SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 1348

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Campbell

SUBJECT: Practice of Medicine; Adverse Incident Reports

DATE: March 23, 1999 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.			FP	
3.				
4.				
5.				

I. Summary:

The Committee Substitute for Senate Bill 1348 requires any medical physician, osteopathic physician, or physician assistant to notify the Department of Health of any adverse incident that involved the physician or physician assistant which occurred on or after January 1, 2000, in any office maintained by the physician for the practice of medicine that is not licensed under chapter 395, F.S., relating to licensure for hospitals and ambulatory surgical centers. Any medical physician, osteopathic physician, or physician assistant must also notify the department in writing and by certified mail of any adverse incident within 15 days after the adverse incident occurred. The bill requires the Department of Health to review each adverse incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action.

The bill authorizes the Board of Medicine to establish by rule requirements for the registration and inspection of settings in which Level II or Level III office surgery, as defined by board rule, is performed. The Department of Health must conduct registration and inspection of settings in which office surgery is performed for the purpose of determining compliance with the Board of Medicine's rules. The bill authorizes the Board of Medicine to approve appropriate accreditation agencies for the purpose of conducting required inspections. The bill requires the actual costs for registration and inspection to be paid by the person seeking to register and operate the office setting in which Level II or Level III office surgery is performed.

This bill creates sections 458.351 and 459.026, Florida Statutes; and amends ss. 458.331 and 458.309, Florida Statutes, 1998 Supplement.

II. Present Situation:

Licensed medical physicians may perform surgery in their medical offices, ambulatory surgical centers, or hospitals. Ambulatory surgical centers and hospitals must be licensed under chapter 395, F.S. Chapter 395, F.S., imposes requirements on ambulatory surgical centers and hospitals

which include inspection and accreditation, and reporting of adverse incidents that result in serious patient injury. Ambulatory surgical centers and hospitals, under s. 395.0197(8), F.S., must report the following incidents within 15 calendar days after they occur to the Agency for Health Care Administration: death of a patient; brain or spinal damage to a patient; performance of a surgical procedure on the wrong patient; performance of a wrong-site surgical procedure; performance of a wrong surgical procedure; performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition; surgical repair of damage resulting to the patient from a planned surgical procedure where damage is not a recognized specific risk, as disclosed to the patient and documented through the informed consent process; or performance of procedures to remove unplanned foreign objects remaining in a patient following surgery.

Pursuant to s. 395.0197(8), F.S., the incident reports filed with the Agency for Health Care Administration may not be made available to the public pursuant to s. 119.07(1), F.S., or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the Department of Health or the appropriate regulatory board. The incident reports may not be made available to the public as part of the records of investigation for and prosecution in disciplinary proceedings that are made available to the public. The Department of Health or the appropriate regulatory board must make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. The Department of Health must review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action under the provisions of s. 455.621, F.S.

Chapter 458, F.S., authorizes the Board of Medicine (board) to regulate the practice of medicine. Section 458.309, F.S., authorizes the board to adopt rules pursuant to provisions within the Administrative Procedure Act to implement the provisions of the chapter conferring duties upon it. Chapter 458, F.S., provides grounds for which a physician may be subject to disciplinary action by the board. Section 458.331(1)(t), F.S., requires physicians to practice with a minimum standard of care. Physicians may not accept or perform professional responsibilities that they are not competent to perform or delegate professional responsibilities to any person that the physician has reason to know is not qualified by training, experience, or licensure to perform. Section 458.331(1)(v), F.S., prohibits a medical physician from practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform.

The Board of Medicine initially adopted an administrative rule providing standards of care for office surgery in 1994. The board's rule defines surgery to mean any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; extraction of tissue including premature extraction of the products of conception from the uterus; or an endoscopic examination with use of local or general anesthetic. The board rule defines office surgery to mean surgery which is performed outside a hospital, an ambulatory surgical center, abortion clinic, or other medical facility licensed by the Department of Health and Rehabilitative Services, the

Department of Business and Professional Regulation, the Agency for Health Care Administration, or a successor agency. The board rule defines Level I office surgery to mean minor procedures such as the excision of moles, warts, cysts, lipomas, and repair of simple lacerations performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient. The board rule defines Level II office surgery to mean surgery in which peri-operative medication and sedation are required intravenously, intramuscularly, or rectally, that makes post-operative monitoring necessary and includes: hemorrohoidectomy, hernia repair, reduction of simple fractures, large joint dislocations, breast biopsies, and colonoscopy. The board rule defines Level III office surgery to mean surgery which requires, or reasonably should require the use of a general anesthetic or major conduction anesthetic and pre-operative sedation.

