SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Health Care Committee

BILL:	CS/ SB 938
SPONSOR:	Health Care Committee and Senator Peaden
SUBJECT:	Adverse Medical Incidents
DATE:	April 1, 2005 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HE	**Fav/CS**
2.			JU	
3.			WM	
4.				
5.				
6.				

I. Summary:

The committee substitute would implement s. 25, Art. X, of the State Constitution, which provides patients access to records of adverse medical incidents. The bill requires hospitals, ambulatory surgical centers, mobile surgical facilities, medical physicians, osteopathic physicians, and podiatric physicians to provide access to records of adverse medical incidents that occurred on or after November 2, 2004.

The bill defines terms; specifies patients' right of access to records relating to an adverse medical incident; prohibits the disclosure of the identity of certain patients; provides for maintaining privacy restrictions imposed by federal law; provides restrictions on the use of the records; provides a process for the identification and production of the records; and provides for fees charged for copies of records.

This bill creates s. 381.028, F.S.

II. Present Situation:

Constitutional Amendment 7

Constitutional Amendment 7, which had the ballot title "Patient's Right to Know About Adverse Medical Incidents," was proposed through the citizens' initiative process and was filed with the Secretary of State on April 1, 2003. The amendment was placed on the November 2, 2004 ballot and approved by the voters. The final certification by the Canvassing Commission of the vote for

the election of November 2, 2004, was November 14, 2004. The amendment provides that it takes effect on the date approved by the electorate.[1]

Amendment 7 is codified in s. 25, Article X of the Florida Constitution[2] and states:

> (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.
>
> (b) In providing such access, the identity of patients involved in the incidents shall not be disclosed, and any privacy restrictions imposed by federal law shall be maintained.
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> (c) For purposes of this section, the following terms have the following meanings:
>
> (1) The phrases "health care facility" and "health care provider" have the meaning given in general law related to a patient's rights and responsibilities.
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> (2) The term "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.
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> (3) The phrase "adverse medical incident" means 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.
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> (4) The phrase "have access to any records" means, in addition to any other procedure for producing such records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that current records which 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.

A number of trial court orders have been issued relating to Amendment 7, and these decisions are only binding on the parties to the order. There is no consensus on the legal issues relating to whether Amendment 7:

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[1] Amendment 7 provides that the "amendment shall be effective on the date it is approved by the electorate. If any portion of this measure is held invalid for any reason, the remaining portion of this measure, to the fullest extent possible, shall be severed from the void portion and given the fullest possible force and application."

[2] This section, originally designated section 22 by Amendment No. 7, 2004, was redesignated section 25 in order to avoid confusion with section 22, relating to parental notice of termination of a minor's pregnancy, as contained in Amendment No. 1, 2004, added by H.J.R. 1, 2004, adopted 2004.

- May have a retrospective application to records before its effective date[3], or
- Is a constitutional provision that is self-executing or not self-executing.

Some trial courts have granted motions for protective orders of documents requested under Amendment 7, and other trial courts have denied such orders or only granted them in part. Some trial courts have found that there is no intent for Amendment 7 to have retrospective application and other courts have found that Amendment 7 is retrospective. Some trial courts have expressly found that Amendment 7 is self-executing and other trial courts have found that Amendment 7 is not self-executing.

A constitutional provision may be self-executing and require no legislative action to put its terms into operation, or it may not be self-executing and require legislative action to make it operative. The test for determining whether a constitutional provision should be construed to be self-executing or not self-executing is whether the provision lays down a sufficient rule by means of which the right or purpose which it gives or is intended to accomplish may be determined, enjoyed, or protected without the aid of legislative enactment. See *Gray v. Bryant*, 125 So.2d 846 (Fla. 1960). Committee staff is not aware of any binding appellate decisions regarding whether Amendment 7, codified in s. 25, Art X of the Florida Constitution, is self-executing or not self-executing.

The summary below describes some of the trial court decisions involving Amendment 7:

Kendall v Dupree – St. Johns County Circuit Court (November 23, 2004) – Order issued: Information neither relevant nor admissible. On appeal to 5th DCA.

