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OFFICE OF PROGRAM POLICY ANALYSIS & GOVERNMENT ACCOUNTABILITY

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Patient Safety Corporation Has Made Progress; Needs to Continue Developing Its Infrastructure

at a glance

The 2004 Legislature created the Florida Patient Safety Corporation to promote a culture of patient safety and serve as a learning organization to assist health care providers improve the quality and safety of health care and reduce harm to patients. Since its inception in July 2004, the corporation has made progress toward fulfilling its statutory duties and responsibilities. It has carried out administrative and organizational tasks necessary to begin operating and addressing its statutory duties. In addition, the corporation has contracted to design and pilot a near-miss reporting system and developed a proposal to study adverse incident data. It also has taken some initial steps to educate health care providers and the public about patient safety.

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. 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.

Scope

Chapter 2004-297, *Laws of Florida,* directs the Office of Program Policy Analysis and Government Accountability to review the Florida Patient Safety Corporation.[1] This report discusses the progress that the corporation has made toward its statutory duties since its inception in July 2004 and provides recommendations for continued progress.[2]

Background

The importance of reducing medical errors and improving patient safety was highlighted by a 1999 report issued by the National Academies' Institute of Medicine.[3] This report, entitled *To Err Is Human: Building a Safer Health System,* concluded that preventable medical errors were one of the leading causes of injury and death in

[1] Section 381.0271(10), *F.S.*

[2] As directed by s. 381.0271(10), *F.S.*, OPPAGA met with representatives from the Agency for Health Care Administration, the Department of Health, and fiscal and substantive legislative committee staff to develop standards by which to measure the corporation's progress in fulfilling its purpose. The group identified both short- and long-term standards and examples to demonstrate that the corporation is meeting expectations. OPPAGA considered these standards when conducting this review.

[3] Four organizations comprise the National Academies: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine and the National Research Council. These organizations bring together committees of experts in all areas of science and technology to address critical national issues and give advice to the federal government and the public.

the nation. The report noted that the American Hospital Association estimated that between 44,000 and 98,000 Americans died in hospitals each year as a result of medical errors. The report also concluded that medical errors increase health care costs. For example, recent estimates of increased hospital costs related to adverse drug events average $8,750 per incident. [4]

In response to this report as well as issues surrounding medical malpractice, the Florida Legislature created the Commission on Excellence in Healthcare and the Executive Office of the Governor created the Select Task Force on Health Care Professional Liability Insurance to research ways to reduce preventable medical errors and improve patient safety. Both of these groups recommended creating a statewide patient safety authority. In response, the Legislature directed the Agency for Health Care Administration in consultation with the Department of Health and the state's university patient safety centers to study how to establish the authority. [5] Based on this group's recommendations, the 2004 Legislature created the Florida Patient Safety Corporation. (See Exhibit 1.)

The Florida Patient Safety Corporation is a not-for-profit entity with the mission of promoting a culture of safety and serving as a patient safety learning organization by helping health care providers (practitioners and facilities) improve the quality and safety of health care and reduce harm to patients. [6] To accomplish this purpose, the Legislature directed the corporation to fulfill specific duties. These include recommending improvements in health care practice based on analyzing medical errors and other patient safety data; educating both the public and providers on patient safety issues; and working with state agencies to coordinate patient safety efforts, including developing electronic health records.

The corporation's role in analyzing data on medical errors is important to improving patient safety. Medical errors, whether they cause serious harm or death (adverse incidents) or occur without serious consequence (near-miss events), are not typically the result of a single individual's actions; rather they often can occur because of a system failure in the health care environment. [7, 8] By collecting and analyzing data on adverse incidents and near-miss events, the corporation seeks to identify system problems and work with health professionals to develop recommendations

[4] *Report Briefing: Preventing Medication Errors,* Institute of Medicine of the National Academies, July 2006.

[5] The Florida university patient safety centers include the University of South Florida, University of Florida, University of Miami, Florida State University, and Nova Southeastern University.

[6] State law specifies that the corporation should not serve in a regulatory role. To promote and protect the health care safety of Florida's citizens, the Agency for Health Care Administration (AHCA) and the Department of Health (DOH) fulfill regulatory roles. AHCA licenses and inspects hospitals, nursing homes, and assisted living facilities. DOH licenses and disciplines practitioners in 37 health care professions.

[7] Per s. 395.0197, *F.S.*, an adverse incident is any event that causes serious harm or death over which health care personnel could have exercised control and which is associated with medical intervention.

[8] Per s. 381.0271, *F.S.*, a near-miss event is any potentially harmful event that could have resulted in serious harm or death but was prevented through chance intervention.

