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:	PCS/ SB 938
SPONSOR:	Health Care Committee and Senator Peaden
SUBJECT:	Adverse Medical Incidents
DATE:	March 14, 2005
REVISED:	03/25/05

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HE	**Pre-meeting**
2.			JU	
3.			WM	
4.				
5.				
6.				

I. Summary:

The proposed committee substitute amends statutes and creates statutes in order to 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 requires timely availability of the records and specifies charges for copies of the records. The bill establishes fines for failure to provide access to the records and for disclosing the identity of a patient involved in an incident.

This bill substantially amends ss. 395.0193, 395.0197, 395.3025, 395.51, and 456.057, F.S. The bill creates ss. 395.3016, 458.352, 459.027, and 461.019, 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.
>
> (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.
>
> (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.
>
> (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.
>
> (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:

- May have a retrospective application to records before its effective date[3], or

[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.

- 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.

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.

[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).

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 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.

[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.

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 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.

AHCA 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 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 belief 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.

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 and Quality Assurance Activities of Trauma Agencies

Section 395.51, F.S., provides that confidential information that is obtained by a local or regional trauma agency retains its confidential status and is exempt from the public records provisions of s. 119.07(1), F.S. This exemption pertains to records obtained by a hospital.

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.

III. Effect of Proposed Changes:

The proposed committee substitute would amend statutes and create statutes in order to implement s. 25, Art. X, of the State Constitution.

Section 1. Creates s. 395.3016, F.S., to provide that a patient who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility licensed under ch. 395, F.S., has a right to have access to any records made or received in the course of business by the health care facility relating to any adverse medical incident. In providing such access, a facility may not disclose the identity of patients involved in the incidents, and any privacy restrictions imposed by federal law must be maintained. This section applies only to records of adverse medical incidents that occur on or after November 2, 2004.

For the purposes of this requirement, *adverse medical incident* means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider as defined in s. 381.026, F.S., 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.

In addition to any other procedure for producing such records provided by general law, a facility must make 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. The records must be made available in a timely manner without delay for legal review. The records must be made available at reasonable times of day and days of the week within the facility's business hours. The exclusive charge for copies of the records may include sales tax and actual postage, and, except for nonpaper records that are subject to a charge not to exceed $2, may not exceed $1 per page. These charges shall

apply to all records furnished, whether directly from the facility or from a copy service providing these services on behalf of the facility.

The bill establishes fines for failure to comply with the requirements of this section. The failure of a facility to provide access to the records, or to provide copies if requested, shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by AHCA. A facility that discloses the identity of a patient in the provision of the records shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by AHCA.

Section 2. Amends s. 395.0193, F.S., to provide access to peer review reports and records of peer review proceedings that contain records of adverse medical incidents that must be made available under s. 25, Art. X, of the State Constitution and s. 395.3016, F.S.

Section 3. Amends s. 395.0197, F.S., to provide access to adverse incident reports and records of adverse incidents reported to AHCA that must be made available under s. 25, Art. X, of the State Constitution and s. 395.3016, F.S.

Section 4. Amends s. 395.3025, F.S., to require a hospital, ambulatory surgical center, or mobile surgical facility, to provide access to records of adverse medical incidents that must be made available under s. 25, Art. X, of the State Constitution and s. 395.3016, F.S. When patient records are provided, the facility must not disclose the identity of a patient who is the subject of the records. A facility must also provide employee records that include records of an adverse medical incident.

Section 5. Amends s. 395.51, F.S., to require a trauma agency to provide access to a hospital's records of adverse medical incidents that must be made available under s. 25, Art. X, of the State Constitution and s. 395.3016, F.S.

Section 6. Amends s. 456.057, F.S., to require a practitioner who owns patient records to make available upon request those records that must be made available under s. 25, Art. X, of the State Constitution and s. 458.352, s. 459.027, or s. 461.019, F.S.