Florida Hospital Association, et al. v Agency for Health Care Administration and Department of Health - Leon County Circuit Court (December 7, 2004) – Order issued: No case in controversy, case dismissed without ruling on merits. On appeal to 1st DCA, the initial briefs have not yet been filed.

HCA, Health Services of Florida (Regional Medical Center Bayonet Point), et al. v Agency for Health Care Administration, et al. - Leon County Circuit Court (January 4, 2005) – Order issued: Denied Plaintiff's Motion for Temporary Injunction, reserved ruling on merits.

Bridgman v Health Management Associates (Pasco Hospital) - Pasco County Circuit Court (January 14, 2005) – Order issued: Amendment 7 is not self-executing.

Richardson v Nath, M.D. and St. Anthony's Hospital - Pinellas County Circuit Court (January 18, 2005) - Order issued: Amendment 7 not self-executing and not retroactive. Order was issued granting motion by St. Anthony's Hospital Motion for a protective order.

[3] "Unless specifically stated in the text or in the statement placed on the ballot, constitutional amendments are generally given prospective effect only." *In re Advisory Opinion to the Governor- Terms of County Court Judges*, 750 S0.2d 610 at 614. (Fla.1999). See also *State v. Lavazzoli*, 434 So.2d 321 at 323-324 (Fla.1983).

Rusiecki v Jackson-Curtis, M.D., and All Children's Hospital - Pinellas County Circuit Court (January 31, 2005) Order issued: Amendment 7 not self-executing and not retroactive and Order was issued granting motion by All Children's Hospital Motion for a protective order.

McHale v Tenewitz, M.D. and Omni Health Care, P.A. - Brevard County Circuit Court (February 28, 2005) – Ordered issued: Amendment 7 is self-executing and retroactive. Order was issued denying defendant's motion for a protective order.

Mullen v Miller - Dade County Circuit Court (February 24, 2005) - Ordered issued: Amendment 7 not retroactive.

Michota v Bayfront Medical Center and Hirsh, M.D. - Pinellas County Circuit Court (February 24, 2005) – Order issued: Amendment 7 is not retroactive but is self-executing. Amendment 7 does not impact existing litigation rules of admissibility but information can be discovered. Defendant's motion for a protective order granted and denied in part.

The Florida Patient's Bill of Rights and Responsibilities

Section 381.026, F.S., creates the "Florida Patient's Bill of Rights and Responsibilities," which includes a listing of rights related to individual dignity, basic information rights, the right to grievances, the right to obtain information related to accepted payment by the facility, the right to be provided a reasonable estimate of the expected charges, the right to access to emergency care, and the right to know if the treatment is for the purpose of experimental research. In addition, the current statutes specify the responsibilities of a patient of a health care facility and or health care provider. This section defines *health care facility* as a facility licensed under ch. 395, F.S. Hospitals, ambulatory surgical centers and mobile surgical facilities are licensed under ch. 395, F.S. A *health care provider* is defined as a physician licensed under ch. 458, F.S., an osteopathic physician licensed under ch. 459, F.S., or a podiatric physician licensed under ch. 461, F.S. In s. 25, Art. X of the Florida Constitution, the phrases "health care facility" and "health care provider" have the meaning given in general law relating to a patient's rights and responsibilities. Thus, the requirements of s. 25, Art. X, apply to hospitals, ambulatory surgical centers, mobile surgical facilities, medical physicians, osteopathic physician, and podiatric physicians.

Adverse Medical Incidents

In 1999, the Institute of Medicine reported that at least 44,000, and perhaps as many as 98,000, American hospital patients die each year as a result of medical error. The lower number is extrapolated from a study conducted in Colorado and Utah and the higher number from a study in New York. Medication errors both in and out of the hospital account for more than 7,000 deaths annually.[4]

As the 2003 Legislature addressed Florida's medical malpractice insurance crisis, the reduction of medical errors received renewed attention as one method of lowering the number of

[4] Institute of Medicine, Kohn, Linda T., Corrigan, Janet M., and Donaldson, Molla S., Eds. *To Err is Human: Building a Safer Health System*, National Academy Press. 1999.

malpractice claims. A review of professional liability closed-claims data for the period 1990 - 2002 revealed that, in each of those years, more than 60 percent of indemnity claims paid in Florida were for injuries that occurred in the hospital setting.

