

# 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: Judiciary Committee

BILL: CS/SB 938

SPONSOR: Health Care Committee and Senator Peadar

SUBJECT: Adverse Medical Incidents

DATE: April 5, 2005

REVISED: 04/07/05

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harkey	Wilson	HE	Fav/CS
2.	Cibula	Maclure	JU	Fav/4 amendments
3.			HA	Withdrawn
4.			WM	Withdrawn
5.			RC	Withdrawn
6.				

## Please see last section for Summary of Amendments

- Technical amendments were recommended
- Amendments were recommended
- Significant amendments were recommended

### I. Summary:

This committee substitute is designed to clarify and implement the provisions of Amendment 7, the Patients' Right to Know About Adverse Medical Incidents amendment to the State Constitution. Accordingly, this committee substitute: specifies how a patient may obtain records of adverse medical incidents; identifies the records to which Amendment 7 applies; and states how the records may be used.

This bill creates section 381.028, Florida Statutes.

### II. Present Situation:

Under existing statutory law, patients generally have access to their medical records.<sup>1</sup> Patients must also be informed when they have been subjected to adverse incidents.<sup>2</sup> Although a patient must be informed of adverse incidents, existing statutory law does not provide patients with access to all of the records related to an adverse incident.<sup>3</sup>

<sup>1</sup> See ss. 395.3025 and 456.057(4), F.S.

<sup>2</sup> See ss. 395.1051 and 456.0575, F.S.

<sup>3</sup> See ss. 395.0193, 395.0197, 458.337, 459.016, and 766.101, F.S.

## Amendment 7

Amendment 7, which was approved by the voters in the November 2, 2004, general election, and codified as s. 25, Art. X, State Const., provides patients with access to all records related to adverse incidents.<sup>4</sup> The text of Amendment 7 is reproduced below.

### **Patients' right to know about adverse medical incidents.—**

(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.

The Florida Supreme Court in its advisory opinion on Amendment 7 stated:

Unquestionably, the amendment would affect sections 395.0193(8) and 766.101(5) of the Florida Statutes (2003), which currently exempt the records of investigations, proceedings, and records of the peer review panel from discovery

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<sup>4</sup> Amendment 7 was the seventh constitutional amendment proposal on the November 2, 2004, general election ballot. See Department of State, Division of Elections, November 2, 2004 General Election: Official Results, at <http://election.dos.state.fl.us/elections/resultsarchive/index.asp>.

in a civil or administrative action. Indeed, this is a primary purpose of the amendment.<sup>5</sup>

### **Enforcement of Amendment 7**

Trial courts reviewing the provisions of Amendment 7 have not reached a consensus on whether the amendment requires legislative implementation or whether the amendment may be applied retroactively. No appellate courts have issued opinions on the enforceability of Amendment 7 as of the date of this staff analysis. Three of the trial court orders have found that Amendment 7 applies prospectively from its effective date of November 2, 2004, and requires implementation by the Legislature.<sup>6</sup> One order found that Amendment 7 is not self-executing, but expressly declined to determine whether the amendment is retroactive.<sup>7</sup> One order found that Amendment 7 is self-executing and prospective only.<sup>8</sup> One order found that Amendment 7 is prospective.<sup>9</sup> One order found that Amendment 7 is both self-executing and retroactive.<sup>10</sup>

### **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, State Const., appear to apply to hospitals, ambulatory surgical centers, mobile surgical facilities, medical physicians, osteopathic physicians, and podiatric physicians.

### **Access to Patients' Protected 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 was originally scheduled to go

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<sup>5</sup> *Advisory Opinion to the Attorney General re Patients' Right to Know about Adverse Medical Incidents*, 880 So. 2d 617, 620-621 (Fla. 2004).

<sup>6</sup> *Richardson v. Nath*, 2005 WL 408132 (Fla. 6th Cir. Ct. 2005); *Rusiecki v. Jackson-Curtis, M.D.*, 2005 WL 408133 (Fla. 6th Cir. Ct. 2005); and *Brown v. Graham, M.D.*, Case No.501999CA007754 XXXXMPAF (Fla. 15th Cir. Ct. Mar. 18, 2005).

<sup>7</sup> *Bridgman v. Health Management Assoc., Inc.*, Case No. 51-04-CA-59-ES (Fla. 6th Cir. Ct. Jan. 14, 2005).

<sup>8</sup> *Michota v. Bayfront Medical Center*, Case No. 04-1057-CI-19 (Fla. 6th Cir. Ct. Feb. 24, 2005).

