HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1797 CS PCB JU 05-02 Patient Right to Know
SPONSOR(S): Judiciary Committee and Simmons
TIED BILLS: **IDEN./SIM. BILLS:** SB 2218

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Judiciary Committee	12 Y, 0 N	Hogge	Hogge
1) Health Care Regulation Committee	11 Y, 0 N, w/CS	Hamrick	Mitchell
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

On November 2, 2004, the voters approved Constitutional Amendment 7, known as the "Patients' Right- to-Know About Adverse Medical Incidents."

This bill incorporates provisions from Constitutional Amendment 7 and supplements those with statutory provisions in creating a new act entitled the "Patients' Right-to-Know About Adverse Medical Incidents Act."

The bill defines the scope of the amendment as applying to records of adverse medical incidents held by hospitals, allopathic physicians, and osteopathic physicians.

The bill applies to records that were created, adverse medical incidents that occurred on or after November 3, 2004. It further preserves existing laws regulating the use of, as opposed to patient accessibility to, records of adverse medical incidents, such as laws relating to the discoverability or admissibility of these records and testimony related to these records in civil and administrative proceedings.

Finally, the bill includes provisions pertaining to the production of records such as specifying the owner of the records, timeframes for responding to a records request, the amount of fees hospitals and medical doctors may charge for copies, and the requirements for a records request.

State and local government, and private hospitals and medical doctors, are expected to experience an indeterminate recurring negative fiscal impact, not from the bill, but from Constitutional Amendment 7.

The bill actually has an indeterminate recurring positive fiscal impact by permitting public and private hospitals and medical doctors to recover the actual costs associated with these records requests.

The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government—To the extent any additional government is provided, it would be the result of the constitutional amendment itself and not this bill.

Ensure lower taxes—The authority of health care providers to charge fees to cover the cost of records requests is made applicable to records requested under Constitutional Amendment 7. Additionally, authority is provided to hospitals to recover the "reasonable and actual" costs of complying with the records requests.

B. EFFECT OF PROPOSED CHANGES:

On November 2, 2004, the voters approved Constitutional Amendment 7, known as the Patient Right-to-Know amendment, effective on the date enacted by the voters.

This bill incorporates provisions from Constitutional Amendment 7 and supplements those with statutory provisions in creating a new act entitled the "Patient Right-to-Know Act."

Purpose

The bill describes the purpose of Constitutional Amendment 7. Amendment 7 grants patient's access to records of adverse medical incidents made or received in the course of business by a health care facility or provider, but not altering existing laws regulating the way in which the records may be used.

Patient right of access

The bill incorporates language drawn directly from the Constitutional Amendment 7, establishing a patient's right to have access to records made or received in the course of business by a health care facility or provider relating to any adverse medical incidents, prohibiting the facility or provider from disclosing the identity of patients involved in the incidents, and requiring the facility or provider to maintain any privacy restrictions imposed by federal law.

The bill supplements the provisions of Constitutional Amendment 7 by specifying that the adverse medical incident records to which the patient is granted access are those affecting the patient or any other patient whose condition, treatment, or diagnosis is the same as or substantially similar to the patient requesting access.

Therefore, to illustrate: a patient seeking treatment for lung cancer at Hospital A could receive records of adverse medical incidents involving any patients with lung cancer at Hospital A but not records of patients with kidney stones.

Federal law, including federal decisional law, imposes numerous privacy restrictions on the disclosure of patient health records. One such act, the Health Insurance Portability and Accountability Act (HIPAA) establishes certain privacy protections to guard against disclosure of health information; states are free to adopt more stringent requirements. The HIPAA privacy protections have been implemented through the so-called "Privacy Rule," promulgated by the U.S. Department of Health. The Privacy Rule is of limited scope, applying to health care providers, health plans, and health care clearinghouses engaging in certain electronic transactions. It covers the disclosure of "individually identifiable health information" by these covered entities. Another privacy restriction under federal law is the self- critical analysis privilege found in federal evidentiary law. The self-critical analysis privilege, first recognized in

Bredice v. Doctor's Hospital, Inc., 50 F.R.D. 249 (D.D.C. 1970), protects certain critical appraisals from discovery. The privilege allows individuals and businesses to investigate compliance with the law without fear of creating evidence to be used against them in litigation, in hopes that a retrospective review of treatment will improve the general quality of the industry.

In Florida, patients have a constitutional right to privacy.[1] In addition, the Legislature has prohibited the disclosure of medical records to any person other than the patient or the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient, subject to certain limited exceptions, without the written authorization of the patient.[2] Furthermore, except in certain specified legal proceedings, a health care practitioner can only disclose information provided by the patient in the course of care and treatment to other practitioners and providers involved in the care or treatment of the patient and in certain other limited circumstances (e.g., compelled by subpoena at a deposition). Patient records received, and any other documents held, by the Department of Health (DOH), identifying the patient by name are confidential and exempt from public inspection.

