1	A bill to be entitled
2	An act relating to regulation of health care
3	practitioners; creating ss. 458.351 and
4	459.026, F.S.; requiring reports to the
5	Department of Health of adverse incidents in
6	specified settings; providing for review of
7	such incidents and initiation of disciplinary
8	proceedings, where appropriate; authorizing
9	department access to certain records and
10	preserving exemption from public access
11	thereto; providing rulemaking authority;
12	providing an effective date.
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14	Be It Enacted by the Legislature of the State of Florida:
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16	Section 1. Paragraph (v) of subsection (1) of section
17	458.331, Florida Statutes, 1998 Supplement, is amended to
18	read:
19	458.331 Grounds for disciplinary action; action by the
20	board and department
21	(1) The following acts shall constitute grounds for
22	which the disciplinary actions specified in subsection (2) may
23	be taken:
24	(v) Practicing or offering to practice beyond the
25	scope permitted by law or accepting and performing
26	professional responsibilities which the licensee knows or has
27	reason to know that he or she is not competent to perform. The
28	board may establish by rule standards of practice and
29	standards of care for particular practice settings, including,
30	but not limited to, education and training, equipment and
31	supplies, medications including anesthetics, assistance of and
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delegation to other personnel, transfer agreements, 1 2 sterilization, records, performance of complex or multiple 3 procedures, informed consent, and policy and procedure 4 manuals. 5 Section 2. Subsections (3) and (4) are added to 6 section 458.309, Florida Statutes, 1998 Supplement, to read: 7 458.309 Authority to make rules.--8 (3) The board may establish by rule standards of 9 practice and standards of care for particular practice settings, including, but not limited to, education and 10 training, equipment and supplies, medications including 11 12 anesthetics, assistance of and delegation to other personnel, transfer agreements, sterilization, records, performance of 13 14 complex or multiple procedures, informed consent, and policy 15 and procedure manuals. (4) In addition to the standards listed under 16 17 subsection (3), the board may establish by rule requirements for the registration and inspection of settings in which Level 18 19 II or III office surgery, as defined by board rule, is 20 performed. Such registration and inspections shall be 21 conducted by the department for the purpose of determining compliance with board rules. The board may approve appropriate 22 23 accreditation agencies for the purpose of conducting inspections. The actual costs for registration and inspection 24 25 shall be paid by the person seeking to register and operate the office setting in which Level II or III office surgery is 26 performed. 27 28 Section 3. Section 458.351, Florida Statutes, is 29 created to read: 30 458.351 Reports of adverse incidents in office 31 practice settings .--2

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(1) Any adverse incident that occurs on or after 1 2 January 1, 2000, in any office maintained by a physician for 3 the practice of medicine which is not licensed under chapter 4 395 must be reported to the department in accordance with the 5 provisions of this section. 6 (2) Any physician or other licensee under this chapter 7 practicing in this state must notify the department if the 8 physician or licensee was involved in an adverse incident that 9 occurred on or after January 1, 2000, in any office maintained by a physician for the practice of medicine which is not 10 licensed under chapter 395. 11 (3) The required notification to the department must 12 be submitted in writing by certified mail and postmarked 13 14 within 15 days after the occurrence of the adverse incident. 15 (4) For purposes of notification to the department pursuant to this section, the term "adverse incident" means an 16 17 event over which the physician or licensee could exercise 18 control and which is associated in whole or in part with a 19 medical intervention, rather than the condition for which such 20 intervention occurred, and which results in the following 21 patient injuries: (a) The death of a patient. 22 23 (b) Brain or spinal damage to a patient. (c) The performance of a surgical procedure on the 24 25 wrong patient. 26 (d)1. The performance of a wrong-site surgical 27 procedure; 28 2. The performance of a wrong surgical procedure; or 29 The surgical repair of damage to a patient 3. 30 resulting from a planned surgical procedure where the damage 31 3 CODING: Words stricken are deletions; words underlined are additions.

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is not a recognized specific risk as disclosed to the patient 1 2 and documented through the informed-consent process 3 4 if it results in: death; brain or spinal damage; permanent disfigurement not to include the incision scar; fracture or 5 6 dislocation of bones or joints; a limitation of neurological, 7 physical or sensory function; or any condition that required 8 the transfer of the patient. 9 (e) A procedure to remove unplanned foreign objects 10 remaining from a surgical procedure. (f) Any condition that required the transfer of a 11 12 patient to a hospital licensed under chapter 395 from an 13 ambulatory surgical center licensed under chapter 395 or any 14 facility or any office maintained by a physician for the 15 practice of medicine which is not licensed under chapter 395. 16 (5) The department shall review each incident and 17 determine whether it potentially involved conduct by a health care professional who is subject to disciplinary action, in 18 19 which case s. 455.621 applies. Disciplinary action, if any, 20 shall be taken by the board under which the health care professional is licensed. 21 The board may adopt rules to administer this 22 (6) 23 section. 24 Section 4. Section 459.026, Florida Statutes, is 25 created to read: 26 459.026 Reports of adverse incidents in office 27 practice settings. --28 (1) Any adverse incident that occurs on or after 29 January 1, 2000, in any office maintained by an osteopathic 30 physician for the practice of osteopathic medicine which is 31 4

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not licensed under chapter 395 must be reported to the 1 2 department in accordance with the provisions of this section. 3 (2) Any osteopathic physician or other licensee under 4 this chapter practicing in this state must notify the 5 department if the osteopathic physician or licensee was 6 involved in an adverse incident that occurred on or after 7 January 1, 2000, in any office maintained by an osteopathic 8 physician for the practice of osteopathic medicine which is 9 not licensed under chapter 395. (3) The required notification to the department must 10 be submitted in writing by certified mail and postmarked 11 12 within 15 days after the occurrence of the adverse incident. (4) For purposes of notification to the department 13 14 pursuant to this section, the term "adverse incident" means an event over which the physician or licensee could exercise 15 control and which is associated in whole or in part with a 16 17 medical intervention, rather than the condition for which such intervention occurred, and which results in the following 18 19 patient injuries: 20 (a) The death of a patient. 21 (b) Brain or spinal damage to a patient. 22 (c) The performance of a surgical procedure on the 23 wrong patient. (d)1. The performance of a wrong-site surgical 24 25 procedure; 26 2. The performance of a wrong surgical procedure; or 27 3. The surgical repair of damage to a patient resulting from a planned surgical procedure where the damage 28 29 is not a recognized specific risk as disclosed to the patient 30 and documented through the informed-consent process 31 5 CODING: Words stricken are deletions; words underlined are additions.

if it results in: death; brain or spinal damage; permanent 1 disfigurement not to include the incision scar; fracture or 2 3 dislocation of bones or joints; a limitation of neurological, 4 physical or sensory function; or any condition that required 5 the transfer of the patient. 6 (e) A procedure to remove unplanned foreign objects 7 remaining from a surgical procedure. 8 (f) Any condition that required the transfer of a 9 patient to a hospital licensed under chapter 395 from an ambulatory surgical center licensed under chapter 395 or any 10 facility or any office maintained by a physician for the 11 12 practice of medicine which is not licensed under chapter 395. 13 (5) The department shall review each incident and 14 determine whether it potentially involved conduct by a health 15 care professional who is subject to disciplinary action, in which case s. 455.621 applies. Disciplinary action, if any, 16 17 shall be taken by the board under which the health care professional is licensed. 18 (6) The board may adopt rules to administer this 19 20 section. 21 Section 5. This act shall take effect upon becoming a 22 law. 23 24 25 26 27 28 29 30 31 6 CODING: Words stricken are deletions; words underlined are additions.