<sup>9</sup> *Mullen v. Miller*, Case No. 98-21149 CA (09) (Fla. 11th Cir. Ct. Feb. 24, 2005).

<sup>10</sup> *McHale v. Tenewitz, M.D.*, Case No. 05-2003-CA-054153-XXXX-XX (Fla. 18th Cir. Ct. Feb. 28, 2005).

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).

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.

### **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. 395.0191, F.S., which governs staff membership and clinical privileges at a licensed health care facility, investigative proceedings and records of the facility 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:**

This committee substitute is designed to clarify and implement the provisions of Amendment 7, the Patients’ Right to Know About Adverse Medical Incidents amendment to the State Constitution. Accordingly, this committee substitute: specifies how a patient may obtain records of adverse medical incidents; identifies the records to which Amendment 7 applies; and states how the records may be used.

#### **Process for Accessing Records**

A patient must request access in writing to records of adverse medical incidents. These records must be provided to the patient in a “timely manner.” A patient must pay the actual cost for the facility to comply with the request, including the cost of staff time to search for the records and

redact personal identifying information. A health care facility or provider “may require payment, in full or in part, before acting on [a] records request.”

## **Records to Which Amendment 7 Applies**

### ***Adverse Medical Incident Records***

The committee substitute directs health care facilities and providers to use the processes provided in s. 395.0197 and s. 458.351, F.S. to identify records of adverse medical incidents. A record is “the final report of any adverse medical incident.” Sections 395.0197 and 458.351, F.S., however, require health care facilities and certain health care providers to report “adverse incidents” to government agencies. An “adverse incident” as used in s. 395.0197 and s. 458.351, F.S., appears to be much narrower than the definition of “adverse medical incident” provided in Amendment 7.<sup>11</sup> As such, the committee substitute appears to provide access only to adverse incident reports made to government agencies as opposed to “any record” . . . “relating to any adverse medical incident.”

### ***Patient Records from Patient’s Health Care Facility or Provider***

Under the provisions of Amendment 7 and the committee substitute, “[p]atients 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.” Under Amendment 7, “[t]he 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.” This constitutional definition is arguably broad enough that a person who was a patient anywhere in this state is also a patient of any other health care facility or provider in this state. The committee substitute codifies the

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<sup>11</sup> Section 395.0197(5), F.S., for example, defines an “adverse incident” as:

For purposes of reporting to the agency pursuant to this section, the term “adverse incident” means an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:

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

constitutional definition of patient. However, the committee substitute also appears to restrict the definition of patient by limiting patient access to records 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.<sup>12</sup>

#### ***Applicable Health Care Facilities and Providers***

The committee substitute provides that the adverse incident records to which Amendment 7 applies are records made or received by health care providers licensed under chs. 458, 459, and 461, F.S., and health care facilities licensed under ch. 395, F.S. The health care providers and facilities licensed under chs. 395, 458, 459, and 461, F.S., include the following:

- Medical doctors;
- Osteopathic physicians;
- Podiatric physicians;
- Hospitals;
- Ambulatory surgical centers; and
- Mobile surgical facilities.

#### ***Retroactivity of Amendment 7***

The committee substitute appears to provide that Amendment 7 is not applicable to records created before the amendment was adopted by the voters. Specifically the committee substitute states that Amendment 7:

applies to records created, incidents occurring, and actions pending on or after November 2, 2004. [Amendment 7] does not apply to records created, incidents occurring, or actions pending before November 2, 2004.<sup>13</sup>

However, for clarity, the committee substitute could be amended to provide that Amendment 7 *applies to records created on or after November 2, 2004.*

#### ***Excluded Records***

The committee substitute also excludes some records created on or after November 2, 2004, related to adverse medical incidents. The records that are not available under the committee substitute include records of the following:

- Individually identifiable health information;
- Patient privacy information;
- Non-final adverse medical incident reports, including notes and drafts;
- Attorney-client privileged communications;
- Attorney-client work product;<sup>14</sup> and

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<sup>12</sup> Committee Substitute for Senate Bill 938, page 5, lines 26-31.

<sup>13</sup> *Id.* at page 4, lines 22-26.

<sup>14</sup> Under the work-product privilege:

- Adverse medical incident records over four years old after November 2, 2008.

### ***Process to Identify Records***

The committee substitute directs health care facilities and health care providers to identify records of an adverse medical incidents “using the process provided in” ss. 395.0197 and 458.351, F.S. Neither of these statutes provides a process for identifying records. These statutes require certain health care facilities and licensees under ch. 458, F.S., to report “adverse incidents” to the Agency for Health Care Administration or the Department of Health. These provisions of the committee substitute suggest that patients may have access only to adverse incident reports that are provided to regulatory agencies.

