

**STORAGE NAME:** h1847.hcl

**DATE:** March 19, 1999

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

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

**RELATING TO:** Health Care Practitioners/Adverse Incident Reports

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

**COMPANION BILL(S):** SB 1348(s) and SB 1824(c)

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

(1) HEALTH CARE LICENSING & REGULATION YEAS 11 NAYS 0

(2)

(3)

(4)

(5)

---

**I. SUMMARY:**

HB 1847 provides that effective January 1, 2000, medical and osteopathic physicians must file reports on adverse incidents that occur as a result of office surgery in their offices. The reports must be filed within 15 days after the occurrence of the adverse incident.

These reports will be confidential and exempt from the public records law. Section 119.07(1), Florida Statutes, and section 24(a), Article I of the State Constitution, permit the Legislature to provide by general law for the exemption of certain records. The general law exempting the records must state with specificity the public necessity justifying the exemption. PCB HCL 99-06 (traveling with this bill) meets these requirements to ensure the confidentiality of these reports.

Adverse incidents are identified to include an incident which results in one of the following: 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, to identify a few of the named procedures.

The report is filed with the Department of Health with the information available to the department to determine if disciplinary action is required against a licensee of the department. If disciplinary action is necessary, it will be administered by the board with whom the health care practitioner is licensed.

Also, this will 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.

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

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Currently, 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. However, s. 395.0198, F.S., requires the reporting of all adverse incidents that occur in facilities licensed pursuant to ch. 395 (mainly hospitals and ambulatory surgery centers). The report is filed with the Agency for Health Care Administration with the information available to the Department of Health to determine if disciplinary action is required against a licensee of the department.

Adverse incidents are described as an incident which results in one of the following: 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, to identify a few of the named procedures.

These reports that are filed 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.

Section 119.07(1), Florida Statutes, and section 24(a), Article I of the State Constitution, provide for public access to any records produced or obtained by a government agency. However, it permits the Legislature to provide by general law for the exemption of certain records. The general law exempting the records must state with specificity the public necessity justifying the exemption.

The justification for the exemption is the fact that the Legislature found that these exemptions are a public necessity, and that it would be an invasion of a patient's privacy for such personal, sensitive information contained in these reports to be publicly available. Also, the fact that an investigation is being conducted, would deter the collection and reporting of this information to the department. This would prevent the agency or department and the appropriate regulatory boards from effectively carrying out their responsibility to protect the health, safety, and welfare of the public. The Legislature has consistently and repeatedly acknowledged the public necessity of these type exemptions.

The need for the Board of Medicine to adopt more stringent rules relating to office surgery has recently become a topic of concern. The board 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 Ft. 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 at least 34 people have died in Florida after plastic surgery, performed in physicians' offices, surgery centers or hospitals since 1986. Many of the cases reported 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 like is required for hospitals or ambulatory surgery centers license under ch. 395. 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 compromise 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.). 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:**

The bill provides that effective January 1, 2000, medical and osteopathic physicians must file reports on adverse incidents that occur as a result of office surgery in their offices. The reports must be filed within 15 days after the occurrence of the adverse incident.

These reports will be confidential and exempt from the public records law. Section 119.07(1), Florida Statutes, and section 24(a), Article I of the State Constitution, permit the Legislature to provide by general law for the exemption of certain records. The general law exempting the records must state with specificity the public necessity justifying the exemption. PCB HCL 99-06 (traveling with this bill) meets these requirements to ensure the confidentiality of these reports.

Adverse incidents are identified to include an incident which results in one of the following: 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, to identify a few of the named procedures.

The report is filed with the Department of Health with the information available to the department to determine if disciplinary action is required against a licensee of the department. If disciplinary action is necessary, it will be administered by the board with whom the health care practitioner is licensed.

Also, this will 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 chs. 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:

(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?

N/A

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

N/A

4. Individual Freedom:

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

N/A

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

Yes. The bill provides for physicians to report adverse incidents that occur as a result of office surgery.

5. Family Empowerment:

a. If the bill purports 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?

N/A

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:

(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, Florida Statutes

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates s. 458.351, Florida Statutes, to require effective January 1, 2000, physicians licensed under chapter 458 to file adverse incidents reports within 15 days of the occurrence of the incident. Also, it includes a definition of adverse incidents and rulemaking authority to implement this section.

Section 2. Creates s. 459.026, Florida Statutes, to require effective January 1, 2000, physicians licensed under chapter 459 to file adverse incidents reports within 15 days of the occurrence of the

incident. Also, it includes a definition of adverse incidents and 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 provides that effective January 1, 2000, medical and osteopathic physicians must file reports on adverse incidents that occur as a result of office surgery in their offices. These reports must be filed within 15 days after the occurrence of the adverse incident.

This will 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 and thus better protect the health, safety, and welfare of the general public.

**STORAGE NAME:** h1847.hcl

**DATE:** March 19, 1999

**PAGE 7**

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:

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

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This 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:

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

V. COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:

Staff Director:

---

Robert W. Coggins

---

Lucretia Shaw Collins