By Senator Saunders

37-1027-05

A bill to be entitled

An act relating to patients' right to know about adverse medical incidents; creating s. 381.028, F.S.; providing a short title; providing a purpose; providing definitions; requiring health care facilities and health care providers to observe certain delineated rights of patients; providing that certain records obtained through the act may not be subject to discovery or introduced into evidence in any civil or administrative proceeding; providing that the person responsible for providing or preparing such records cannot be compelled to testify about the information in the records in any civil or administrative proceeding; providing that the limited use of records obtained through this act does not alter or repeal other statutory restrictions regarding discoverability or admissibility; providing that the limited use of records in this act does not require disclosure of documents regarding attorney-client communications or attorney work product; authorizing a patient to waive his or her right to request records under certain conditions; providing for applicability of the act to certain records; amending s. 381.0271, F.S.; authorizing the Florida Patient Safety Corporation to use hypothetical cases to evaluate quality assurance and safety programs; prohibiting the investigations, proceedings,

and records of the corporation from being discovered or introduced into evidence in any civil or administrative proceeding under certain circumstances; providing that the person in attendance at a meeting of the corporation cannot be compelled to testify about the information, findings, opinions, or recommendations of the corporation in any civil or administrative proceeding; providing that certain information is not immune from discovery; providing for severability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.028, Florida Statutes, is created to read:

381.028 Florida Patients' Right to Know About Adverse Medical Incidents Act.--

(1) SHORT TITLE.--This section may be cited as the "Florida Patients' Right to Know About Adverse Medical Incidents Act."

(2) PURPOSE.--It is the purpose of this section to implement the provisions of Article X, s. 22 of the Florida Constitution which the Legislature finds not to be self-executing. The Legislature finds that the intent of the voters was to provide patients and prospective patients with access to quality of care information relating to adverse medical incidents to assist patients and prospective patients in evaluating the quality of care that they receive or can reasonably expect to receive from health care facilities and

health care providers in this state. In enacting this section, it is the intent of the Legislature to maintain all existing provisions concerning criminal and civil immunity for persons providing information to quality of care committees or organizations or to render any records of any adverse medical incident discoverable or admissible into evidence in any judicial or administrative proceeding. Records required to be made available under this section are not public records inasmuch as they are to be made available only to patients and prospective patients and not the public at large.

(3) DEFINITIONS.--As used in this section, the term:

(a) "Adverse medical incident" means medical negligence, intentional misconduct, and any other act of medical neglect, or default of a health care facility or health care provider which caused or could foreseeably have caused injury to or the death of a patient, including, but not limited to, those medical 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.

(b) "Agency" means the Agency for Health Care Administration.

(c) "Department" means the Department of Health.

(d) "Have access to any records" means making the records available for inspection and copying them upon written request by the patient or a representative of the patient if any current records that have been made publicly available by publication or on the Internet may be provided by reference to the location at which the records are publicly available. Any

health care facility or health care provider responding to a request for records has a reasonable amount of time to respond to the request. In addition, in responding to a request for records, any health care facility or health care provider has that time which is necessary to make sure that all patient identifying information and other information required to be made private under state or federal law is not improperly disclosed. Any record that contains information about a health care facility or health care provider must be disclosed to the health care facility or the health care provider named in the record sufficiently before it is made available to the patient or the patient's representative so as to allow the health care facility or health care provider to correct any errors in the record and to correct any errors in the required redaction of patient identifying information or other information required to be made private under state or federal law. Patients or any representative of a patient requesting records shall pay in advance all anticipated costs of preparing requested records for inspection and copying, including, but not limited to, clerical and administrative costs of locating, assembling, reviewing for, and redacting any patient identifying and other private information, reviewing for and redacting any attorney client or attorney work product information, and producing such records for inspection and copying. Patients and representatives of patients shall pay in advance all anticipated costs of copying, including labor and supplies, any records selected for copying by the patient or the representative of the patient. A request for information must be written and must identify the patient requesting access to records by name, address, date of birth, and social security number, describe the condition, treatment, or diagnosis for

which the patient is undergoing, has undergone, or is seeking health care, and specify the name of each health care facility or health care provider from whom the patient is undergoing, has undergone, or is seeking health care relating to the condition, treatment, or diagnosis identified. Requests for access to information shall be made directly to health care facilities and health care providers that made or received the records and not to the department or to the agency.

(e) "Health care facility" means a facility licensed under chapter 395.

(f) "Health care provider" means a physician licensed under chapter 458, an osteopathic physician licensed under chapter 459, or a podiatric physician licensed under chapter 461.

(g) "Identity of patient" means any individually identifiable health information as defined by the Health Insurance Portability and Accountability Act of 1996 or its implementing regulations.

(h) "Patient" means an individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.

(i) "Privacy restrictions imposed by federal law" means the requirements with respect to disclosure of information under federal law, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-91 (HIPAA) and its implementing regulations, and the Federal Privacy Act, 5 U.S.C. s. 552(a) and its implementing regulations, and any privilege, including, but not limited to, the attorney-client, the attorney work product, or the self-critical analysis

privilege, that has been recognized under federal law that prohibits disclosure of information contained in the record.