Section 458.331(1)(v), F.S., was amended by the Legislature in 1998 to authorize the board to establish by rule standards of practice and standards of care for particular practice settings, including, but not limited to, education and training, equipment and supplies, medications including anesthetics, assistance of and delegation to other personnel, transfer agreements, sterilization, records, performance of complex or multiple procedures, informed consent, and policy and procedure manuals.

The board's Surgical Care Committee has held four workshops during 1998 in its development of recommended changes to applicable rules for surgical care provided by medical physicians in their offices. The board's Surgical Care Committee recommendations included, but are not limited to: a restriction on surgery in doctor's offices to surgeries that are expected to take no more than eight hours to perform; and a restriction on the amount of fat (4,000 cc) that may be removed by liposuction. The Surgical Care Committee's recommendations were presented to the board at its December 3, 1998, meeting and the board unanimously moved to discuss the rule during a January conference call. At a telephone conference call held on January 6, 1998, the Board of Medicine voted to approve a draft rule which closely tracks the committee's recommendations except the draft rule:

- Restricts surgery in doctor's offices to four hours rather than eight hours;
- Significantly restricts the amount of fat (2000 cc rather than 4000 cc) that may be removed by liposuction in doctor's offices; and
- Requires the presence of a licensed medical physician or osteopathic physician who is an anesthesiologist, other than the surgeon, to provide direct supervision over any anesthesia provider who is not an anesthesiologist for certain surgical procedures.

The definition of surgery is revised under the proposed rule to include any elective procedure for anesthetic or cosmetic purposes and the insertion of natural or artificial implants. The proposed rule requires surgeons in offices where surgery is performed to obtain accreditation of the office setting by specified accrediting agencies or to submit to annual inspections by the Department of Health. The proposed rule requires surgeons in offices where surgery is performed to pay for all expenses related to accreditation or inspection. The proposed rule revises the definition of office surgery to mean surgery which is performed outside a hospital, an ambulatory surgical center, abortion clinic, or other medical facility licensed by the Department of Health, the Agency for Health Care Administration, or a successor agency. The proposed rule was noticed in the Florida Administrative Weekly on January 22, 1999. The staff of the Joint Committee on Administrative

Procedures has raised questions regarding the board's specific rulemaking authority for the provisions within the proposed rule that: authorize the board and the Department of Health to inspect premises where office surgery is performed; require accreditation of the office setting and the optional annual inspection of the office setting; require all expenses related to accreditation or inspection be paid by the surgeon. The board has scheduled a hearing on the proposed rule on April 11, 1999. Once noticed, any interested party may challenge the proposed rule under procedures specified in the Administrative Procedure Act.

Chapter 459, F.S., authorizes the Board of Osteopathic Medicine to regulate the practice of osteopathic medicine. Section 459.005, F.S., authorizes the Board of Osteopathic Medicine to adopt rules pursuant to provisions within the Administrative Procedure Act to implement the provisions of the chapter conferring duties upon it. The chapter provides grounds for which an osteopathic physician may be subject to disciplinary action by the Board of Osteopathic Medicine. Section 459.015(1)(z), F.S., was amended by the Legislature in 1998 to authorize the Board of Osteopathic Medicine to establish by rule standards of practice and standards of care for particular practice settings, including, but not limited to, education and training, equipment and supplies, medications including anesthetics, assistance of and delegation to other personnel, transfer agreements, sterilization, records, performance of complex or multiple procedures, informed consent, and policy and procedure manuals.

Part II, chapter 455, F.S., provides the general regulatory provisions for professions regulated by the Department of Health. Section 455.621, F.S., provides procedures to be used for the discipline of health care practitioners. Disciplinary complaints and all information obtained by the Department of Health are confidential and exempt from the public records and meetings laws until 10 days after probable cause is found or the subject of the complaint waives confidentiality. Section 455.667(8), F.S., provides that all patient records obtained by the Department of Health and any other documents maintained by the department which identify the patient by name are confidential and exempt from the public records and meetings laws, and may be used solely by the department and the appropriate regulatory board in their investigation, prosecution, and appeal of disciplinary proceedings. The patient records may not be made available to the public as part of the record of investigation for and prosecution in disciplinary proceedings.