At present, Florida's system for reporting adverse medical incidents that occur in licensed facilities assures confidentiality to the facility, the providers involved in the incident, and to the employees who report an incident. Confidentiality is based on the premise that many adverse incidents are caused by a breakdown in a system rather than because of a single individual's action or inaction. Providing for reporting in a blame-free environment is thought to encourage individuals to contribute information that will enable the facility to correct the malfunction in a system. If "near-misses" are reported in a blame free environment, the facility could correct a problem before a patient suffers harm.

Section 395.0197, F.S., requires every licensed hospital, ambulatory surgical enter, and mobile surgical facility to have an internal risk management program that includes the following components:

- The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.
- The development of appropriate measures to minimize the risk of adverse incidents to patients.
- The analysis of patient grievances that relate to patient care and the quality of medical services.
- A system for informing a patient or the patient's health care proxy according to s. 765.401(1), F.S., that the patient was the subject of an adverse incident.
- The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

For purposes of submitting an annual report to the Agency for Health Care Administration (AHCA), the statute defines adverse incident to be:

- An event over which health care personnel could exercise control, which is associated with the medical intervention rather than the condition for which the intervention was performed, and which resulted in one of the following:
  - Death;
  - Brain or spinal damage;
  - Permanent disfigurement;
  - Fracture or dislocation of bones or joints;
  - Limitation of neurological, physical, or sensory functioning;
  - Any condition that required specialized medical attention or surgical intervention; or
  - Any condition that required transfer of the patient to another facility or a unit providing a more acute level of care.

- 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;
- 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
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.

Under s. 395.0197(6)(c), F.S., the annual report summarizing the adverse incidents in each facility is confidential and is not available to the public pursuant to a public records request under s. 119.07(1), F.S.

A hospital must report to AHCA within 15 days of the occurrence of any of the following incidents:

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- The performance of a wrong-site surgical procedure;
- The performance of a wrong surgical procedure;
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;
- The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.

This 15-day report is popularly known as a “Code 15 report.” AHCA may investigate these code 15 incidents as it deems appropriate and prescribe measures that must be taken, or may be taken, in response to the incident. Under s. 395.0197(7), F.S., the code 15 reports are exempt from the public records law and are not available to the public.

The Agency for Health Care Administration may have access to all facility records necessary to carry out the reviews of adverse incidents. Under s. 395.0197(13), F.S., the records obtained by AHCA are not available to the public.

Reports of Adverse Incidents in Physician Office Practice Settings

Under s. 458.351, F.S., any adverse incident that occurs on or after January 1, 2000, in any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S., must be reported to the Department of Health. Any physician or other licensee under ch. 458, F.S., who is practicing in Florida, must notify the department if he or she was involved in an adverse incident that occurred on or after January 1, 2000, in any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

The required notification must be submitted to the department in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident. For purposes of notification, the term “adverse incident” means an event over which the physician or licensee could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

- The death of a patient.
- Brain or spinal damage to a patient.
- The performance of a surgical procedure on the wrong patient.
- The performance of a wrong-site surgical procedure; the performance of a wrong surgical procedure; or the surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process if any of these result in death; brain or spinal damage; permanent disfigurement not to include the incision scar; fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory function; or any condition that required the transfer of the patient.
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.
- Any condition that required the transfer of a patient to a hospital licensed under ch. 395, F.S., from an ambulatory surgical center licensed under ch. 395, F.S., or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

The Department of Health must review each incident and determine whether it potentially involved conduct by a health care professional who is subject to disciplinary action, in which case s. 456.073, F.S. applies. Disciplinary action, if any, must be taken by the board under which the health care professional is licensed.

