

STORAGE NAME: h1851s1.hcl

DATE: April 10, 2000

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
ANALYSIS**

BILL #: CS/HB 1851

RELATING TO: Hospital Incident Reporting/Report Cards

SPONSOR(S): Committee on Health Care Licensing & Regulation and Representative Crow and others

TIED BILL(S): None

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE LICENSING & REGULATION YEAS 11 NAYS 2
- (2) JUDICIARY
- (3) HEALTH & HUMAN SERVICES APPROPRIATIONS
- (4)
- (5)

I. SUMMARY:

This bill amends the internal risk management program provisions for licensed hospitals, mobile surgical centers, and ambulatory surgical centers. First, it changes the definition of "adverse incident" to require reporting of damage resulting to a patient from a planned surgical procedure which necessitated surgical repair, regardless of whether the damage was a recognized specific risk disclosed to the patient at the time of the informed consent. Secondly, this bill requires the Agency for Health Care Administration to annually publish on the Internet and other commonly used means of distribution a report card of each hospital, mobile surgical center, and ambulatory surgical center individually and by county.

The report card for each licensed facility must include its name and address; whether the facility is private, for-profit or not-for-profit, public, or teaching; the total number of beds; a description of the categories of services provided by the facility; the percentage of adverse incidents per total number of patients in the facility on an annual basis organized into types of incidents and types of professionals involved; a listing by category of the types of operations, diagnostic or treatment procedures, or other actions or inactions giving rise to the adverse incident and the number of adverse incidents reported in each of these categories; the types of malpractice claims filed organized by type of professional involved; and disciplinary actions taken against professionals organized by type of professional involved.

The report card must contain a specific statement to educate patients and readers of the report cards that other sources of information should be considered when making a decision regarding a health care facility and that the information on the report card has not been adjusted for size of facility or complexity of the health problems treated at each facility. The bill is effective October 1, 2000. It also corrects a cross-reference to the licensure provisions for risk managers.

This bill will have a fiscal impact on the Agency for Health Care Administration.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

- | | | | |
|-----------------------------------|------------------------------|--|---|
| 1. <u>Less Government</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. <u>Lower Taxes</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. <u>Individual Freedom</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. <u>Personal Responsibility</u> | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 5. <u>Family Empowerment</u> | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a "no" above, please explain:

This bill creates new work for the Agency for Health Care Administration. The beneficiaries of the legislation, consumers and competitors, do not pay any portion of the cost for implementation and operation. It is not specified how the costs of this program will be paid.

B. PRESENT SITUATION:

Section 395.0197, F.S., sets forth the requirements for all licensed facilities to establish an internal risk management program, to report and investigate adverse incidents that occur within the facility, and to implement a plan of corrective action following an adverse incident. That section also requires the Agency for Health Care Administration to compile annual reports summarizing adverse incidents, types of malpractice claims, and disciplinary actions taken against professionals in the aggregate.

Specifically, s. 395.0197(1), F.S., requires every licensed facility as defined in s. 395.002(17), F.S., to establish an internal risk management program that investigates and analyzes the frequency and causes of general categories and specific types of adverse incidents to patients, develops appropriate measures to minimize the risk of adverse incidents to patients, analyzes patient grievances that relate to patient care and the quality of medical services, and develops and implements an incident reporting system based on the affirmative duty of all health care providers and all employees to report adverse incidents to the risk manager within 3 business days following the adverse incident occurring. Section 395.0197(2), F.S., requires each facility to hire a licensed risk manager who is responsible for implementation and oversight of such facility's internal risk management program. (Licensure of risk managers is currently found in ss. 395.10971-395.10975, F.S., not part IX of chapter 626, F.S. as cross-referenced in chapter 395.--see amendment to correct this glitch.)

Section 395.002(17), F.S., defines "licensed facility" as a hospital, mobile surgical facility or ambulatory surgical center licensed pursuant to chapter 395, F.S. Section 395.0197(5), F.S., defines "adverse incident" for purpose of reporting to the Agency for Health Care Administration as an event over which the 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. In order to meet the requirements for reporting, the adverse incident must also have:

- 1) resulted in death, brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; limitation of neurological, physical, or sensory function which continues after discharge from the facility; any condition that required specialized medical attention or surgical intervention; or any condition requiring the transfer of the patient to a unit providing more acute care; or
- 2) involved 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; or
- 3) required the surgical repair of damage resulting to a patient from a planned surgical procedure where the damage was not a recognized specific risk and disclosed to the patient and documented through the informed-consent process; or
- 4) required a surgical procedure to remove unplanned foreign objects remaining from a surgical procedure.