Exhibit 1
The 2004 Florida Legislature Created the Patient Safety Corporation in Response to Commission and Task Force Recommendations

November 1999	Institute of Medicine reports that medical errors are one of the leading causes of injury and death.
Spring 2000	The Legislature creates the Commission on Excellence in Healthcare which recommends creating a patient safety authority.
August 2002	The Governor creates the Select Task Force on Health Care Professional Liability Insurance which recommends creating a patient safety authority and electronic health records.
Spring 2003	As directed by the Legislature, the Agency for Health Care Administration, the Department of Health, and the university patient safety centers develop a detailed plan for a patient safety authority to include developing a near-miss reporting system.
Spring 2004	The Legislature creates the Florida Patient Safety Corporation to promote a culture of patient safety and serve as a learning organization dedicated to assisting health care providers in the state improve the quality and safety of health care and reduce harm to patients.

Source: *Startup Activities*, December 1, 2004, Florida Patient Safety Corporation.

for preventing or avoiding these problems. (See Appendix A for examples of medical errors.)

Educating health care providers and the public is also important to improving patient safety. To disseminate reliable, valid, and current best practice information, the corporation is charged with developing a library of evidence-based medicine and patient safety practices. [9] To reduce medical errors and improve the quality of care, the corporation also is charged with developing patient safety core competencies for colleges and universities to incorporate into medical and health education curriculum. Further, the corporation is charged with developing patient safety programs to educate the public on its role in receiving safe medical care. (See Exhibit 2 for a detailed list of the corporation's statutory duties.)

Exhibit 2
The Legislature Directed the Corporation to Conduct These Statutory Duties in Fulfilling Its Purpose

- Secure staff necessary to administer the corporation.
- Collect, analyze, and evaluate patient safety and quality data, medical malpractice closed claims, and adverse incident data to recommend changes to practitioners and facilities.
- Establish a voluntary and anonymous near-miss patient safety reporting system for hospitals, birthing centers, and ambulatory surgery centers to identify system problems and develop recommendations to prevent adverse incidents.
- Work with state agencies to develop electronic health records.
- Provide practitioners, facilities, and the public access to an interactive evidenced-based medical library.
- Develop undergraduate and graduate core competencies in patient safety to incorporate into health care curriculum.
- Develop and recommend programs to educate the public about its role in promoting patient safety.
- Provide recommendations for interagency coordination of patient safety in the state.

Source: Section 381.0271(7)(a)1.-8., *Florida Statutes.*

To guide the corporation, the Legislature also defined board and advisory committee membership and responsibilities. The board must include 15 representatives from practitioner disciplines, the health care industry, and consumers. The corporation must also establish seven advisory committees with specified memberships and responsibilities related to the corporation's statutory duties. (See Appendix B for details on the board and advisory committees.) In addition, the corporation is charged with working with other patient safety stakeholders in the state, annually reporting its progress to the Legislature, and seeking grant and private-sector funding.

The Legislature appropriated $650,000 non-recurring general revenue to the corporation in Fiscal Year 2004-05 and $750,000 recurring general revenue in Fiscal Years 2005-06, and 2006-07. [10] In Fiscal Year 2005-06, the corporation's expenditures totaled $1.03 million. [11] As shown in Exhibit 3, the majority (78%) of these expenditures paid for a near-miss reporting system and a research contract with the University of South Florida patient safety center. [12] The remaining expenditures paid for staff and administrative expenses.

Exhibit 3
Florida Patient Safety Corporation Fiscal Year 2005-06 Expenditures Totaled $1.03 Million

Expenditure Category	Amount
Near-Miss Reporting System Three-Year Pilot Project	$605,635 [1]
Research Project with the University of South Florida patient safety center	200,000 [2]
Corporation staff (executive director and general counsel)	148,733
Administrative expenses (e.g., accounting, board travel expenses, and website development)	74,123
Total	**$1.03 million**

[1] The total contract amount for the near-miss reporting system is $1.2 million. The corporation will pay the remaining $594,365 in Fiscal Years 2006-07 and 2007-08.
[2] The contract amount for the research project totaled $300,000. The remaining $100,000 was paid in the first quarter of Fiscal Year 2006-07.

Source: The Florida Patient Safety Corporation.

[9] Evidence-based medicine is the practice of making patient care decisions using the best available information and results from medical research. It promotes patient safety, positive clinical outcomes, and quality care through a rigorous evaluation of research.

[10] The Legislature appropriates the corporation's funds to AHCA, which transfers the appropriation to the corporation through a contract agreement.

[11] Expenditures exceeded the annual appropriation because the corporation carried over $605,852 of its Fiscal Year 2004-05 funds to Fiscal Year 2005-06. The corporation carried over $327,362 of its Fiscal Year 2005-06 funds to Fiscal Year 2006-07.

[12] The corporation signed a six-month, $300,000 contract from January through June 2006 with the University of South Florida patient safety center to provide recommendations for achieving its statutory duties. To assist with the research, the University of South Florida subcontracted with the patient safety centers at the Florida State University, Nova Southeastern University, and the University of Florida.