(j) "Record" means the final report of any adverse medical incident occurring after November 2, 2004, that involves the patient who is seeking access to the report, or that involves the treatment, condition, or diagnosis of the patient and involves the health care facility or health care provider identified in the request for records, excluding, however, any medical records that are not the final report of any adverse medical incident, drafts, or other nonfinal versions, notes, or any documents that constitute, contain, or reflect any attorney-client communications or any attorney work product, or any information that would be protected from disclosure by any privacy restrictions imposed by federal law. The identities of reviewers, complainants, or any other persons who provided information relied upon in the preparation of the final report, or who otherwise participated in the creation of the final report shall be redacted from the report before it is provided to the patient.

(k) "Relating to" means either directly involving the patient who is requesting access to records or directly involving the treatment, condition, or diagnosis for which the patient has undergone, is undergoing, or is seeking health care and the health care facility or health care provider from whom records are requested.

(l) "Representative of the patient" means a parent of a minor patient, a court appointed guardian for the patient, or a person holding a power of attorney or notarized consent appropriately executed by the patient reflecting the patient's permission to disclose the patient's health care information to that person.

(m) "Seeking access" means actively requesting access to a health care provider or health care facility as demonstrated either by documented appointments or consultations with a health care provider or health care facility, or by a written referral to a health care provider or health care facility by another licensed health care practitioner.

(4) RIGHTS OF PATIENTS.--Each health care facility or health care provider shall observe the following requirements:

(a) In addition to any other similar rights provided herein or by general law, patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident involving the patient or the provider to which the patient is seeking access.

(b) In providing such access, the identity of patients involved in the adverse medical incidents may not be disclosed, and any privacy restrictions imposed by state or federal law shall be maintained.

(5) USE OF RECORDS.--Records obtained through this section and any of the information contained in those records, including information relating to performance or quality improvement initiatives, the identities of reviewers, complainants, or other persons providing information contained in or participating in the creation of records of adverse medical incidents, may not, without limitation or exception, be subject to discovery or introduction into evidence, for any purpose, including impeachment, in any civil or administrative action in whatever form or cause of action against a health care facility or health care provider, and a person who provided information that was used in the preparation of the

record or who participated in the creation of the record is not permitted or required to testify in any such civil or administrative action as to any evidence or other matters used in the preparation of the record or that relate to the adverse medical incident covered by the record. However, information or documents otherwise available from other sources are not immune from discovery or use in any such civil or administrative action under this section. This section does not repeal or otherwise alter any existing restrictions on the discoverability or admissibility of records relating to adverse medical incidents otherwise provided by law, including, but not limited to, ss. 395.0191(8), 395.0193(8), and 766.101(5) nor to repeal or otherwise alter any immunity provided to persons providing information or participating in any peer review, medical review, or hospital committee otherwise provided by law, including, but not limited to, ss. 395.0191(7), 395.0193(5) and 766.101. This section does not require disclosure of documents that constitute or contain attorney-client communications or attorney work product information.

(6) WAIVER.--A patient may waive the right to request the records that are subject to the provisions of this section and Article X, s. 22, Florida Constitution, if any such waiver is in writing and signed by the patient or the patient's representative.

(7) APPLICABILITY.--This section shall apply to all records of adverse medical incidents made after November 2, 2004, and to all actions pending on or filed after November 3, 2004. A request for records which is made on or before November 3, 2006, is only eligible to receive records created on or after November 3, 2004. A request for records which is

made on or after November 3, 2006, is only eligible to receive records created within 24 months of the date of the request.

Section 2. Subsection (7) of section 381.0271, Florida Statutes, is amended and subsection (11) is added to that section, to read:

381.0271 Florida Patient Safety Corporation.--

(7) POWERS AND DUTIES.--

(a) In addition to the powers and duties prescribed in chapter 617, and the articles and bylaws adopted under that chapter, the corporation shall, directly or through contract:

1. Secure staff necessary to properly administer the corporation.

2. Collect, analyze, and evaluate patient safety data and quality and patient safety indicators, medical malpractice closed claims, and adverse incidents reported to the Agency for Health Care Administration and the Department of Health for the purpose of recommending changes in practices and procedures that may be implemented by health care practitioners and health care facilities to improve health care quality and to prevent future adverse incidents. Notwithstanding any other provision of law, the Agency for Health Care Administration and the Department of Health shall make available to the corporation any adverse incident report submitted under ss. 395.0197, 458.351, and 459.026. To the extent that adverse incident reports submitted under s. 395.0197 are confidential and exempt, the confidential and exempt status of such reports shall be maintained by the corporation.

