

By Senator Campbell

33-1001-99

1                                   A bill to be entitled  
 2           An act relating to the practice of medicine;  
 3           creating s. 458.351, F.S.; requiring that a  
 4           physician or person licensed under ch. 458,  
 5           F.S., notify the Department of Health of any  
 6           adverse incident occurring in a setting that is  
 7           not licensed under ch. 395, F.S.; defining the  
 8           term "adverse incident"; requiring that the  
 9           department review adverse incidents;  
 10          authorizing the Board of Medicine to adopt  
 11          rules; amending s. 458.331, F.S., relating to  
 12          grounds for disciplinary action by the board;  
 13          deleting provisions made obsolete by the act;  
 14          amending s. 458.309, F.S.; authorizing the  
 15          board to adopt standards of practice and care  
 16          for particular practice settings; authorizing  
 17          the board to adopt standards for conducting  
 18          surgery in settings other than a hospital;  
 19          authorizing the board to approve other agencies  
 20          to conduct inspections; providing an effective  
 21          date.

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 23 Be It Enacted by the Legislature of the State of Florida:

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

27           458.351 Reports of adverse incidents in specified  
 28           settings.--

29           (1) Effective January 1, 2000, any adverse incident  
 30           that occurs in any setting that is not licensed under chapter  
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1 395 must be reported to the department in accordance with this  
2 section.

3 (2) Any physician or other person licensed under this  
4 chapter who practices in this state must notify the department  
5 of any adverse incident that involved the physician or  
6 licensee and occurred in a setting that is not licensed under  
7 chapter 395, or of any patient whom the physician or licensee  
8 accepted for care or treatment due to an injury that was the  
9 result of an adverse incident that occurred in a setting that  
10 is not licensed under chapter 395.

11 (3) The physician or licensee must notify the  
12 department in writing and by certified mail of the adverse  
13 incident, which notice must be postmarked within 15 days after  
14 the adverse incident occurred.

15 (4) As used in this section, the term "adverse  
16 incident" means an event over which the physician or licensee  
17 could exercise control and which is associated in whole or in  
18 part with a medical intervention, rather than the condition  
19 for which such intervention occurred, and which results in the  
20 following patient injuries:

21 (a) The death of a patient.

22 (b) Brain or spinal damage to a patient.

23 (c) The performance of a surgical procedure on the  
24 wrong patient.

25 (d) The performance of a wrong-site surgical  
26 procedure.

27 (e) The performance of a wrong surgical procedure.

28 (f) The performance of a surgical procedure that is  
29 medically unnecessary or otherwise unrelated to the patient's  
30 diagnosis or medical condition.

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1       (g) The surgical repair of damage resulting to a  
2 patient from a planned surgical procedure, where the damage  
3 was not a recognized specific risk, as disclosed to the  
4 patient and documented through the informed-consent process.

5       (h) A procedure to remove unplanned foreign objects  
6 remaining from a surgical procedure.

7       (5) The department shall review each adverse incident  
8 and determine whether the incident potentially involved  
9 conduct by a health care professional who is subject to  
10 disciplinary action, in which case s. 455.621 applies. The  
11 department shall have access to all medical records necessary  
12 to administer this section.

13       (6) The department or the appropriate regulatory board  
14 shall make available, upon written request by a health care  
15 professional against whom probable cause has been found, any  
16 such records that form the basis of the determination of  
17 probable cause, except that s. 766.101 applies with respect to  
18 records of a medical review committee.

19       (7) The board may adopt rules to administer this  
20 section.

21       Section 2. Paragraph (v) of subsection (1) of section  
22 458.331, Florida Statutes, 1998 Supplement, is amended to  
23 read:

24       458.331 Grounds for disciplinary action; action by the  
25 board and department.--

26       (1) The following acts shall constitute grounds for  
27 which the disciplinary actions specified in subsection (2) may  
28 be taken:

29       (v) Practicing or offering to practice beyond the  
30 scope permitted by law or accepting and performing  
31 professional responsibilities which the licensee knows or has

1 reason to know that he or she is not competent to perform. ~~The~~  
2 ~~board may establish by rule standards of practice and~~  
3 ~~standards of care for particular practice settings, including,~~  
4 ~~but not limited to, education and training, equipment and~~  
5 ~~supplies, medications including anesthetics, assistance of and~~  
6 ~~delegation to other personnel, transfer agreements,~~  
7 ~~sterilization, records, performance of complex or multiple~~  
8 ~~procedures, informed consent, and policy and procedure~~  
9 ~~manuals.~~

10 Section 3. Subsections (3) and (4) are added to  
11 section 458.309, Florida Statutes, 1998 Supplement, to read:

12 458.309 Authority to make rules.--

13 (3) The board may establish by rule standards of  
14 practice and standards of care for particular practice  
15 settings, including, but not limited to, education and  
16 training, equipment and supplies, medications including  
17 anesthetics, assistance of and delegation to other personnel,  
18 transfer agreements, sterilization, records, performance of  
19 complex or multiple procedures, informed consent, and policy  
20 and procedure manuals.

21 (4) The board may establish by rule standards of  
22 practice and standards of care for the conduct of surgery in  
23 office settings other than a hospital, including an ambulatory  
24 surgical center, abortion clinic, or other facility licensed  
25 by the Department of Health, the Agency for Health Care  
26 Administration, or a successor agency. In addition to the  
27 standards listed under subsection (3), the board may establish  
28 by rule requirements for the registration and inspection of  
29 settings in which office surgery is performed. Such  
30 registration and inspections shall be conducted by the  
31 department for the purpose of determining compliance with

1 board rules. However, the board may approve appropriate  
2 accreditation agencies for the purpose of conducting required  
3 inspections. The actual costs for registration and inspection  
4 shall be paid by the person or entity seeking to register or  
5 operate the office setting at which surgery is performed.

6 Section 4. This act shall take effect July 1, 1999.

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9 SENATE SUMMARY

10 Requires that a physician or person licensed under ch.  
11 458, F.S., notify the Department of Health of any adverse  
12 incident that occurs in a setting other than a hospital.  
13 Specifies the events that constitute an adverse incident.  
14 Requires that the Department of Health review reported  
15 adverse incidents. Provides rulemaking authority for the  
16 Board of Medicine with respect to reports of adverse  
17 incidents. (See bill for details.)  
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