Findings

The Florida Patient Safety Corporation has made progress toward meeting its statutory duties and responsibilities

Since July 2004, the corporation has carried out administrative and organizational tasks necessary to begin operating and addressing its statutory duties. The corporation has taken initial steps to collect and analyze medical errors data by contracting for a near-miss reporting system pilot project and approving a proposal to analyze adverse incident data. In addition, the corporation has begun addressing some of its duties related to patient safety education.

The corporation has taken steps to establish itself as an organization and to address its other responsibilities. Since its creation in July 2004, the corporation has filed articles of incorporation, established by-laws, and filled board membership. In February 2005, it hired an executive director who provides management and administrative support, such as coordinating board and advisory committee meetings, developing and maintaining the corporation's website, and managing the corporation's finances and vendor contracts. The corporation also has contracted for legal counsel, established advisory committees, and appointed chairpersons to these committees. In addition, in October 2006, the board authorized the hiring of a patient safety specialist.

The corporation has taken initial steps to address other responsibilities. In June 2005, the board developed a strategic plan with short- and long-term objectives and assigned those objectives to specific advisory committees. The corporation contracted with the University of South Florida's patient safety center to provide recommendations on how to address its statutory requirements. In addition, the corporation launched its website in November 2005 and has met its legislative reporting requirements. [13, 14]

The corporation contracted to design and pilot a near-miss reporting system and has developed a proposal to study adverse incident data. In June 2005, the corporation signed a three-year contract with the University of Miami Jackson Memorial Hospital Center for Patient Safety to develop and pilot a voluntary and anonymous near-miss reporting system. [15] Studying adverse incidents or near-miss events provides researchers, medical professionals, and health care providers with information they can use to develop ways to reduce medical errors. The contract requires the center to collect detailed information on near-miss events from 20 hospitals, two ambulatory surgery centers, and two birthing centers. The center tested the system in March 2006, and as of November 2006, 13 hospitals and two ambulatory surgery centers were voluntarily reporting into the system. [16, 17]

To encourage facilities to participate, the Legislature mandated that the near-miss reporting system be anonymous and not used for regulatory purposes. However, passage of the November 2004 constitutional amendment known as the Patient Right to Know Act is hindering participation. [18] Facilities are reluctant to participate in the near-miss reporting system, fearing that information that they report could be used against them. This may impede the corporation's success in expanding the pilot to include all hospitals, ambulatory surgery centers, and birthing centers in Florida.

[13] The Florida Patient Safety Corporation website provides information about the corporation, including its purpose and organizational structure, board and committee meeting times, and patient safety resources. http://www.floridapatientsafetycorp.com/

[14] Per statute, the corporation reviewed and reported on evidence-based medicine to the Legislature in January and September 2005. The corporation also submitted annual reports in December 2004, 2005, and 2006.

[15] The Jackson Memorial Hospital Center for Patient Safety subcontracted with a private health care consultant to help it develop and implement the pilot system.

[16] Risk managers at participating facilities enter details of near-miss events into the reporting system software and submit it to the Center for Patient Safety. The director of the center has 72 hours to collect any additional information from the facility that may be needed to further explain the near-miss event. After 72 hours, the system automatically removes all facility identification from the reported information.

[17] As of November 2006, the center had accepted two more hospitals to participate in the pilot system that were not yet reporting into it. The center continues to seek birthing centers for participation.

[18] This constitutional amendment allows individuals the right to access any hospital, nursing home, or physician records related to any action that may have caused bodily injury or death. The interpretation of the amendment for medical malpractice lawsuits is pending decision by the Florida Supreme Court. Federal patient safety legislation passed in November 2005 may nullify Florida's amendment, clarifying that near-miss event data is confidential and therefore, not admissible in court. Final rules for this legislation have not been issued.

The University of Miami Jackson Memorial Hospital Center for Patient Safety analyzes the near-miss data from reporting facilities to identify problems and recommend solutions that should reduce the likelihood that similar problems will recur and thereby, improve patient safety. Beginning December 2006, the center will issue quarterly patient safety advisories featuring analyses of commonly reported near-miss events and also will include analyses of events that occur infrequently but could cause serious harm. The advisories will discuss potential reasons that a particular type of near-miss event occurred, what prevented the near-miss event from becoming an adverse incident, and recommend ways to reduce or prevent that type of near-miss event from recurring. Advisories will be published on the corporation's website and distributed to the participating facilities, the Florida Hospital Association, and the corporation's email distribution list.

In addition to establishing the near-miss reporting system, the corporation has taken steps to analyze and evaluate adverse incident data reported by health care facilities to the Agency for Health Care Administration. [19] In October 2006, the corporation approved a $500,000 proposal from the University of Miami Jacksonville Memorial Hospital Center for Patient Safety to establish an electronic database for the adverse incident data. [20] The corporation also established a task force to study issues related to health care facilities reporting adverse incident data to the Agency for Health Care Administration. [21] The task force includes the Florida Hospital Association and risk managers from two major health care providers. At its first meeting in October 2006, the task force discussed problems with the adverse incident reporting system and assigned tasks to begin addressing these problems.