Under s. 459.026, F.S., these same provisions apply to osteopathic physicians.

Peer Review in Licensed Facilities

Under s. 395.0193, F.S., as a condition of licensure, each licensed facility must provide for peer review of physicians who deliver health care services at the facility. If there is reasonable beliefs that conduct by a staff member may constitute one or more grounds for discipline, a peer review panel must investigate and determine whether grounds for discipline exist. The possible grounds for discipline are:

- Incompetence.
- Being found to be a habitual user of intoxicants or drugs to the extent that he or she is deemed dangerous to himself, herself, or others.
- Mental or physical impairment which may adversely affect patient care.
- Being found liable by a court of competent jurisdiction for medical negligence or malpractice involving negligent conduct by the staff member.
- Medical negligence other than as specified above.

- Failure to comply with the policies, procedures, or directives of the risk management program or any quality assurance committees of any licensed facility.

Any disciplinary action taken against a staff member must be reported to the Division of Health Quality Assurance of AHCA within 30 working days after its initial occurrence. The division must review each report and determine whether it potentially involves conduct by the licensee that is subject to disciplinary action under s. 456.073, F.S. The proceedings of peer review panels and the reports to AHCA are exempt from the public records requirements of s. 119.07(1), F.S.

Access to Patients' Protected Health Information

In Florida, patients have a constitutional right to privacy under Article I, Section 23 of the State Constitution, and judicial decisions. Although Florida courts have recognized patients' rights to secure the confidentiality of their health information (medical records) under the right to privacy under the State Constitution, that right must be balanced with, and yields to, any compelling state interest. Since 1951, Florida law (ch. 26684, L.O.F.) has granted a patient access to his or her own medical records and has required the health care practitioner who created the records to maintain the confidentiality of the records. Two primary sections of Florida law address medical records and grant patients access to their health information. Section 456.057, F.S., deals with the confidentiality of, and patient's access to, medical records created by specified health care practitioners, including medical physicians. Section 395.3025, F.S., addresses the confidentiality of, and patient's access to, medical records held by a Florida hospital. In addition to ss. 456.057 and 395.3025, F.S., a number of statutory provisions and administrative agency rules provide additional confidentiality and patient access for specialized individual health information.

The federal Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, (HIPAA) protects the privacy of certain health information. The United States Department of Health and Human Services (HHS) issued Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) on December 28, 2000, which were originally scheduled to go into effect on February 26, 2001. The effective date for the Privacy Rule was delayed and the rule took effect on April 14, 2003. The regulations only apply to covered entities (health providers who engage in certain electronic transactions, health plans, and health care clearinghouses). HHS issued transaction and code sets rules for which the compliance date was October 16, 2003. Compliance with a security rule under HIPAA is not mandated until April 2005.

The HIPAA regulations, at 45 CFR S. 160.103, define "individually identifiable health information" as information that is a subset of health information, including demographic information collected from an individual, and:

> (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
>
> (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment of the provision of health care to an individual; and
>
> (i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Hospitals' Patient and Personnel Records

Section 395.3025, F.S., governs access to hospitals' patient and personnel records. Section 395.3025(4), F.S., makes patient records confidential and prohibits the disclosure of the records without the consent of the person to whom they pertain. However, this subsection permits disclosure without the patient's consent to specified state agencies, the State Long-Term Care Ombudsman Council, a local or regional trauma agency, and organ procurement organizations for the purposes specified in the statute.

Section 395.3025(9), F.S., permits a facility to prescribe the content and custody of limited-access records that the facility may maintain on its employees. The statute limits these records to information regarding evaluations of employee performance including records forming the basis for evaluation and subsequent actions. Such limited-access records are exempt from public records requirements under s. 119.07(1), F.S.

Section 395.3025(1), F.S., establishes maximum fees for furnishing a patient or a representative of the patient a complete copy of all patient records, provided the person requesting the records agrees to pay a charge. The charge may include sales tax and actual postage and, except for nonpaper records that are subject to a charge not to exceed $2, the charge may not exceed $1 per page.