3. Establish a "near-miss" patient safety reporting system. The purpose of the near-miss reporting system is to: identify potential systemic problems that could lead to

adverse incidents; enable publication of systemwide alerts of potential harm; and facilitate development of both facility-specific and statewide options to avoid adverse incidents and improve patient safety. The reporting system shall record "near misses" submitted by hospitals, birthing centers, and ambulatory surgical centers and other providers. For the purpose of the reporting system:

a. The term "near miss" means any potentially harmful event that could have had an adverse result but, through chance or intervention in which, harm was prevented.

b. The near-miss reporting system shall be voluntary and anonymous and independent of mandatory reporting systems used for regulatory purposes.

c. Near-miss data submitted to the corporation is patient safety data as defined in s. 766.1016.

d. Reports of near-miss data shall be published on a regular basis and special alerts shall be published as needed regarding newly identified, significant risks.

e. Aggregated data shall be made available publicly.

f. The corporation shall report the performance and results of the near-miss project in its annual report.

4. Work collaboratively with the appropriate state agencies in the development of electronic health records.

5. Provide for access to an active library of evidence-based medicine and patient safety practices, together with the emerging evidence supporting their retention or modification, and make this information available to health care practitioners, health care facilities, and the public. Support for implementation of evidence-based medicine shall include:

a. A report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Agency for Health Care Administration by January 1, 2005, on:

(I) The ability to join or support efforts for the use of evidence-based medicine already underway, such as those of the Leapfrog Group, the international group Bandolier, and the Healthy Florida Foundation.

(II) The means by which to promote research using Medicaid and other data collected by the Agency for Health Care Administration to identify and quantify the most cost-effective treatment and interventions, including disease management and prevention programs.

(III) The means by which to encourage development of systems to measure and reward providers who implement evidence-based medical practices.

(IV) The review of other state and private initiatives and published literature for promising approaches and the dissemination of information about them to providers.

(V) The encouragement of the Florida health care boards under the Department of Health to regularly publish findings related to the cost-effectiveness of disease-specific, evidence-based standards.

(VI) Public and private sector initiatives related to evidence-based medicine and communication systems for the sharing of clinical information among caregivers.

(VII) Regulatory barriers that interfere with the sharing of clinical information among caregivers.

b. An implementation plan reported to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Agency for Health Care Administration by September 1, 2005, that must include, but need not be

limited to: estimated costs and savings, capital investment requirements, recommended investment incentives, initial committed provider participation by region, standards of functionality and features, a marketing plan, and implementation schedules for key components.

6. Develop and recommend core competencies in patient safety that can be incorporated into the undergraduate and graduate curricula in schools of medicine, nursing, and allied health in the state.

7. Develop and recommend programs to educate the public about the role of health care consumers in promoting patient safety.

8. Provide recommendations for interagency coordination of patient safety efforts in the state.

(b) In carrying out its powers and duties, the corporation may also:

1. Assess the patient safety culture at volunteering hospitals and recommend methods to improve the working environment related to patient safety at these hospitals.

2. Inventory the information technology capabilities related to patient safety of health care facilities and health care practitioners and recommend a plan for expediting the implementation of patient safety technologies statewide.

3. Recommend continuing medical education regarding patient safety to practicing health care practitioners.

4. 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.

5. Conduct other activities identified by the board of directors to promote patient safety in this state.

(c) In lieu of any specific cases reported by any health care facility licensed under chapter 395 or any health care provider licensed under chapter 458 or chapter 459, the corporation may rely upon and use hypothetical cases in order to evaluate the quality assurance and patient safety programs of the health care facility and the health care provider.

(11) The investigations, proceedings, and records of the corporation as described in this section may not be subject to discovery or introduced into evidence in any civil or administrative action against a health care facility or health care provider arising out of the matters that are the subject of evaluation and review by the corporation or any of its committees, and any person who was in attendance at a meeting of the corporation or any of its committees are not permitted or required to testify in any such civil or administrative action as to any evidence or other matters produced or presented during the proceedings of the corporation or any of its committees as to any findings, recommendations, evaluations, opinions, or other actions of the corporation or any of its committees. However, except as otherwise provided by statute, information, documents, or records otherwise available from original sources are not immune from discovery or use in any such civil or administrative action merely because they were presented during proceedings of the corporation or any of its committees, and any person who testifies before or participates in the meetings of the corporation or any of its committees are not prevented from testifying as to matters within his or her knowledge. Such witness may not be asked about his or her testimony or participation in the proceedings of the corporation or any of its committees or opinions formed

by him or her as a result of participation in such proceedings.

Section 3. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are declared severable.

Section 4. This act shall take effect upon becoming a law.

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SENATE SUMMARY

Requires health care facilities and health care providers to observe certain delineated rights of patients. Provides that certain records obtained through the act may not be subject to discovery or introduced into evidence. Provides that the person responsible for providing or preparing such records cannot be compelled to testify about the information in the records. Provides that the limited use of records obtained through this act does not alter or repeal other statutory restrictions regarding discoverability or admissibility. Provides that the limited use of records in this act does not require disclosure of documents regarding attorney-client communications or attorney work product. Authorizes a patient to waive his or her right to request records under certain conditions. Provides for the applicability of the act to certain records. Authorizes the Florida Patient Safety Corporation to use hypothetical cases to evaluate quality assurance and safety programs. Prohibits investigations, proceedings, and records of the corporation from being discovered or introduced into evidence in any civil or administrative proceeding under certain circumstances. Provides that the person in attendance at a meeting of the corporation cannot be compelled to testify about the information, findings, opinions, or recommendations of the corporation.