The corporation has taken initial steps to provide patient safety education to providers and the public. The corporation developed and submitted to the Legislature a preliminary plan for designing an electronic library of evidence-based medicine and patient safety practices. The library will provide research on best medical practices and serve as a resource for health care providers and the public. [22] The corporation also has established an Education Advisory Committee. This committee held its first meeting in September 2006 to begin developing core patient safety educational curricula for medical and health education programs at colleges and universities. In addition, the corporation's website features consumer resources, which include links to general patient safety websites and information about medication safety. Further, the corporation sponsored a Patient Safety Awareness Week in March 2006. This involved distributing Florida Patient Safety Corporation magnets to patients at county public health departments and community health centers, featuring daily tips on its website, and issuing a press release marketing patient safety to health care reporters statewide.

(See Appendix C for detailed information on the corporation's progress for each of its statutory duties.)

To facilitate continued progress, the corporation needs to develop its infrastructure

While the Florida Patient Safety Corporation has made initial progress, it should take additional steps to achieve its statutory responsibilities fully and establish itself as a leader in patient safety. Similar entities in other states, also in their initial stages, have taken steps that would be useful if emulated by the Florida corporation:

[19] In accordance with s. 395.0197(7), *F.S.*, the Agency for Health Care Administration collects adverse incidents on the following medical conditions: death of a patient; brain or spinal cord damage to a patient; surgery performed on the wrong patient; wrong site surgical procedures; wrong surgical procedure, surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis; surgical repair of damage resulting to a patient from a planned surgical procedure; or procedures to remove unplanned foreign objects remaining from a surgical procedure. Florida hospitals are required to report adverse incidents to the Agency for Health Care Administration within 15 days of the event.

[20] Once the corporation acquires private funding for the project, the center will begin evaluating adverse incident data collected since 2000 and designing the database in January and February 2007. After analyzing the data, the center plans to educate providers on the trends, anecdotes, lessons learned, and best practices via patient safety advisories and seminars in November and December 2007.

[21] Research by the Florida university patient safety centers has identified problems with the Agency for Health Care Administration's adverse incident reporting system, including significant under-reporting by facilities of adverse medical incidents, lack of uniform data reporting requirements, and no systematic analyses of adverse incidents.

[22] The plan identified steps the corporation needs to take to create an evidenced-based medicine library, including researching the components of an evidenced-based medicine library and costs to establish and maintain the library.

- employing full-time staff with patient safety expertise.
- developing an annual work plan,
- working in partnership with stakeholders, and
- acquiring grant and private-sector funding. [23]

Employing full-time staff with patient safety expertise will allow the corporation to identify and manage patient safety projects and facilitate meeting the corporation's objectives. Patient safety centers in other states employ clinical staff, such as medical doctors, nurses, public health practitioners, risk managers, and/or pharmacists. These staff identify patient safety issues in the state, develop and implement activities and projects to address these issues, and seek funding alternatives for activities and projects. In January 2006, the corporation executed a $300,000 contract with the University of South Florida patient safety center to advise the corporation on how to address its statutory duties. Given that the corporation's contract with the University of South Florida was a one-time expenditure, the corporation could allocate a portion of its annual $750,000 recurring legislative appropriation to pay for a full-time patient safety specialist while continuing to meet its other obligations.

Employing at least one full-time patient safety staff will help the corporation's board function in an advisory capacity, guiding the work and direction of the corporation. Board members, who have full-time obligations to their individual professions, are limited in the amount of time they can dedicate to accomplishing statutory duties that also require assistance from staff with patient safety expertise. [24] For example, although the corporation outlined a preliminary plan in September 2005 to develop an evidence-based library, the corporation has not moved forward with this plan, in part, because it does not have a full-time patient safety specialist.

Developing a work plan will help focus the corporation and assist it to fulfill its purpose. The corporation developed a strategic plan in June 2005 that identifies goals and initiatives which align with its statutory duties and responsibilities and assigns responsibility for these goals to its advisory committees. However, the strategic plan does not include a plan of action that details how to achieve these goals or a timeframe in which to complete them. In addition, while the corporation has initiated some of its statutory duties, such as piloting a near-miss reporting system, it has not yet identified and implemented projects to address specific patient safety issues that may be of concern to Florida health providers.

Other state patient safety centers use information acquired from reporting systems, issues identified by nationally recognized organizations, such as the Joint Commission on Accreditation of Healthcare Organizations, or feedback from providers and stakeholders, to identify specific patient safety problems and then develop projects to address them. [25] For example, the New York, Oregon, and Massachusetts patient safety centers develop annual work plans that include potential patient safety projects and then select three or four key projects to implement based on recommendations from providers or advisory groups.