Confidentiality of Health Care Practitioners' Records

Section 456.057, F.S., establishes requirements for ownership and control of patient records by a health care practitioner or health care practitioner's employer. This section prohibits furnishing copies of records to, or discussing a patient's condition with, any person other than the patient or the patient's legal representative or other health care practitioners and providers except upon written consent of the patient. The section provides exceptions to this requirement under limited circumstances.

Discoverability or Admissibility of Records in Legal Proceedings

Certain statutes protect records of health care facilities and health care providers from discoverability or admissibility in legal proceedings. Under s. 395.0101, F.S., which governs staff membership and clinical privileges at a licensed health care facility, investigative proceedings and records of the board or the board's agent are not subject to discovery and may not be introduced into evidence in a civil action against a provider. Under s. 395.0193, F.S., peer review records and investigative proceedings are not subject to discovery and may not be introduced into evidence in a civil or administrative action against a provider. Under s. 395.0197, F.S., which governs the internal risk management programs of health care facilities, incident reports are part of the working papers of the attorney defending the licensed facility and are not subject to discovery or admissible as evidence in court. Under ss. 766.101 and 766.1016, F.S., relating to medical malpractice, the investigations, proceedings, and records of a medical review

committee and patient safety data are not subject to discovery and may not be introduced into evidence in a civil or administrative action against a provider.

III. Effect of Proposed Changes:

Section 1. Creates s. 381.028, F.S., concerning adverse medical incidents.

Subsection (1) provides that the act may be cited as the "Patients' Right-to-Know About Adverse Medical Incidents Act."

Subsection (2) states that the purpose of this act to implement s. 25, Art. X of the State Constitution. The bill states a legislative finding that this section of the State Constitution is intended to grant patient access to records of adverse medical incidents, which records were made or received in the course of business by a health care facility or provider, and not to repeal or otherwise modify existing laws governing the use of these records and the information contained therein. The bill also states a legislative finding that all existing laws extending criminal and civil immunity to persons providing information to quality-of-care committees or organizations and all existing laws concerning the discoverability or admissibility into evidence of records of an adverse medical incident in any judicial or administrative proceeding remain in full force and effect.

Subsection (3) provides definitions for terms "as used in s. 25, Art. X of the State Constitution and this act." The bill defines the following terms:

Agency means the Agency for Health Care Administration.

Adverse medical incident means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider which caused or could have caused injury to or the 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, incidents that are 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 committee.

Department means the Department of Health.

Have access to any records means, in addition to any other procedure for producing the records provided by general law, making the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that 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.

Health care provider means a physician licensed under ch. 458, ch. 459, or ch. 461, F.S.

Health care facility means a facility licensed under ch. 395, F.S.

Identity means any "individually identifiable health information" as defined by the Health Insurance Portability and Accountability Act of 1996 or it's implementing regulations.

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.

Privacy restrictions imposed by federal law means the provisions relating to the disclosure of patient privacy information under federal law, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 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 other federal law, including, but not limited to, federal common law and decisional law, that would prohibit the disclosure of patient privacy information.

Records mean the final report of any adverse medical incident. Medical records that are not the final report of any adverse medical incident, including drafts or other nonfinal versions; notes; and any documents or portions thereof which constitute, contain, or reflect, any attorney-client communications or any attorney-client work product may not be considered "records" for purposes of s. 25, Art. X of the State Constitution and this bill.

Representative of the patient means a parent of a minor patient, a court-appointed guardian for the patient, a health care surrogate, or a person holding a power of attorney or notarized consent appropriately executed by the patient granting permission to a health care facility or health care provider to disclose the patient's health care information to that person. In the case of a deceased patient, the term also means the personal representative of the estate of the deceased patient; the deceased patient's surviving spouse, surviving parent, or surviving adult child; the parent or guardian of a surviving minor child or the deceased patient; or the attorney for any such person.

