By the Committee on Health, Aging and Long-Term Care; and Senator Campbell

317-1883-99

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A bill to be entitled An act relating to the practice of medicine; creating s. 458.351, F.S.; requiring that a physician or person licensed under ch. 458, F.S., notify the Department of Health of any adverse incident occurring in a setting that is not licensed under ch. 395, F.S.; defining the term "adverse incident"; requiring that the department review adverse incidents; authorizing the Board of Medicine to adopt rules; amending s. 458.331, F.S., relating to grounds for disciplinary action by the board; deleting provisions made obsolete by the act; amending s. 458.309, F.S.; authorizing the board to adopt standards of practice and care for particular practice settings; authorizing the board to adopt standards for conducting surgery in settings other than a hospital; authorizing the board to approve other agencies to conduct inspections; creating s. 459.026, F.S.; requiring that an osteopathic physician or person licensed under ch. 459, F.S., notify the Department of Health of any adverse incident occurring in a setting that is not licensed under ch. 395, F.S.; defining the term "adverse incident"; requiring that the department review adverse incidents; authorizing the Board of Osteopathic Medicine to adopt rules; providing an effective date. 31 Be It Enacted by the Legislature of the State of Florida:

CODING: Words stricken are deletions; words underlined are additions.

Section 1. Section 458.351, Florida Statutes, is created to read:

458.351 Reports of adverse incidents in specified settings.--

- (1) Any adverse incident that occurs on or after

 January 1, 2000, in any office maintained by a physician for

 the practice of medicine which is not licensed under chapter

 395 must be reported to the department in accordance with this section.
- (2) Any physician or other licensee under this chapter practicing in this state must notify the department if the physician or licensee was involved in an adverse incident that occurred on or after January 1, 2000, in any office maintained by a physician for the practice of medicine which is not licensed under chapter 395.
- (3) The required notification to the department must be submitted in writing by certified mail of the adverse incident, which notice must be postmarked within 15 days after the occurrence of the adverse incident.
- (4) For purposes of notification to the department pursuant to this section, the term "adverse incident" 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.

31 read:

1 (d)1. The performance of a wrong-site surgical 2 procedure; 3 2. The performance of a wrong surgical procedure; or The surgical repair of damage to a patient 4 5 resulting from a planned surgical procedure where the damage 6 is not a recognized specific risk as disclosed to the patient 7 and documented through the informed-consent process 8 9 if it results in: death; brain or spinal damage; permanent 10 disfigurement not to include the incision scar; fracture or 11 dislocation of bones or joints; a limitation of neurological, physical, or sensory function; or any condition that required 12 the transfer of the patient. 13 (e) A procedure to remove unplanned foreign objects 14 15 remaining from a surgical procedure. (f) Any condition that required the transfer of a 16 17 patient to a hospital licensed under chapter 395 from an ambulatory surgical center licensed under chapter 395 or any 18 19 facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395. 20 (5) The department shall review each incident and 21 determine whether it potentially involved conduct by a health 22 care professional who is subject to disciplinary action, in 23 24 which case s. 455.621 applies. Disciplinary action, if any, 25 shall be taken by the board under which the health care professional is licensed. 26 27 The board may adopt rules to administer this 28 section. 29 Section 2. Paragraph (v) of subsection (1) of section 30 458.331, Florida Statutes, 1998 Supplement, is amended to

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 $$458.331\:$ Grounds for disciplinary action; action by the board and department.--

- (1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:
- (v) 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 may 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.

Section 3. Subsections (3) and (4) are added to section 458.309, Florida Statutes, 1998 Supplement, to read: 458.309 Authority to make rules.--

- (3) The board may 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.
- (4) In addition to the standards listed under subsection (3), the board may establish by rule requirements for the registration and inspection of settings in which Level

II or III office surgery, as defined by board rule, is performed. Such registration and inspections shall be conducted by the department for the purpose of determining compliance with board rules. The board may approve appropriate accreditation agencies for the purpose of conducting inspections. The actual costs for registration and inspection shall be paid by the person seeking to register and operate the office setting in which Level II or III office surgery is performed.

Section 4. Section 459.026, Florida Statutes, is created to read:

459.026 Reports of adverse incidents in office practice settings.--

- (1) Any adverse incident that occurs on or after

 January 1, 2000, in any office maintained by an osteopathic

 physician for the practice of osteopathic medicine which is

 not licensed under chapter 395 must be reported to the

 department in accordance with the provisions of this section.
- (2) Any osteopathic physician or other licensee under this chapter practicing in this state must notify the department if the osteopathic physician or licensee was involved in an adverse incident that occurred on or after January 1, 2000, in any office maintained by an osteopathic physician for the practice of osteopathic medicine which is not licensed under chapter 395.
- (3) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.
- (4) For purposes of notification to the department pursuant to this section, the term "adverse incident" means an event over which the osteopathic physician or licensee could

wrong patient;

exercise control and which is associated in whole or in part
with medical intervention, rather than the condition for which
such intervention occurred, and which results in any of 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

- (d)1. The performance of a wrong-site surgical procedure;
 - 2. The performance of a wrong surgical procedure; or
- 3. The surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process

- if it results in: death; brain or spinal damage; permanent disfigurement not to include the incision scar; 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.
- (e) The performance of procedures to remove foreign objects left unintentionally during a previous surgical procedure.
- (f) Any condition that required the transfer of a patient to a hospital licensed under chapter 395 from an ambulatory surgical center licensed under chapter 395 or any facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395.
- (5) The department shall review each incident and determine whether it potentially involved conduct by a health

care professional who is subject to disciplinary action, in which case the provisions of s. 455.621 shall apply; and disciplinary action, if any, shall be taken by the board under which the health care professional is licensed. The board may adopt rules to implement this (6) section. Section 5. This act shall take effect July 1, 1999. STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN 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. Revises the definition of adverse incident. Limits the Board of Medicine's authority to establish by rule requirements for the registration and inspection of settings in which Level II or Level III office surgery, as defined by the board rule, is performed rather than all office surgery