Types of projects implemented by these state centers include conducting or sponsoring health summits and training/education conferences; issuing patient safety advisories; and using best practice collaboration models to identify ways to address patient safety issues. [26] For example, Maryland's patient safety center applied an Institute of Healthcare Improvement collaborative model, bringing together health care professionals to identify causes of high incidences of hospital-acquired infections and ventilator-dependant pneumonia and to develop training for reducing these infections. [27]

[23] The following states have established patient safety centers that have goals and purposes similar to Florida's Patient Safety Corporation: Maryland, Massachusetts, New York, Oregon, and Pennsylvania.

[24] The board meets every other month, and, as of November 2006, with the exception of the Health Care Provider Advisory Committee, each advisory committee, chaired by a board member, has met no more than twice.

[25] The Joint Commission on Accreditation of Healthcare Organizations is an accrediting body that issues patient safety standards.

[26] Collaborations bring together medical professionals and subject matter experts to discuss specific health care problems, share ideas, and develop recommendations.

[27] The Institute for Healthcare Improvement is a non-profit organization dedicated to improving health care by cultivating and sharing promising concepts.

Working in partnerships with stakeholders would assist the corporation to achieve broad-based support for promoting a culture of patient safety. In addition to its current advisory committees, the corporation should establish stakeholder partnerships to address specific patient safety issues, mobilize expertise and support, and reduce duplication of effort among health care providers and other stakeholders. [28] This could be achieved through forming workgroups charged with seeking solutions to identified patient safety issues as well as by partnering with state agencies to disseminate patient safety information. This would also help the corporation become a leader in promoting a culture of patient safety in the state's health care system and potentially lead to opportunities to co-fund patient safety projects.

Including stakeholders in identifying and addressing patient safety issues facilitates information sharing and use of existing expertise. For example, Oregon's patient safety center partnered with rural hospitals to improve emergency care based on one rural hospital's successful emergency rapid response protocol. In addition, New York's patient safety center partnered with their state's licensing board to distribute patient safety alerts and bulletins to practitioners and facilities.

Efforts to identify funding sources would provide resources to sustain and expand existing and long-term initiatives and assist the corporation to become independent of state funding. Although the Legislature directed the corporation to seek private-sector funding and apply for grants, it has not yet done so. Seeking external funding sources could reduce or eliminate the need for state funding. In addition, the corporation will need additional funding to meet some of its responsibilities. For example, the corporation's $1.2-million contract for the near-miss reporting system pilot supports initial database development and participation for a maximum of 25 health care facilities. Expanding this system statewide would require investments to install software at additional reporting facilities and to expand and maintain the system at the University of Miami. [29] Furthermore, establishing and maintaining an evidenced-based medicine library and developing educational seminars will require additional resources.

Four of the five state patient safety centers that we contacted can acquire private funding to support patient safety initiatives. [30] For example, Maryland's patient safety center received grant funding from the Maryland's Department of Health for a project to reduce injuries to newborns. Maryland's center also received funding from Blue Cross Blue Shield of Maryland to conduct a study to identify ways to reduce or eliminate staphylococcus infections in hospitals.

Recommendations

In order to better achieve its purpose of reducing harm to patients, improving the quality and safety of medical care, and establishing a culture of patient safety, the Florida Patient Safety Corporation should take additional steps to develop its infrastructure. Specifically, it should take the actions discussed below.

- Employ full-time staff with patient safety expertise. The corporation should employ at least one full-time patient safety specialist who can lead and direct patient safety initiatives for the corporation. In October 2006, the corporation advertised for a patient safety specialist to assist the board in achieving its legislative goals, including identifying and applying for external funding. It will be important that this position operate as a full-time position so that the board and its committees can function in an advisory capacity.
- Develop an annual work plan. The corporation should develop a work plan that details activities and projects for addressing specific patient safety issues, including implementation timeframes and funding requirements. The work plan should align

[28] Stakeholders include hospital systems, pharmaceutical and equipment manufacturers, health insurers, health care associations, practitioners, state and federal agencies, research and advocacy organizations, and consumers.

[29] As of November 2006, there are 244 acute care hospitals and 551 ambulatory surgery centers operating in Florida.

[30] Maryland and Oregon's centers are 100% dependent upon external funding to operate their centers and to implement patient safety initiatives. Only Massachusetts' patient safety center is prohibited from acquiring private funding.

with the corporation's strategic plan. The corporation should monitor its progress throughout the year and revise the work plan annually.

