near-miss"[9] patient safety reporting system;
- Work collaboratively with state agencies in the development of electronic health records;
- 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;

[6] The full text of the report is available at: <http://www.doh.state.fl.us/myflorida/DOH-Large-Final%20Book.pdf> (Last visited on October 22, 2007).
[7] Chapter 2003-416, Laws of Florida.
[8] S. 381.0271(5), F.S.
[9] S. 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 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;
- Recommendation 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.

**Performance Audit**

The Legislature mandated the OPPAGA, AHCA, and DOH to develop performance standards by which to measure the success of the corporation in fulfilling the purposes of the law. The OPPAGA was charged with conducting a performance audit of the corporation during 2006 and submitting a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 1, 2007. The OPPAGA submitted Report No. 06-76, *Patient Safety Corporation Has Made Progress; Needs to Continue Developing Its Infrastructure* in December 2006.[10]

The OPPAGA report found that the corporation has made progress toward fulfilling its statutory duties and responsibilities. However, for the corporation to fully achieve its purpose and be recognized as a leader in promoting a culture of patient safety, it needs to take steps to develop its infrastructure. The report further states that to accomplish this, the corporation should:

- Employ full-time staff with patient safety expertise,
- Develop an annual work plan,
- Establish working partnerships with stakeholders, and
- Acquire grant and private sector funding.

**Constitutional Amendment 7**

In 2004, Floridians adopted an amendment to the Florida Constitution titled "Patients' Right to Know About Adverse Medical Incidents," commonly known as Amendment 7.[11] This amendment, in part, provides that patients have a right to access any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident. The identity of patients involved in the incidents must not be disclosed, and any privacy restrictions imposed by federal law must be maintained.

The phrase "adverse medical incident" is defined to mean medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient, including but not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees.

**The Patient Safety and Quality Improvement Act**

The federal Patient Safety and Quality Improvement Act of 2005[12] establishes a structure to improve patient safety and reduce the incidence of events that adversely affect patient safety by facilitating Patient Safety

[10] The full text of the report is available at: <http://www.oppaga.state.fl.us/reports/pdf/0676rpt.pdf> (Last visited on October 22, 2007).
[11] Article X, section 25 of the Florida Constitution.
[12] Public Law 109-41.

Organizations (PSOs) and other entities collecting, aggregating, and analyzing confidential information reported by health care providers. The federal act 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 ("patient safety work product") for the conduct of patient safety activities notwithstanding any other provision of federal, state, or local law.[13]

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.

The act provides exceptions related to documents such as the patient's medical record; billing information; information separate from a patient safety evaluation system; discoverable information in a criminal, civil, or administrative proceeding; and information required to be submitted to governmental entities for public health or oversight purposes.

**Adverse Incidents**

An adverse incident is an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention rather than the condition for which such intervention occurred, and which:

- Results in one of the following injuries:
    - Death;*
    - Brain or spinal damage;*
    - Permanent disfigurement;
    - Fracture or dislocation of bones or joints;
    - A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;
    - Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or
    - Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;*
- Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process;* or
- Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.[14]*

If any condition identified above with an asterisk (*) occurs, a licensed facility must report it to the AHCA within 15 calendar days after its occurrence. These are commonly known as "Code 15" incidents. Additionally facilities are required to annually report to the AHCA all adverse incidents as well as information related to all malpractice claims filed against a licensed facility. The AHCA publishes on its website a summary and trend analysis of "Code 15" incidents quarterly and an annual summary and trend analysis of all adverse incident reports and malpractice claims information. These publications do not include identifying information of any of the parties or entities involved.

## METHODOLOGY

Senate professional staff contacted the staff of the corporation and reviewed corporate publications and documents to determine the corporation's progress in implementing OPPAGA's recommendations as set forth in report number 06-76 and to determine whether the legislation related to the corporation should be amended to delete obsolete provisions and improve the effectiveness of the corporation. Staff also attended a meeting of the board of directors of the corporation. In addition, staff is monitoring activity by the Florida Supreme Court for a decision concerning Amendment 7 or the "Patients' Right to Know About

[13] *Ibid* Sec. 922.

[14] S. 395.0197(5), F.S.

Adverse Medical Incidents" amendment that could significantly affect the functions of the corporation.

# FINDINGS

## Accomplishment and Activities

The corporation is organizationally complete with an active board of directors and staffed advisory committees, all of whom serve in a voluntary capacity. Independent contractors (an executive director, general counsel, and scientific director) staff the corporation. The corporation does not have any direct employees. To date, the corporation has complied with all statutory reporting responsibilities.

The corporation has a web site[15] with information to assist health care providers and the public become more aware of patient safety issues. The corporation has also sponsored two annual Patient Safety Awareness Weeks to educate patients about becoming more involved in their own health care and building / strengthening partnerships between health care providers and their patient communities. A third Patient Safety Awareness Week is scheduled for early 2008.