III. Effect of Proposed Changes:

The bill requires any medical physician, osteopathic physician, or physician assistant to notify the Department of Health of any adverse incident that involved the physician or physician assistant which occurred on or after January 1, 2000, in any office maintained by the physician for the practice of medicine that is not licensed under chapter 395, F.S., relating to licensure for hospitals and ambulatory surgical centers. The bill requires any medical physician, osteopathic physician, or physician assistant to notify the department in writing and by certified mail of the adverse incident within 15 days after the adverse incident occurred. The notice must be postmarked within 15 days after the adverse incident occurred. The bill defines "adverse incident" to mean an event over which the physician or physician assistant 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: death of a patient; brain or spinal damage to a patient; performance of a surgical procedure on the wrong patient; any condition that required the transfer of a patient to a hospital licensed under chapter 395, F.S., from an

ambulatory surgical center licensed under chapter 395, F.S., or any facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395; or performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure. Under the definition of adverse incident, a medical physician, osteopathic physician, or physician assistant must provide notice of any of the following patient injuries only if it results in death, brain or spinal damage, permanent disfigurement, fracture or dislocation of bones or joints, a limitation of neurological, physical or sensory function, or any condition that required the transfer of the patient: the performance of a wrong-site surgical procedure; performance of a wrong surgical procedure; or surgical repair of damage resulting to the 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.

The bill requires the Department of Health to review each adverse incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action, and provides that the procedures for handling disciplinary complaints under chapter 455.621, F.S., apply.

The bill relocates in statute a provision that authorizes the Board of Medicine to adopt by rule standards of practice and standards of care for particular settings, including but not limited to, education and training, equipment and supplies, medications including anesthetics, assistance of and delegation to other personnel, transfer agreements, sterilization, records, performance of complex or multiple procedures, informed consent, and policy and procedure manuals. The bill authorizes the Board of Medicine to establish by rule requirements for the registration and inspection of settings in which Level II or Level III office surgery, as defined by board rule, is performed. The Department of Health must conduct registration and inspection of settings in which office surgery is performed for the purpose of determining compliance with the Board of Medicine's rules. The bill authorizes the Board of Medicine to approve appropriate accreditation agencies for the purpose of conducting required inspections. The bill requires the actual costs for registration and inspection to be paid by the person seeking to register and operate the office setting in which Level II or Level III office surgery is performed. The bill provides an effective date of July 1, 1999.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

SB 1824 has been filed to create exemptions from chapter 119, Florida Statutes, relating to the public records and meetings laws and Section 24(a), Article I of the State Constitution for information contained in a notice of an adverse incident submitted to the Department of Health and provides findings of necessity to justify the creation of the exemptions. The legislation also specifies that the notice is not discoverable or admissible in any civil or administrative action, unless the action is a disciplinary proceeding by the Department of

Health or an appropriate regulatory board. The legislation provides that the information contained in the notice of an adverse incident report maintained by the Department of Health may not be made available to the public as part of the record of an investigation for and prosecution in disciplinary proceedings made available to the public by the Department of Health or an appropriate regulatory board. The legislation makes the exemptions subject to a review prior to a repeal date of October 2, 2003, in accordance with the Open Government Sunset Review Act of 1995.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

Surgeons that perform surgery in any office maintained by the physician for the practice of medicine that is not licensed under chapter 395, F.S., relating to licensure for hospitals and ambulatory surgical centers, will be subject to the actual costs for registration and inspection under the bill. The Department of Health estimates that the registration fee will be $25 and the inspection fee will be $1500. There are approximately 42,000 actively licensed medical physicians and 2,157 actively licensed osteopathic physicians in Florida according to the Department of Health. The number of physicians performing surgery in office settings who will be subject to the requirements of the bill is unknown. Approximately 1,800 members of the Florida Medical Association have reported surgery as their medical specialty. The Florida Osteopathic Medical Association estimates that 194 members of its association have reported surgery as their medical specialty.

B. Private Sector Impact:

Physicians who perform surgery in any office maintained by the physician for the practice of medicine that is not licensed under chapter 395, F.S., relating to licensure for hospitals and ambulatory surgical centers will incur costs associated with filing reports of adverse incidents. Charges for office visits in physician practices that perform surgery may increase to cover expenses that a surgeon will incur under the bill to obtain and maintain surgical office accreditation.

C. Government Sector Impact:

The Agency for Health Care Administration will incur additional costs to complete the additional investigations based on adverse incident reporting required under the bill. According to the Agency for Health Care Administration the adverse incident reporting requirement will not constitute a significant fiscal impact on the agency.

The Department of Health estimates that its expense to implement the registration and inspection of office settings in which surgery is performed will be $437,500 for fiscal year

1999-2000 and $337,500 for fiscal year 2000-2001. The Department of Health estimates that its expenses will be offset by revenue collected from physicians, for fiscal year 1999-2000: 2,500 surgeons registering @ $25 ($62,500); 250 surgeon's offices subject to inspection @ $1,500 ($375,000) totaling $437,500. For fiscal year 2000-2001: 100 surgeons registering @ $25 ($2,500); 250 surgeon's offices subject to inspection @ $1,500 ($375,000) totaling $377,500.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.