Subsection (4) provides that patients have a right to have access to any records made or received in the course of business by a health care facility or health care provider relating to any adverse medical incident. In providing access to these records, the health care facility or health care provider may not disclose the identity of patients involved in the incidents and must maintain any privacy restrictions imposed by federal law.

Subsection (5) provides that s. 25, Art. X of the State Constitution applies to records created, incidents occurring, and actions pending on or after November 2, 2004; s. 25, Art. X of the State Constitution does not apply to records created, incidents occurring, or actions pending before November 2, 2004. A patient requesting records on or after November 2, 2008, will be eligible to receive records created within 4 years before the date of the request.

Subsection (6) restricts the use of records obtained by patients under the provisions of s. 25, Art. X of the State Constitution. The bill provides that s. 381.028, F.S., created in this bill, 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, those contained in ss. 395.0191, 395.0193, 395.0197, 766.101, and 766.1016, F.S., or repeal or otherwise alter any immunity provided to, or prohibition against compelling testimony by, persons providing information or participating in any peer review panel, medical review

committee, hospital committee, or other hospital board otherwise provided by law, including, but not limited to, ss. 395.0191, 395.0193, 766.101, and 766.1016, F.S.

Except as otherwise provided by act of the Legislature, records of adverse medical incidents, including any information contained therein, obtained under s. 25, Art. X of the State Constitution, are not discoverable or admissible into evidence and may not be used for any purpose, including impeachment, in any civil or administrative action against a health care facility or health care provider. This includes information relating to performance or quality-improvement initiatives and information relating to the identity of reviewers, complainants, or any person providing information contained in or used in, or any person participating in the creation of the records of adverse medical incidents.

Subsection (7) states that, "pursuant to s. 25, Art. X of the State Constitution," the adverse medical incident records to which a patient is granted access are those of the facility or provider of which he or she is a patient and which pertain to any adverse medical incident affecting the patient or any other patient which involves the same or substantially similar condition, treatment, or diagnosis as that of the patient requesting access.

The bill requires the health care facility or health care provider to identify the records that meet the requirements of s. 25, Art. X of the State Constitution:

- Using the process provided in s. 395.0197, the health care facility must be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution.

- Using the process provided in s. 458.351, the health care provider shall be responsible for identifying records as records of an adverse medical incident, as defined in s. 25, Art. X of the State Constitution, occurring in an office setting.

Fees charged by a health care facility for copies of records requested by a patient under s. 25, Art. X of the State Constitution may not exceed the reasonable and actual cost of complying with the request, including a reasonable charge for the staff time necessary to search for records and prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means as required by HIPAA or its implementing regulations. The health care facility may require payment, in full or in part, before acting on the records request.

Fees charged by a health care provider for copies of records requested by a patient under s. 25, Art. X of the State Constitution may not exceed the amount established under s. 456.057(16), which may include a reasonable charge for the staff time necessary to prevent the disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means as required by HIPAA or its implementing regulations. The health care provider may require payment, in full or in part, before acting on the records request.

Requests for production of adverse medical incident records must be processed by the health care facility or health care provider in a timely manner, after having a reasonable opportunity to determine whether or not the requested record is a record subject to disclosure and to prevent the

disclosure of the identity of any patient involved in the adverse medical incident through redaction or other means.

A request for production of records must be submitted in writing and must identify the patient requesting access to the records by name, address, and the last four digits of the patient's social security number; describe the patient's condition, treatment, or diagnosis; and provide the name of the health care providers whose records are being sought.

Section 2. The effective date of the bill is upon the bill becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

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

D. Other Constitutional Issues:

The bill implements s. 25, Art. X of the State Constitution. A constitutional provision may be self-executing and require no legislative action to put its terms into operation or it may not be self executing and require legislative action to make it operative. The test for determining whether a constitutional provision should be construed to be self-executing or not self-executing is whether the provision lays down a sufficient rule by means of which the right or purpose which it gives or is intended to accomplish may be determined, enjoyed, or protected without the aid of legislative enactment. See *Gray v. Bryant*, 125 So.2d 846 (Fla. 1960). Committee staff is not aware of any binding appellate decisions regarding whether s. 25, Art X of the State Constitution is self-executing or not self-executing.