Section 7. Creates s. 458.352, F.S., to provide that a patient who has sought, is seeking, is undergoing, or has undergone care or treatment by a physician licensed under ch. 458, F.S., has a right to have access to any records made or received in the course of business by the physician relating to any adverse medical incident. In providing such access, the identity of patients involved in the incidents must not be disclosed, and any privacy restrictions imposed by federal law must be maintained. This section applies only to records of adverse medical incidents that occur on or after November 2, 2004.

For the purpose of this requirement, *adverse medical incident* means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility licensed under ch. 395, F.S., or health care provider as defined in s. 381.026, F.S., 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.

In addition to any other procedure for producing such records provided by general law, a physician must make 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. The records must be made available in a timely manner without delay for legal review. The records must be made available at reasonable times of day and days of the week within the physician's business hours. The charge for copies of the records must be no more than the actual cost of copying, including reasonable staff time, and the charges may not exceed $1.00 per page for the first 25 pages and 25 cents per page for each page in excess of 25 pages. These charges shall apply to all records furnished, whether directly from the physician or from a copy service providing these services on behalf of the physician.

The failure of a physician to provide access to the records, or to provide copies if requested, shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by the board. A physician who discloses the identity of a patient in the provision of the records shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by the board.

Section 8. Creates s. 459.027, F.S., to provide that a patient who has sought, is seeking, is undergoing, or has undergone care or treatment by an osteopathic physician licensed under ch. 459, F.S., has a right to have access to any records made or received in the course of business by the osteopathic physician relating to any adverse medical incident. In providing such access, the identity of patients involved in the incidents shall not be disclosed, and any privacy restrictions imposed by federal law must be maintained. This section applies only to records of adverse medical incidents that occur on or after November 2, 2004.

For the purpose of this requirement, *adverse medical incident* means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility licensed under ch. 395, F.S., or health care provider as defined in s. 381.026, F.S., 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.

In addition to any other procedure for producing such records provided by general law, an osteopathic physician must make 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. The records must be made available in a timely manner without delay for legal review. The records must be made available at reasonable times of day and days of the week within the physician's business hours. The charge for copies of the records must be no more than the actual cost of copying, including reasonable staff time, and the charges may not exceed $1.00 per page for the first 25 pages and

25 cents per page for each page in excess of 25 pages. These charges shall apply to all records furnished, whether directly from the physician or from a copy service providing these services on behalf of the physician.

The failure of a physician to provide access to the records, or to provide copies if requested, shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by the board. A physician who discloses the identity of a patient in the provision of the records shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by the board.

Section 9. Creates s. 461.019, F.S, to provide that a patient who has sought, is seeking, is undergoing, or has undergone care or treatment by a podiatric physician licensed under this chapter has a right to have access to any records made or received in the course of business by the podiatric physician relating to any adverse medical incident. In providing such access, the identity of patients involved in the incidents shall not be disclosed, and any privacy restrictions imposed by federal law must be maintained. This section applies only apply to records of adverse medical incidents that occur on or after November 2, 2004.

For the purpose of this requirement, “adverse medical incident” means medical negligence, intentional misconduct, and any other act, neglect, or default of a health care facility licensed under ch. 395, F.S., or health care provider as defined in s. 381.026, F.S., 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.

In addition to any other procedure for producing such records provided by general law, a podiatric physician must make 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. The records must be made available in a timely manner without delay for legal review. The records must be made available at reasonable times of day and days of the week within the physician’s business hours. The charge for copies of the records must be no more than the actual cost of copying, including reasonable staff time, and the charges may not exceed $1.00 per page for the first 25 pages and 25 cents per page for each page in excess of 25 pages. These charges shall apply to all records furnished, whether directly from the physician or from a copy service providing these services on behalf of the physician.

The failure of a podiatric physician to provide access to the records, or to provide copies if requested, shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by the board. A physician who discloses the identity of a patient in the provision of the records shall be punished by a fine of up to $500 for a nonwillful violation and up to $1,000 for a willful violation, to be imposed and collected by the board.

Section 10. 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 Florida 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 Florida Constitution is self-executing or not self-executing.

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:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.