The corporation has developed policies and procedures, a strategic plan, and an annual work plan for July 2007–June 2008 with expected completion dates. Activities in this work plan include:[16]

- Create corporation-driven project to reduce hospital acquired infections – project kick-off is scheduled for November 2007, with a written evaluation of the outcome presented to the board in June 2008;
- On-going activities with the Near-Miss Reporting System - the corporation has implemented the Near-Miss Reporting System, with analytical advisories as discussed more fully below;
- Become a federally-designated Patient Safety Organization – see discussion below;
- Create corporation-driven project to reduce wrong-patient; wrong site procedures – project kick-off is scheduled for January 2008, with a written evaluation of outcome presented to the board in June 2008;
- Enhance health literacy within Florida – a collaborative effort emphasizing language barriers, with a written evaluation of outcome presented to the board in June 2008;
- Conduct Florida Patient Safety Summit in May 2008 [will be postponed due to scheduling conflicts and the need for additional planning but a smaller, more intimate gathering with industry leaders is proposed for May 2008];
- Create patient safety evaluation system – to store and analyze patient safety related information for health care providers – timeline contingent on Patient Safety Organization certification; and
- Seek grant funding.

## Near-Miss Reporting System

The corporation rolled out the Near-Miss Reporting System in April 2006. This is a voluntary, essentially anonymous reporting system. The overall purpose of capturing near misses is to: identify areas for improvement in the delivery of health care in Florida; provide participating institutions with evidence-based best practices where deficiencies are shown to exist; learn and disseminate insights obtained from analyzing near-miss data; enhance patient outcomes; and potentially bring about a reduction in the frequency and severity of medical errors.[17]

The corporation has published three trending and analytical advisories since the Near-Miss Reporting System's inception. The first advisory was published in December 2006. The advisory for the quarter ending June 2007 reported that there are 16 institutions participating in the Near-Miss Reporting System. The corporation believes that the low participation is attributable to the uncertainty surrounding the effect of Amendment 7 and facilities have declined to participate until after the Supreme Court rules on the cases discussed below and the confidentiality of the data that would be reported in the system. Initially the corporation intended to publish the advisory quarterly, however due to the limited participation and lack of ongoing data, the advisory will be published less frequently.

## Analysis of Adverse Incidents

In 2005, the corporation engaged the Florida Academic Patient Safety Centers to assess the AHCA's Code 15 adverse reporting system. In June 2006, the Florida Academic Patient Safety Centers reported that under-reporting by facilities of adverse events is pervasive and that the data in the system is unreliable for a

[15] Found at < http://www.floridapatientsafetycorp.com/> (Last visited on October 22, 2007).

[16] Florida Patient Safety Corporation Work Plan July 2007- June 2008.

[17] Activities Report through August 2007 provided by the Corporation to Senate staff.

variety of reasons.[18] In July 2007, the Secretary of the AHCA created a Patient Safety Workgroup to examine s. 395.0197, F.S., and the rules governing adverse incidents and draft recommendations to improve the statute. The corporation's scientific director is a member of this workgroup. The corporation has postponed analysis of adverse incidents until a more accurate, complete, and reliable data collection system is in place.

**Supreme Court Cases**

On June 7, 2007, the Florida Supreme Court heard oral arguments on two related cases, referred to as the Buster case[19] and the Bowen case.[20] These cases arose out of medical malpractice lawsuits and concern Amendment 7. The issues on appeal relevant to this report include 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 (simply, whether [federal or state] statutory or regulatory provisions providing for the confidentiality of credentialing, peer review, quality assurance, and risk management information is nonetheless accessible to patients) and
- Applies retroactively to information (or records) created prior to November 2, 2004, the date upon which the constitutional amendment became effective.

The corporation filed an *Amicus Curie* brief in the Buster case. This brief argues that privacy provisions in the federal Patient Safety and Quality Improvement Act and the Health Insurance Portability and Accountability Act of 1996[21] (HIPPA) are superior to the state's Amendment 7, and Amendment 7 recognized that any privacy restrictions imposed by federal law shall be maintained.[22] Briefly, the corporation also argues that HIPPA limits access to health information about another individual without authorization by that individual or a court order, and pre-empts contrary provisions under state law.

The disposition of these cases will have an impact on the extent to which health care providers will make information available to the corporation. Without access to information related to adverse incidents and near-miss scenarios, the corporation's effectiveness will be limited.

**Patient Safety Organization**

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 (the Act). During 2006, the corporation actively followed and participated in the development of the Patient Safety Organization certification program and submitted proposed language related to criteria and guidelines for certification. 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 the Act. The corporation believes this Act over-rides any state constitutional or statutory provisions that would make patient safety work product discoverable or otherwise available to a patient or any other person.