Patient records held by hospitals are likewise confidential and must not be disclosed without the consent of the patient, subject to certain exceptions.[3]

Applicability

The bill defines several terms not defined in Constitutional Amendment 7, including the type of facilities and providers subject to the amendment. The bill defines a "health care facility" as a facility regulated under chapter 395, F.S. In chapter 395, F.S., health care facilities include hospitals and trauma centers.

A "health care provider" is defined as a physician licensed under chapter 458 or 459, F.S. Chapter 458 physicians are allopathic physicians, and chapter 459 physicians are osteopathic physicians. Other terms defined in the bill include "identity," "privacy restrictions imposed by federal law," "records," and "representative of the patient."

The bill incorporates the definitions of other terms precisely as defined in Constitutional Amendment 7, including "adverse medical incident"[4] and "patient."

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[1] Art. I, s. 23. Fla. Const.
[2] S. 456.057(5), Fla. Stat. (2004)
[3] S. 395.3025, Fla. Stat. (2004)
[4] However, the definition of "adverse medical incident" in the constitutional amendment differs from that in current statutory law principally by including so-called "near misses," i.e., conduct that "could have caused injury to or death of a patient…." As defined in current statutory law, "adverse incident" does not include near misses and, as applied to physicians engaged in the practice of medicine under s. 458.351, F.S., 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:

(a) The death of a patient.
(b) Brain or spinal damage to a patient.
(c) The performance of a surgical procedure on the wrong patient.
(d)1. The performance of a wrong-site surgical procedure;
2. The performance of a wrong surgical procedure; or
3. The surgical repair or damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk…

If it results in: death; brain or spinal damage; permanent disfigurement…, fracture…, a limitation of neurological, physical, or sensory function; or any condition that required the transfer of the patient**.**
(e) A procedure to remove unplanned foreign objects….
(f) Any condition that required the transfer of a patient to a hospital….

"Adverse incident" is similarly defined for hospitals licensed under ch. 395, F.S. See 395.0197(5), F.S.

The bill gives the amendment prospective application from the date approved by the voters by applying the amendment to records created, incidents occurring on or after November 3, 2004. The bill limits records requests to a four year period - the period of time equal to the statute of repose for medical malpractice actions.[5]

Effect of Constitutional Amendment 7 on existing laws governing use of records

The bill expressly preserves existing laws governing the use of records of adverse medical incidents, including laws relating to the discoverability or admissibility of these records and testimony related to these records.

Current law provides numerous quality control mechanisms and reporting requirements for health care facilities and providers, including medical review committees, peer review panels, Florida Patient Safety Corporation[6], and risk management programs. The investigations, proceedings, and records of these entities generally are not discoverable or admissible into evidence in any civil or administrative action.[7] The proceedings and records of these entities generally also are confidential and exempt from public inspection under the public meetings laws, and exempt from the open meetings laws.[8]

Medical review committees are formed to "evaluate and improve the quality of health care rendered by providers of health service(s)" or to determine that rendered health care services were professionally indicated, were performed in compliance with the applicable standard of care, or were of a reasonable cost. Medical review committees include, among others, hospital committees and a committee of the DOH when reviewing quality of care.

Hospitals are required to create a peer review process for physicians delivering health care services at their facilities. This includes the creation of a peer review panel. The panel determines whether or not certain conduct constitutes grounds for disciplinary action. The recommendations of the peer review panel are transmitted to the governing board of the hospital for a final determination. Any disciplinary actions taken by the hospital must be reported to the DOH within 30 working days. The DOH must review each report and determine if the conduct is subject to disciplinary action pursuant to s. 456.073, F.S.

Hospitals are required to establish an internal risk management program for the purpose of investigating and analyzing the frequency and causes of general and specific types of adverse incidents, developing appropriate measures to minimize the risk of adverse incidents to patients, analyzing patient grievances relating to patient care, notifying patients that were the subject of an adverse incident, and implementing an incident reporting system. These programs are established pursuant to rules promulgated by the Agency for Health Care Administration (AHCA). These incident reports are filed with the AHCA and used by the hospitals to identify problem areas and institute corrective actions.

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[5] S. 95.11(4), Fla. Stat. (2004)

[6] The Florida Patient Safety Corporation (s. 381.0271, F.S.) is such an organization. It not only collects data related to adverse incidents, but also to "near misses." The "near-miss" reporting system is voluntary and anonymous. The corporation is required to remove all patient identifying information.