Section 395.0197(7), F.S., requires the facility to report to the Agency for Health Care Administration no later than 1 day following the risk manager's receipt of an adverse incident report of an incident which occurred in the licensed facility or prior to admission to the facility which involved 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, or the performance of a wrong surgical procedure. Section 395.0197(8), F.S., requires the facility to report within 15 calendar days from the date of occurrence adverse incidents arising within the facility or prior to admission to the facility which involved 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 medically unnecessary procedure, the surgical repair of damage resulting from a planned surgical procedure which is not a recognized specific risk disclosed to the patient as part of the informed-consent process, or the performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.

In addition to the individual adverse incident reports required to be filed, the facility is also required by s. 395.0197(6), F.S., to file with the agency an annual report summarizing data regarding adverse incidents. The facility annual report must include the total number of adverse incidents; a listing by category of the types of operations, diagnostic or treatment procedures, or other actions causing the injuries, and the number of incidents occurring within each category; a listing by category of the types of injuries caused and the number of incidents occurring within each category; a code number using the health care professional's license number and a separate code number identifying all other individuals directly involved, the relationship of the individuals to the facility, and the number of incidents in which each individual has been involved; and a description of all malpractice claims filed against the facility including pending and closed claims, the nature of the incident and the persons involved, and the status and disposition of each claim.

There are no less than four sections of law that protect information relating to adverse incidents which occur in facilities from being available to the general public. Thus, the Florida Legislature has taken the position that requiring adverse incidents to be reported to the agency for investigation of the facility and the health care practitioners involved is preferable to requiring disclosure of preliminary and possibly inflammatory information to the public who may use this information for competitive and other purposes.

For instance, section 395.0198, F.S., provides a public records exemption for information contained on the notification of an adverse incident required by s. 395.0197(7), F.S. Adverse incidents are not discoverable or admissible in a civil or administrative action, except that such information may be used in disciplinary proceedings by the agency against the facility or by the regulatory boards against the health care practitioners involved. The public records exemption also precludes public access to adverse incident information used as part of the investigation or prosecution of the disciplinary case. Moreover, the records obtained by the agency in enforcing this section are not available to the public, nor discoverable or admissible in any civil or administrative action, except that the records may be used in disciplinary proceedings by the agency or appropriate regulatory board in actions against the license of the facility or health care practitioner. Sections 395.0197(6)(c) and (8), F.S., have additional exemptions from the public records laws for adverse incident reports and the annual report to the agency regarding adverse incidents.

Additionally, s. 395.0193, F.S., encourages facilities to participate in peer review and, if appropriate, to take disciplinary action against the individuals responsible. Sections 458.337 and 459.016, F.S., require such disciplinary action taken against physicians to be reported to the agency for possible licensure discipline as well. Again, the Legislature has provided a public records exemption for such peer review proceedings pursuant to s. 395.0193(4) and (8), F.S., in addition to the public records exemption for all complaints filed against practitioners until 10 days following a finding of probable cause that a violation of law occurred.

Pursuant to s. 395.0197(18), F.S., the Agency for Health Care Administration uses the information reported by the facility relating to adverse incidents and disciplinary action to compile a statewide aggregate report which summarizes adverse incident reports by category of reported incident and type of professional involved, types of malpractice claims filed by type of professional involved, and disciplinary actions taken against professionals, by type of professional involved. This annual statistical report is not required to be broken down by county, city, or facility. The annual report does not contain specific names of practitioners or facilities which might undermine the process of self-reporting.

C. EFFECT OF PROPOSED CHANGES:

This bill corrects a cross-reference to the licensure provisions for risk managers.

This bill amends the internal risk management program provisions for licensed hospitals, mobile surgical centers, and ambulatory surgical centers. First, it changes the definition of "adverse incident" to require reporting of damage resulting to a patient from a planned surgical procedure which necessitated surgical repair, regardless of whether the damage was a recognized specific risk disclosed to the patient at the time of the informed consent.