- Establish working partnerships with stakeholders. The corporation should identify stakeholders from which it can form partnerships for identifying patient safety issues and developing projects to address these issues. Stakeholders include hospitals and other health care provider systems, practitioners, health care associations, advocacy groups, and consumers. The corporation can form workgroups comprising representative stakeholders to implement collaborative models to address specific patient safety issues.
- Acquire grant and private-sector funding. The corporation should seek grant and private-sector funding for patient safety initiatives. The corporation should consider potential funding sources identified in its January and September 2005 reports to the Legislature on evidence-based medicine initiatives and implementation. The sources identified include the federal Centers for Disease Control and Prevention and the National Institute of Health. Other sources to consider include the federal Agency for Healthcare Research and Quality, the Robert Wood Johnson Foundation, and the Commonwealth Fund.

Agency Response

In accordance with the provisions of s. 11.51(5), *Florida Statutes,* a draft of our report was submitted to the Board of Directors of the Florida Patient Safety Corporation to review and respond. The board did not provide a written response to this report.

Appendix A

Medical Errors Can Result in Serious Harm or Death or Occur Without Serious Consequences

Medical errors can cause serious harm or death (adverse incidents) or occur without serious consequence (near-miss events). In the Institute of Medicine's report *To Err Is Human: Building a Safer Health System,* the American Hospital Association estimated that between 44,000 and 98,000 Americans died in hospitals each year as a result of medical errors. In addition, studies suggest that for every adverse incident resulting in patient harm, approximately 100 near-miss events occur. As described in the real-life examples below, medical errors are not always the result of a single individual's actions; rather they can occur due to a system failure in the health care environment. (See A-1 and A-2 for examples of adverse incidents and A-3 and A-4 for examples of near-miss events.)

Adverse incidents

- Example A-1: Administering Wrong Medication -- Epinephrine (used to treat life-threatening allergic reactions) is accidentally placed in the Oxytocin storage bin in the hospital's medicine supply. A technician reaches for a vial of Oxytocin for the purpose of inducing labor for a patient but instead retrieves the misplaced vial of Epinephrine. Because both vials closely resemble one another (see graphic) and because stress and expectations can interfere with how the mind processes what it sees, the technician does not notice that it is not a vial of Oxytocin. Epinephrine is administered to the obstetrical patient and, as a result, the patient has a heart attack.

- Example A-2: Latex Glove Contamination -- The hospital's emergency medical storage closet contains both yellow latex gloves and purple non-latex gloves. The facility cleaning staff notices that the yellow latex glove box is nearly empty and transfers the remaining latex gloves to the non-latex box, contaminating the non-latex box (see graphic). Staff, attending to a patient that is allergic to latex, pulls gloves from the non-latex labeled box failing to see that the gloves should be purple and uses latex gloves causing severe anaphylactic shock in the patient.

Near-miss events

- Example A-3: Potential Wrong Site Surgery -- The surgical consent form states that a prescribed surgical procedure should take place on the patient's left arm, but the physician's medical notes state that the surgical procedure should be performed on the right arm. Through the hospital's verification process, the discrepancy between the consent form and the physician's medical notes is detected and the correct site is identified.
- Example A-4: Patient Allergy Miscommunication -- Upon admission to the hospital, a patient reports to the admissions staff that he is allergic to latex and had an allergic reaction caused by the tape which was used to secure a bandage in a previous health care experience. The hospital employee noting the history interprets the explanation as an allergy to tape rather than an allergy to latex and fails to screen the patient using the facility's assessment tool that detects latex allergies. Fortunately, another hospital employee sought clarification about the allergy and confirmed the allergy to be latex.

Studying data on adverse incidents and near-miss events provides researchers with valuable information that can help reduce medical errors. The corporation will collect and analyze adverse incident data and data on near-miss events to develop solutions for educating medical professionals and health care providers on ways to improve patient safety and thereby reduce medical errors. For example, to address the real-life medical errors described above, the corporation could develop recommendations for distinctive color coding of medicines and supplies, protocols for storing and verifying medications, and training of clinical and non-clinical staff for facility admissions and surgical preparation procedures. The corporation could also form partnerships with stakeholders to develop solutions based on problems identified from medical errors.

Appendix B

The Legislature Mandated That the Corporation Be Governed and Advised by Statutorily-Defined Board and Advisory Committees

The Legislature mandated that a statutorily-defined, 15-member board govern the corporation. Board membership is to include specific representatives from practitioner disciplines, the health care industry, and consumers (see Table B-1). In addition, the Legislature directed the corporation to establish seven advisory committees composed of specific membership and assigned specific responsibilities to assist the corporation with accomplishing its statutory duties and responsibilities (see Table B-2).