**Advisory Committees**

The corporation indicates that the advisory committee structure in s. 381.0271, F.S., has presented some challenges for the corporation.[23] The seven advisory committees created in law have proscribed membership, which can, and has, created problems for the corporation when the proscribed 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. One example of this is the

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[18] *Assessment of Progress Made By the Florida Patient Safety Corporation Toward Achieving Select Statutory Requirements*, Chapter 1: Assessment of the "Code 15" Adverse Event Reporting System, found at <http://floridapatientsafetycorp.com/Documents/FPSC%20USF%20Research%20Report%20FINAL.pdf> (Last visited on October 22, 2007).

[19] *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.

[20] *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.

[21] Public Law 104-191.

[22] Subsection (b) of S. 25, Article X of the Florida Constitution.

[23] *Florida Patient Safety Corporation Progress Report*, December 1, 2006, page 28.

electronic medical records initiative assigned to the Technology Advisory Committee. The language creating the committees specifies that the duties of the technology advisory committee shall include, but not be limited to, implementation of new technologies, including electronic medical records.[24] However, the AHCA and the former Governor's Health Information Infrastructure Advisory Board have taken the lead with electronic medical records. The corporation believes the focus of the Technology Advisory Committee should be on supporting the work on electronic medical records by these other groups as stated in the corporation's charge to "work collaboratively with the appropriate state agencies in the development of electronic health records,"[25] and concentrate on technologies specifically for patient safety.

The corporation believes its role should entail research, analysis, and education to favorably impact patient safety and that s. 381.0271, F.S., should focus on these activities.

**Funding**

The corporation has not obtained independent funding. Members of the corporation's board of directors have advocated that the state should provide basic financial support for the corporation. They state that this allows the corporation to maintain its perception of independence and impartiality, as well as providing the overhead to complement grant awards. State funding also visibly demonstrates the Legislature's support of patient safety and the mission of the corporation. At the board meeting on October 11, 2007, the corporation appointed a Financial Strategy Committee to explore options for pursuing revenue from primarily three sources to move toward becoming more self-sustaining. The three sources are grants, foundations, and self-sustaining projects. The corporation has approved plans to develop a fee-based, statewide patient safety information repository and analytical service; however, viability of this proposal is dependent upon the corporation being able to guarantee confidentiality of the information obtained. The corporation has received in-kind contributions estimated at $53,000 annually.

**Partnerships with Stakeholders**

The corporation continues to work with a variety of organizations, including but not limited to: AARP Florida, the Florida Hospital Association, the Florida Council of Medical School Deans, the Florida Health Care Coalition, the insurance industry, state university patient safety centers, consumer advocacy groups, and numerous professional medical associations in Florida.

**Library of Evidence-based Medicine**

The corporation suggests removing the directive to provide access to an active library of evidence-based medicine and patient safety practices since it: is not directly connected with advancing patient safety; duplicates a great deal of information already available on the web; and requires an extraordinary level of resources to develop and maintain such a resource repository. A Google search of "evidence-based medicine" produces 67,700,000 hits.[26] Numerous sites from well-respected organizations such as the University of Massachusetts Medical School, Duke University Medical Center, and the Johns Hopkins Medical Institute, to name just a few, have established extensive on-line research libraries related to evidence-based medicine. It is not apparent from the legislative directive and available funding any added benefit the corporation would be able to provide in the area of evidence-based medicine, given the evolution of the discipline and available resources over the last few years.

**Obsolete Language**

A number of provisions in s. 381.0271, F.S., the corporation's authorizing statute, are now obsolete. Subsection (6) provides directives for the AHCA to assist in the initial organization of the corporation. These responsibilities include eliciting appointments for the initial board of directors, assisting in board meetings during the first year of operation of the corporation, assisting in drafting and filing articles of incorporation and by laws, and providing for office space and administrative support during the first year of operations. Other provisions call for reports by the corporation and the OPPAGA to be due on dates in the past. These provisions could be deleted.

**Miscellaneous**

The corporation has suggested changing the language in s. 381.0271(7)(b)4, F.S., which authorizes the corporation to "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 corporation bases this suggestion on the theory that if errors continue at the present level but injuries are reduced by half, patient safety has been improved; yet if errors are reduced in half but injuries continue at the present level, then patient safety has not been enhanced. The corporation

[24] S. 381.0271(5)(b), F.S.

[25] S. 381.0271(7)(a)4., F.S.

[26] Google Search on the Internet on October 3, 2007.

recommends focusing on reducing risks or enhancing safety since the ultimate objective is to cultivate patient safety.

## RECOMMENDATIONS

The Legislature should amend the corporation's authorizing statute to:

- Streamline s. 381.0271, F.S., related to the specified advisory committees by substituting authorization for the corporation to establish and disband advisory committees, subject to board approval, as necessary to carry out the legislative responsibilities and evolving work of the corporation,
- Eliminate the requirement for the corporation to provide access to an active library related to evidence-based medicine,
- Remove obsolete provisions, and
- Strike the phrase "reducing and preventing medical errors and" from s. 381.0271(7)(b)4, F.S.

The Legislature should also continue to monitor the effects of Amendment 7 and the federal Patient Safety and Quality Improvement Act of 2005 on the corporation's ability to perform its functions.