The provisions related to the process for identifying records appears problematic for several additional reasons. First, licensees under s. 459.026, F.S., have a duty to report adverse incidents occurring within their offices in substantially the same manner as ch. 458, F.S., licensees under s. 458.351, F.S. As such, the Legislature may wish to consider creating a provision in the committee substitute to refer to the process provided in s. 459.026, F.S., to identify records of adverse medical incidents. Second, podiatric physicians licensed under ch. 461, F.S., have no legal duty to report adverse incidents occurring within their offices. As a result, podiatric physicians will never have record of adverse incidents that may be identified using the process provided in s. 458.351, F.S.

### **Use of Records**

The committee substitute reaffirms existing laws that limit the discoverability or admissibility of records of adverse medical incidents. However, the committee substitute further restricts the discovery and admission of the following:

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.<sup>15</sup>

### **Effective Date**

The committee substitute takes effect upon becoming a law.

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a party may obtain discovery of documents and tangible things otherwise discoverable under the general provision regulating the scope of discovery and prepared in anticipation of litigation or for trial by or for another party or by or for that party’s representative, including that party’s attorney, consultant, surety, indemnitor, insurer, or agent, only upon a showing that the party seeking discovery has need of the materials in the preparation of the case and is unable to obtain the substantial equivalent of the materials by other means without undue hardship. The work-product privilege applies to documents prepared even when litigation neither is pending nor threatened, as long as there is a possibility that litigation might ensue.

William H. Danne, Jr., J.D., 19A Fla. Jur 2d Discovery and Depositions s. 38, Second Edition, Database updated February 2005 (citations omitted).

<sup>15</sup> Committee Substitute for Senate Bill 938, page 5, lines 17-22.

**IV. Constitutional Issues:**

## A. Municipality/County Mandates Restrictions:

None.

## B. Public Records/Open Meetings Issues:

None.

## C. Trust Funds Restrictions:

None.

## D. Other Constitutional Issues:

Provisions of this committee substitute as described in detail in the Effect of Proposed Changes of this staff analysis may not provide patients with access to all adverse medical incident records described in Amendment 7.

**V. Economic Impact and Fiscal Note:**

## A. Tax/Fee Issues:

None.

## B. Private Sector Impact:

Patients will have greater access to records of health care facilities and providers pertaining to adverse medical incidents. Health care facilities and providers, however, will be authorized to charge patients fees for access.

## C. Government Sector Impact:

The committee substitute has not imposed any obligation on state agencies, other than state health care facilities, to provide patients with records of adverse medical impacts. State health care facilities, however, are authorized to charge fees for providing access to records.

**VI. Technical Deficiencies:**

The words “incidents that are reported to any governmental agency or body” on page 2, lines 18-19, may be a scrivener’s error, as those words are not in the definition of “adverse medical incident” in the constitution.

On page 6, lines 1-9, the committee substitute directs health care facilities and providers to use the processes provided in s. 395.0197 and s. 458.351, F.S., to identify records subject to request under Amendment 7. Those statutes, however, do not appear to provide a process to identify records.



**VII. Related Issues:**

The Legislature may wish to consider whether the committee substitute should authorize the imposition of penalties on health care facilities and providers that fail to timely provide access to records of adverse medical incidents.

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This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

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## VIII. Summary of Amendments:

### **Barcode 603030 by Judiciary:**

Adds a definition for “adverse medical incident records” to the committee substitute. The definition operates to expand the types of records available to patients to include records of a health care provider’s competence; a health care facility’s infection experiences; adverse incidents caused by medication, radiology, pathology, or anesthesia; and level of patient supervision, in addition to adverse incident reports made in accordance with existing law.

### **Barcode 170094 by Judiciary:**

Deletes the definition for “records” from the committee substitute. The term “records” was replaced by the term “adverse medical incident records” in amendment barcode 603030.

### **Barcode 762694 by Judiciary:**

Provides that a patient has access to non-patient specific information related to a health care facility’s infection experiences; adverse medical incidents caused by medication, radiology, pathology, or anesthesia; and level of patient supervision.

### **Barcode 664126 by Judiciary:**

Deletes provisions directing health care facilities and providers to identify records available for patient access using the processes in ss. 395.0197 and 458.351, F.S. (WITH TITLE AMENDMENT)