Table B-1
The Florida Patient Safety Corporation Is Governed by a Statutorily-Defined Board with 15 Representatives from Practitioner Disciplines, the Health Care Industry, and Consumers

Board Member Type	Appointed by
Chair of the Florida Council of Medical School Deans	
Health insurance representative with expertise in patient safety issues for the insurer	Health insurer (with the largest Florida premium market share in the most recent calendar year)
Health Maintenance Organization representative with expertise in patient safety issues for the insurer	Health maintenance organization (with the largest Florida premium market share in the most recent calendar year)
Representative of an authorized medical malpractice insurance company	The Florida Insurance Council
Two representatives from Florida hospitals that are implementing innovative patient safety initiatives	The Florida Hospital Association
Physician with expertise in patient safety	Florida Medical Association
Physician with expertise in patient safety	Florida Osteopathic Medical Association
Physician with expertise in patient safety	Florida Podiatric Medical Association
Physician with expertise in patient safety	Florida Chiropractic Association
Dentist with expertise in patient safety	Florida Dental Association
Nurse with experience in patient safety	Florida Nurses Association
Institutional pharmacist	Florida Society of Health-System Pharmacist
Florida AARP representative	The director of Florida AARP
President of the Central Florida Health Care Coalition	

Source: Section 381.0271(4), *Florida Statutes.*

Table B-2
The Corporation Is Required to Establish Seven Advisory Committees

Advisory Committees	Statutorily Required Committee Composition	Statutory Purpose and Duties
Scientific Research	A representative from each patient safety center or other patient safety program in the universities of the state who are physicians licensed pursuant to Ch. 458 or Ch. 459, *Florida Statutes,* with experience in patient safety and evidenced-based medicine	Duties include the analysis of existing data and research to improve patient safety and encourage evidence-based medicine
Technology	A representative of a hospital that has implemented a computerized physician order entry system and a health care provider that has implemented an electronic medical records system	Duties include implementation of new technologies, including electronic medical records
Health Care Provider	Representatives of hospitals, ambulatory surgical centers, physicians, nurses, and pharmacists licensed in this state and a representative of the Veterans Integrated Service Network 8, Virginia Patient Safety Center	Duties include promotion of a culture of patient safety that reduces errors
Health Care Consumer	Representatives of businesses that provide health insurance coverage to their employees, consumer advocacy groups, and representatives of patient safety organizations	Duties include incentives to encourage patient safety and the efficiency and quality of care
State Agency	A representative from each state agency that has regulatory responsibilities related to patient safety	Duties include interagency coordination of patient safety efforts
Litigation Alternatives	Representatives of medical malpractice attorneys for plaintiffs and defendants and a representative of each law school in the state	Duties include alternative systems to compensate for injuries
Education	The associate dean for education, or the equivalent position, as a representative from each medicine, nursing, public health, or allied health service	Duties include advising 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

Source: Section 381.0271(5), *Florida Statutes.*

Appendix C

The Florida Patient Safety Corporation Has Made Initial Progress Toward Its Statutory Duties

Since July 2004, the corporation has carried out administrative and organizational tasks necessary to begin operating and addressing its statutory duties. It has taken initial steps to collect and analyze medical errors data by piloting a near-miss reporting system pilot project and designing a project to analyze adverse incident data, and begun addressing some of its duties related to patient safety education. Table C-1 explains in detail the status of the corporation's efforts to achieve its statutory duties as of November 2006.

Table C-1
Florida Patient Safety Corporation's Progress of Statutory Duties

Statutory Duties	Activities that the Corporation Accomplished
Secure staff necessary to administer the corporation	In February 2005, the corporation hired an executive director who performs managerial and administrative duties, such as coordinating board meetings and managing the corporation's finances and contracts. The corporation also hired legal counsel and a certified public accountant. In October 2006, the corporation advertised to hire a patient safety specialist. The patient safety specialist will plan, coordinate, and implement patient safety projects. In addition to assisting the corporation with specific projects and activities, the specialist will identify and apply for external funding. The specialist will also be responsible for developing a plan of action for the corporation to obtain approval by the federal Department of Health and Human Services as a federal patient safety organization. The corporation would like to hire someone who has a doctoral degree in medicine, osteopathy, or pharmacy and has experience with or knowledge of patient safety. The corporation plans to hire the specialist by early 2007.
Collect, analyze, and evaluate patient safety data and quality and patient safety indicators, medical malpractice closed claims, and adverse incident data to recommend changes to practitioners and facilities	As an initial step toward analyzing existing patient safety and quality data, the corporation contracted in November 2005 with the University of South Florida patient safety center for $300,000 to conduct research on the corporation's statutory duties. This included conducting an analysis of the Agency for Health Care Administration's Adverse Incident Database (commonly referred to as the Code 15 data). The results of this analysis were similar to those in an earlier study conducted by the Florida university patent safety centers, reiterating that facilities under-report adverse incidents and provide insufficient contextual information. In October 2006, the corporation approved a $500,000 proposal for the University of Miami Jackson Memorial Hospital Center for Patient Safety and private consultants to study adverse incidents. If the corporation is successful in acquiring funding, the center will begin evaluating adverse incident data collected since 2000 and designing the database in January and February 2007. After analyzing the data, the center plans to educate providers on the trends, anecdotes, lessons learned, and best practices via patient safety advisories and seminars in November and December 2007. The corporation also established a task force to study the issues related to health care facilities reporting adverse incident data to the Agency for Health Care Administration.[31] The task force includes the Florida Hospital Association and risk managers from two major health care providers. At its first meeting in October 2006, the task force discussed problems with the adverse incident reporting system and assigned tasks to begin addressing these issues.
Establish a voluntary and anonymous near-miss patient safety reporting system for hospitals, birthing centers, and ambulatory surgery centers to identify system problems and develop recommendations to prevent adverse incidents	In August 2005, the corporation signed a three-year, $1.2-million contract with the University of Miami Jackson Health Memorial's Center for Patient Safety to develop a near-miss reporting system and pilot the system with 20 hospitals, two ambulatory surgery centers, and two birthing centers. Similar to the objective of the Aviation Safety Reporting System, the purpose of this system is to identify potential systemic problems that could lead to adverse incidents and to develop ways to avoid adverse incidents and improve patient safety. As of November 1, 2006, the web-based, near-miss data reporting system was operational with 13 of the 20 proposed hospitals and two ambulatory surgery centers reporting

