

STORAGE NAME: h1847a.go

DATE: April 8, 1999

**HOUSE OF REPRESENTATIVES
AS FURTHER REVISED BY THE COMMITTEE ON
GOVERNMENTAL OPERATIONS
ANALYSIS**

BILL #: HB 1847 (PCB HCL 99-07)

RELATING TO: Health Care Practitioners/Adverse Incident Reports

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

COMPANION BILL(S): CS/SB 1348 (similar), HB 1843 (compare) and SB 1824 (compare)

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

- (1) HEALTH CARE LICENSING & REGULATION YEAS 11 NAYS 0
 - (2) JUDICIARY YEAS 8 NAYS 0
 - (3) GOVERNMENTAL OPERATIONS YEAS 5 NAYS 0
 - (4)
 - (5)
-

I. SUMMARY:

HB 1847 provides that effective January 1, 2000, medical and osteopathic physicians must file reports of adverse incidents that occur during surgery in their offices within 15 days after the occurrence of the adverse incident. Adverse incidents include incidents resulting in the death of a patient, brain or spinal damage, performance of a surgical procedure on the wrong patient, performance of a wrong-site surgical procedure, and performance of a wrong surgical procedure, for example.

The report is filed with the Department of Health, which determines whether disciplinary action is required against a licensee. If disciplinary action is necessary, it will be administered by the board which licensed the health care practitioner. Such records when filed with the Department of Health are not discoverable or admissible in a civil or administrative action, unless the action is a disciplinary proceeding by the department or the respective board.

HB 1843, which is tied to this bill, provides that these reports are confidential and exempt from the public records law.

The bill will have minimal fiscal impact on the State, and no fiscal impact on local government and the private sector in general.

The bill shall be effective upon becoming a law.

Note. On March 30, 1999, the Committee on Judiciary adopted two amendments which are traveling with the bill. The first one creates a section clarifying the authority of the Board of Medicine to promulgate rules and authorizing promulgation of rules relating to office surgeries. The second one clarifies the definition of "adverse incidents" which are to be reported, and deletes the paragraph regarding the public record exemptions and other restrictions on disclosure of the records.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Adverse Incident Reports

Currently, s. 395.0198 (6), F.S., requires the reporting of all adverse incidents that occur in facilities licensed pursuant to Chapter 395, F.S. (mainly hospitals and ambulatory surgery centers). However, there is no requirement for physicians licensed pursuant to chs. 458 or 459, F.S., to file reports of adverse incidents that occur during surgery performed in their offices. The report is filed with the Agency for Health Care Administration and made available to the Department of Health for determination if disciplinary action is required against a healthcare licensee.

Adverse incidents a licensed facility must report include incidents resulting in the death of a patient, brain or spinal damage, performance of a surgical procedure on the wrong patient, performance of a wrong-site surgical procedure, performance of a wrong surgical procedure, and performance of a medically unnecessary procedure.

These reports are filed pursuant to s. 395.0198, F.S., and are confidential and exempt from s. 119.07(1), F.S., and s. 24(a), Art. I, of the State Constitution. In addition, the information is not discoverable or admissible in a civil or administrative action, unless the action is a disciplinary proceeding by the department or appropriate regulatory board.

The Board of Medicine first adopted rules relating to office surgery in 1994. In the past two years, the Board has become increasingly concerned about public safety issues relating to office surgery as reflected by the number of physician cases involving patient disfigurement and deaths related to plastic surgery and other procedures.

The Fort Lauderdale Sun Sentinel published a series of investigative reports from November 29 through December 4, 1998, about deaths and complications resulting from plastic surgery. The Sun Sentinel reported that since 1986 at least 34 people have died in Florida after plastic surgery performed in physicians' offices, surgery centers, or hospitals. Many of the reported cases did not reach the Board for potential disciplinary action because current regulations for office-based surgery do not require a report of all serious injuries. Therefore, the Board does not become aware of the physician's unsafe practice unless a patient files a complaint, a hospital files a report, or a notice of malpractice litigation is submitted, sometimes years after the event. According to the Department of Health, the absence of injury reports and mandatory inspections or accreditation compromises the Board's ability to take rapid action to prevent avoidable patient injuries and protect the general public.

Authority for the Board of Medicine to adopt rules requiring the registration and inspection of physicians' offices used for office surgery is currently under review. The Department of Health and the Board of Medicine maintain that the Board has such authority. The statute cited for the rulemaking authority was passed in 1998 (s. 458.331(1)(v), F.S. (1998 Supp.)). A notice of a proposed rule change was published on January 22, 1999, in the Florida Administrative Weekly with a rule hearing set for April 11, 1999. While the Board's position is that they have rulemaking authority to address this issue, staff of the Joint Administrative Procedures Committee has questioned the board's authority. The board has requested legislation clarifying this rulemaking authority to reaffirm the Legislature's intention that the board adopt the necessary rules to ensure adequate standards of care for office-based surgery.