While the bill defines patient as the constitution does—an individual who has sought, is seeking, is undergoing, or has undergone treatment in a health care facility or by a health care provider—the bill significantly narrows that definition by limiting the records to which a patient can have access to those of the facility or provider of which he or she is a patient and which pertain to any adverse medical incident affecting the patient or any other patient which involves the same or substantially similar condition, treatment, or diagnosis as that of the patient requesting access. This limitation is enforced by the requirement that a person seeking records of adverse medical incidents must do so in

writing and provide the "patient's" name and address, the last 4 digits of his or her social security number, his or her condition, treatment, or diagnosis, and the name of the health care providers whose records are being sought. These restrictions would make it impossible for a person seeking treatment to obtain records of adverse medical incidents as is provided in the constitution.

While the constitution provides that "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 adverse medical incidents," the bill limits records to a "final report" and excludes "any documents or portions thereof which constitute, contain, or reflect any attorney-client communications or any attorney-client work product." The bill further limits a patient's access to records by requiring a patient requesting records of adverse medical incidents to provide the name of the health care providers whose records are being sought. Thus, the requestor would have ask for records of a health care facility by providing the name of each physician whose records were sought, and a health care facility would not have to provide records of all adverse incidents that occurred at the facility unless the requestor gave the name of each physician involved in adverse medical incidents at the facility. The bill also limits the records to which a patient may have access after November 2, 2008, to those records made within 4 years of the request.

Another possible limitation is placed on the types of records to which a patient could have access by the requirement that a health care facility must use the process provided in s. 395.0197, F.S., and a provider must use the process provided in s. 458.351, F.S., to identify adverse medical incident records. Those statutes define certain types of adverse incidents which must be reported, and this requirement in the bill could limit patients' access to only those types of adverse incidents. Further, the reports of adverse incidents that must be reported under s. 395.0197, F.S., are confidential, and the bill's requirement that existing law governing adverse medical incidents must remain in force could have the effect of making no records at all available from a health care facility.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Private hospitals, ambulatory surgical centers, mobile surgical facilities, medical physicians, osteopathic physicians, and podiatric physicians would incur the cost of providing patients access to records of adverse medical incidents occurring after November 2, 2004. These facilities and physicians are authorized to charge fees to recover these costs.

C. Government Sector Impact:

Public hospitals, ambulatory surgical centers, mobile surgical facilities would incur the cost of providing patients access to records of adverse medical incidents occurring after November 2, 2004. These facilities are authorized to charge fees to recover these costs.

VI. Technical Deficiencies:

It appears that the words "incidents that are reported to any governmental agency or body" on page 2, lines 19 and 20, may be a scrivener's error, since those words are not in the definition of "adverse medical incident" in the constitution.

VII. Related Issues:

While the constitution is silent regarding what use the patients may make of the records, the bill provides restrictions on the use of the records. All existing laws concerning the discoverability or admissibility into evidence of records of adverse medical incidents in any judicial or administrative proceeding remain in full force and effect. Laws that prohibit compelling testimony by a person providing information or participating in a peer-review panel, medical review committee, hospital committee or other hospital board remain in effect.

The bill incorporates by specific reference certain federal laws that protect the confidentiality of patient health information—the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-91 (HIPAA) and its implementing regulations, and the Federal Privacy Act, 5 U.S.C. s. 552(a) and it's implementing regulations. Such a specific reference will usually be treated as a reference to those laws only as they existed at the time the reference was adopted[5]. The general reference in the bill to "any other federal law, including, but not limited to, federal common law and decisional law, that would prohibit the disclosure of patient privacy information" would be treated as general cross-references incorporating future amendments.

On page 3, lines 15-16 and 23, the term "patient privacy information" is used. There is no definition of this term.

[5] *Manual for Drafting General Bills.* The Florida Senate. 1999. p. 104.

VIII. Summary of Amendments:

None.