[31] Numerous studies have identified problems associated with AHCA's adverse incident reporting system.

Statutory Duties	Activities that the Corporation Accomplished
	data. Lessons learned from the data will be incorporated into educational materials and training and used to develop safety advisories. Expanding voluntary participation by health care facilities has been hindered by the uncertainty surrounding the legal impact of the November 2004 passage of Florida's Patients' Right to Know Amendment. This constitutional amendment allows individuals the right to access any hospital, nursing home, or physician records related to any action that may have caused bodily injury or death to a patient. The amendment is currently being debated in the legal system as part of medical malpractice lawsuits, pending decision by the Florida Supreme Court. Federal patient safety legislation passed in November 2005 clarifying that near-miss event data is confidential and therefore not admissible in court may nullify Florida's amendment. However, final rules for this legislation have not been issued.
Work with state agencies to develop electronic health records	The corporation's Technology Advisory Committee is monitoring the Governor's Health Information Infrastructure Advisory Board. The Governor established this board to advise and support Agency for Health Care Administration in the development and implementation of electronic health records and the implementation of a Florida health information infrastructure. The advisory committee has been participating in board meetings and monitoring the activities of pilot projects, which include testing electronic record systems in regional health systems across the state.
Provide practitioners, facilities, and the public access to an interactive evidenced-based medical library	To date, the corporation has submitted its statutorily required reports on evidence-based medicine (EBM). The January 2005 report summarizes EBM initiatives occurring with both private and governmental entities in Florida, the Unites States, Canada, and Europe. The report discusses the complications associated with establishing an interactive EBM library, including using non-standardized research. The report also describes the steps that the corporation should take in developing an EBM library and identifies potential sources of funding. The implementation plan, issued September 1, 2005, establishes two phases for the EBM initiative and identifies activities to be completed for both phases. However, the implementation plan did not provide specific timelines or detailed steps for activities. As of November 2006, the corporation has not made progress on the EBM initiative.
Develop undergraduate and graduate core competencies in patient safety to incorporate into health care related curriculum	The Education Advisory Committee met on September 11, 2006, to begin developing patient safety educational curricula for medical and health education at Florida's colleges and universities. The committee discussed developing core competencies that include learning objectives, desired outcomes, potential evaluation methods, and a core curriculum that can be recommended to various health disciplines. The committee intends for the patient safety curriculum to be adopted by colleges and universities.
Develop and recommend programs to educate the public about its role in promoting patient safety	The corporation created a consumer resource webpage on its website which includes links to general patient safety websites that provide information such as questions that patients should ask about medical treatment. It also includes information specific to medication safety. In addition, in 2006, the corporation sponsored a Patient Safety Awareness week from March 5-11 to educate the public on becoming more involved in their own health care. As part of this week, the corporation distributed Florida Patient Safety Corporation magnets to patients at county public health departments and community health centers, featured daily tips on its website, and issued a press release to health care reporters statewide marketing patient safety.
Provide recommendations for interagency coordination of patient safety in the state	The corporation is working with the Agency for Health Care Administration to assess adverse incident data and reporting. In addition, the corporation is participating, via its Technology Advisory Committee, in the Governor's Health Information Infrastructure Advisory Board effort to create an infrastructure for electronic medical records in Florida. However, with the exception of conducting an October 2005 State Agency Advisory Committee meeting to bring stakeholders together and introduce the corporation, the corporation has not taken steps to facilitate interagency coordination of patient safety efforts in the state.

The Florida Legislature

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Project supervised by Yvonne Bigos (850/487-9230)
Project conducted by Jennifer Johnson (850/488-1023) and Kim Shafer (850/487-2978)
Becky Vickers, Staff Director (850/487-1316)
Gary R. VanLandingham, OPPAGA Director