[7] Per medical review committee: s. 766.101 (5) and (7), Fla. Stat. (2004); peer review panels hospital committee governing board, or disciplinary board: s. 395.0193 (8), Fla. Stat. (2004); risk management programs (certain reports discoverable, but not admissible; other reports not discoverable or admissible): s. 395.0197 (4) and (7) Fla. Stat. (2004); and Patient Safety Data: s. 766.1016 (2), Fla. Stat. (2004)

[8] Peer Review panels, hospital committees, governing boards or disciplinary board: s. 395.0193 (7); risk management programs (annual reports): s. 395.0197(7); medical review committee: s. 766.101(7); and patient safety data held by the Florida Patient Safety Corporation: s. 381.0273. F.S.

Production of records

Regarding the production of records under Constitutional Amendment 7, the bill specifies that the records patients must be given access to are those of the facility or provider where they are patients and which pertain to their condition, treatment, or diagnosis. As under current law, the bill assigns responsibility to the owner of the record[9] to determine if it is a record of an adverse medical incident.

The bill also permits health care providers to charge patients for records requests in the amount as currently provided for other records requested pursuant to general law, including a reasonable charge for the staff time necessary to prevent the disclosure of the identity of patients through redaction or other means. Similarly, the bill permits health care facilities to charge an amount equal to the reasonable and actual costs of complying with the request, including a reasonable charge for the staff time necessary to prevent the disclosure of the identity of patients through redaction or other means. Both facilities and providers may request advance payment of the cost of producing the records.

Finally, the bill requires record requests to be submitted in writing and requires the records to be provided in a "timely manner."[10]

Under current law,[11] hospitals may not charge more than $2 for nonpaper patient records and $1 per page for paper records. They also may charge a fee of up to $1 for each year of records requested. Physicians may charge an amount not to exceed the actual cost of copying, including reasonable staff time, or the amount specified by the Board of Medicine.[12] Currently, the amount specified by the board is $1 for each of the first 25 pages, and 25 cents for each additional page.[13]

C. SECTION DIRECTORY:

Section 1. Creates s. 381.028, F.S., relating to adverse medical incidents; creating the "Patients' Right-to-Know About Adverse Medical Incidents Act"; providing for purpose, definitions, right of access; applicability; use of records; and production of records.

Section 2. Provides that the bill will take effect upon becoming a law.

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[9] "Records owner," as it relates to health care practitioners, means "any health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; or to any health care practitioner's employer…." S. 456.057(1), Fla. Stat. (2004)

[10] Regulations adopted under the federal HIPAA, at 425 C.F.R. Section 164.524, provide the following guidance as to timeframes for responding to records requests:
(b) Implementation specifications: requests for access and timely action
(2) Timely action by the covered entity.
(i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.
(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.
(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.
(ii) If the request for access is for protected health information that is not maintained or accessible to the covered entity on-site, the covered entity must take an action required by paragraph (b)(2)(i) of this section by no later than 60 days from the receipt of such a request.
(iii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) or (ii) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (b)(2)(i) or (ii) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and
(B) The covered entity may have only one such extension of time for action on a request for access.

[11] S. 395.3025(1), Fla. Stat. (2004)

[12] S. 456.057(16), Fla. Stat. (2004)

[13] Rule 64B8-10.003(2), Fla. Admin. Code

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Indeterminate recurring positive fiscal impact. See II.D. FISCAL COMMENTS

2. Expenditures:

   Indeterminate recurring positive fiscal impact. See II.D. FISCAL COMMENTS

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   Indeterminate recurring positive fiscal impact. See II.D. FISCAL COMMENTS

2. Expenditures:

   Indeterminate recurring positive fiscal impact. See II.D. FISCAL COMMENTS

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The private sector is expected to experience a recurring negative fiscal impact, not as a result of the bill, but as a result of Constitutional Amendment 7. The bill actually has an indeterminate recurring positive fiscal impact by permitting hospitals and medical doctors to recover the actual costs associated with records requests.

D. FISCAL COMMENTS:

State and local government is expected to experience an indeterminate recurring negative fiscal impact, not as a result of the bill, but as a result of Constitutional Amendment 7, since that is the source of the requirement to produce certain patient records.

The bill actually has an indeterminate recurring positive fiscal impact by permitting hospitals and medical doctors to recover the actual costs associated with these records requests.

The amount is indeterminate because the volume of record requests is unknown and cannot be predicted with any degree of reliability.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 6, 2005, the Health Care Regulation Committee adopted 4 technical amendments sponsored by Representative Simmons. The Committee Substitute differs from the original bill as filed in that the Committee Substitute:

Amendment 1-Removes unnecessary definitions within the bill. "Agency" and "Department" were deleted.
Amendment 2 and 3-Removes "actions pending" from the bill and leaves the applicability to "incidents occurring."
Amendment 4-Adds s. 459.026, F.S., pertaining to reports of adverse incidents in the office practice setting of the Osteopathic Medicine practice act. The bill references a similar section of statute within the Medical Practice act (ch.458, F.S.).

This analysis is drafted to the Committee Substitute.