Secondly, the bill requires the Agency for Health Care Administration to annually publish a report card for each county and for each facility summarizing the information contained in the annual incident reports submitted by licensed facilities pursuant to s. 395.0197(6), F.S., and the disciplinary actions reported to the agency pursuant to s. 395.0193. The report card must be published on the Internet as well as other commonly used means of distribution no later than July 1 of each year.

The annual report card must contain each facility's name and address; whether it is a private for profit, private not for profit, public, or teaching facility; the total number of beds; a

description of the categories of services provided by the facility; the percentage of adverse incidents on an annual basis per total number of patients in the facility, broken down into types of reported incidents and types of professionals involved; a listing of the types of operations, diagnostic or treatment procedures, or other actions or inactions giving rise to the adverse incidents and the numbers of each; types of malpractice claims filed broken down by type of professional involved; and disciplinary actions taken against professionals listed by type of professional involved.

The bill requires a statement to be included on the report card which educates consumers and other persons using the report cards that this information is only one portion of the picture that emerges about a facility. The statement urges readers to consider other sources of information and to consider the size and complexity of the services provided by each facility when making a choice.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 395.0197, F.S., to correct a cross-reference, to broaden the definition of “adverse incident,” and to require the agency to publish annual report cards for each county and each facility specifying certain information.

Section 2. Provides an effective date of October 1, 2000.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. **Revenues:**

None.

2. **Expenditures:**

The bill does not provide any funding to the agency to compile, summarize, and publish the report cards for each facility and each county. The number of additional FTEs and other expenses required to implement this bill is unknown.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. **Revenues:**

None.

2. **Expenditures:**

Local governments that operate facilities may incur expenses related to the additional reporting requirements arising from the change in definition of “adverse incident.” Also, additional investigation and peer review may be required as a result of said change.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private facilities may incur expenses related to the additional reporting requirements arising from the change in definition of "adverse incident." Also, additional investigation and peer review may be required as a result of said change.

D. FISCAL COMMENTS:

See above.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require a city or county to expend funds or to take action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the authority that municipalities or counties have to raise revenue in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

None.

C. OTHER COMMENTS:

It is unclear whether the intent of this bill is to require the facility report cards to specify the names of the practitioners and patients involved in the reported adverse incident. If a facility only has one adverse incident, the names of the persons involved may be ascertainable. If the names of the individuals or other identifying information is released and published, damage may be done to the reputation of such persons without a finding of misconduct or other violation of laws or rules.

This bill may also result in the unintended consequence of discouraging self-reporting of adverse incidents. The intent of the "internal" risk management program was to encourage facilities to identify, report, and correct errors and incidents within the facility. The agency is charged with reviewing these incidents, ensuring that corrective action is taken, and disciplining the facility and practitioners if a violation of law is discovered. Because the

information contained on the report card may be used for competitive purposes or for other unintended purposes, it may cause facilities to be less willing to report adverse incidents and look for other loopholes such as a more strict interpretation of "adverse incident."

Additionally, there appears to be an incorrect cross-reference in s. 395.0197(2), F.S. An amendment is necessary to correct this cross-referencing glitch. The regulation of risk managers is not located in part IX of chapter 626 as referenced in the current statutes. The correct cross-reference is ss. 395.10971-395.10975, F.S.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On March 30, 2000, the Committee on Health Care Licensing and Regulation adopted five amendments and passed this bill as a committee substitute by a vote of 11-2. The differences between the committee substitute and the original bill include:

- ▶ The original bill did not update the cross-reference to risk manager licensure provisions.
- ▶ The original bill did not contain a disclaimer to inform consumers to check other sources and to consider the size of the facility and complexity of services provided before making a health care facility decision based on the information contained in the report card.
- ▶ The effective date of the original bill was upon becoming law.
- ▶ The original bill did not require the report cards to distinguish teaching facilities from other types of facilities.
- ▶ The original bill required a raw number of adverse incidents to be listed instead of a percentage based on the size of the facility.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:

Staff Director:

Wendy Smith Hansen

Lucretia Shaw Collins