B. EFFECT OF PROPOSED CHANGES:

HB 1847 provides that effective January 1, 2000, medical and osteopathic physicians must file reports of adverse incidents that occur during surgery in their offices within 15 days after the occurrence of the adverse incident. Adverse incidents include incidents resulting in the death of a patient, brain or spinal damage, performance of a surgical procedure on the wrong patient, performance of a wrong-site surgical procedure, and performance of a wrong surgical procedure, for example.

The report is filed with the Department of Health, which determines whether disciplinary action is required against a licensee. If disciplinary action is necessary, it will be administered by the board which licensed the health care practitioner. Such records when filed with the Department of Health are not discoverable or admissible in a civil or administrative action, unless the action is a disciplinary proceeding by the department or the respective board.

Also, the bill would enable the department to determine compliance with minimum safety standards in office surgery, instead of being dependent upon patient complaints for information about unsafe surgical offices. This will enable the department to respond immediately to adverse incidents.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

Yes. The bill provides for the department to make rules to implement the new requirements.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

Yes. It requires physicians licensed under Chapters 458 and 459 to file adverse incident reports with the Department of Health.

(3) any entitlement to a government service or benefit?

No.

b. If an agency or program is eliminated or reduced:

The bill does not eliminate or reduce any agency or program.

(1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

(2) what is the cost of such responsibility at the new level/agency?

N/A

(3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

a. Does the bill increase anyone's taxes?

No.

b. Does the bill require or authorize an increase in any fees?

No.

c. Does the bill reduce total taxes, both rates and revenues?

No.

d. Does the bill reduce total fees, both rates and revenues?

No.

e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No.

4. Individual Freedom:

a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No.

b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

No.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

The bill does not purport to provide services to families or children.

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

No.

- c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

The bill does not create or change a program providing services to families or children.

- (1) parents and guardians?

N/A

- (2) service providers?

N/A

- (3) government employees/agencies?

N/A

D. STATUTE(S) AFFECTED:

Creates ss. 458.351 and 459.026, F.S.

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates s. 458.351, F.S., to require physicians licensed under Ch.. 458 to file adverse incident reports within 15 days of the occurrence of the incident. It includes a definition of "adverse incident," and requires the department to review each incident. It provides for public record exemptions and other restrictions on disclosure of the records and provides rulemaking authority to implement this section.

Section 2. Creates s. 459.026, F.S., to require physicians licensed under Ch.. 459 to file adverse incident reports within 15 days of the occurrence of the incident. It includes a definition of "adverse incident," and requires the department to review each incident. It provides for public record exemptions and other restrictions on disclosure of the records and provides rulemaking authority to implement this section.

Section 3. Provides an effective date of upon becoming law.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

See Fiscal Comments.

2. Recurring Effects:

See Fiscal Comments.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

None.

2. Direct Private Sector Benefits:

The bill would benefit the private sector by allowing the state to better regulate those licensees that are involved in adverse incidents, thereby fostering improved medical care for consumers in Florida.

3. Effects on Competition, Private Enterprise and Employment Markets:

None.

D. FISCAL COMMENTS:

According to the Department of Health, the department will incur no direct costs associated with the filing of adverse incidents reports. However, any adverse incident reports will be similar to those filed by hospitals and ambulatory surgery centers, pursuant to ch. 395, F.S., with the Agency for Health Care Administration. These reports are reviewed by the agency's consumer services unit for possible violations that may result in practitioner disciplinary action under s. 455.621, F.S., and investigated by the agency which is under contract with the department. There could be additional investigative costs to the agency resulting from the additional reports to be received. Any additional costs to the agency will ultimately be passed on to the department which will be paid for by licensees. An estimate of these potential costs is not available at this time.

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 any 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 revenues in the aggregate.

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

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

STORAGE NAME: h1847a.go

DATE: April 8, 1999

PAGE 7

V. COMMENTS:

Comments by the Committee on Governmental Operations

The second amendment adopted by the Committee on Judiciary deleted the paragraph regarding the public record exemptions and other restrictions on disclosure of the records. According to sec. 24(c), Art. I, Fla. Const., public record exemption bills must relate to a single subject. A companion bill, HB 1843, contains similar public record exemption language and relates to the single subject of a public record exemption.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On March 30, 1999, the Committee on Judiciary adopted two amendments which are traveling with the bill. The first one creates a section clarifying the authority of the Board of Medicine to promulgate rules and authorizing promulgation of rules relating to office surgeries. The second one clarifies the definition of "adverse incidents" which are to be reported, and deletes the paragraph regarding the public record exemptions and other restrictions on disclosure of the records.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:

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