

	LEGISLATIVE ACTION	
Senate	•	House
Comm: RCS	•	
04/10/2019		
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Appropriations Subcommittee on Health and Human Services (Flores) recommended the following:

## Senate Substitute for Amendment (359744) (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (12) is added to section 456.004, Florida Statutes, to read:

456.004 Department; powers and duties.—The department, for the professions under its jurisdiction, shall:

(12) Deny or revoke the registration of, or impose any

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11 penalty set forth in s. 456.072(2) against, any facility where office surgery, as defined in ss. 458.305(8) and 459.003(9), is 12 performed for failure of any of its physicians, owners, or 13 14 operators to comply with rules adopted under ss. 458.309(3) and 15 459.005(2). Section 456.073 applies to enforcement actions 16 brought against such facilities. If a facility's registration is 17 revoked, the department may deny any person named in the 18 registration documents of the facility, including the persons 19 who own or operate the facility, individually or as part of a 20 group, from registering a facility to perform surgical procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5 21 22 years after the revocation date. 23 Section 2. Subsection (6) is added to section 456.074, 24 Florida Statutes, to read: 2.5 456.074 Certain health care practitioners; immediate 26 suspension of license.-27 (6) The department may issue an emergency order suspending 28 or restricting the registration of a facility in which 29 liposuction procedures in which more than 1,000 cubic 30 centimeters of supernatant fat is removed, Level II office 31 surgery, or Level III office surgery as those terms are defined 32 in ss. 458.305(8) and 459.003(9), are performed upon a finding 33 of probable cause that the facility or its surgeons are not in 34 compliance with the standards of practice for office surgery 35 adopted by the boards pursuant to s. 458.309(4) or s. 36 459.005(3), as applicable, or are in violation of s. 37 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance 38 constitutes an immediate danger to the public. 39 Section 3. Section 458.305, Florida Statutes, is amended to



40	read:
41	458.305 Definitions.—As used in this chapter, the term:
42	(1) "Board" means the Board of Medicine.
43	(2) "Deep sedation and analgesia" means a drug-induced
44	depression of consciousness during which all of the following
45	apply:
46	(a) The patient cannot be easily aroused but responds by
47	purposefully following repeated or painful stimulation.
48	(b) The patient's ability to independently maintain
49	ventilatory function may be impaired.
50	(c) The patient may require assistance in maintaining a
51	patent airway, and spontaneous ventilation may be inadequate.
52	(d) The patient's cardiovascular function is usually
53	maintained.
54	(e) The patient's reflex withdrawal from painful stimulus
55	is not considered a purposeful response.
56	(3) (2) "Department" means the Department of Health.
57	(4) "Epidural anesthesia" means anesthesia produced by the
58	injection of an anesthetic agent into the space on or around the
59	dura mater of the spinal cord.
60	(5) "General anesthesia" means a drug-induced loss of
61	consciousness administered by a qualified general anesthesia
62	provider during which all of the following apply:
63	(a) The patient is not able to be aroused, even by painful
64	stimulation.
65	(b) The patient's ability to independently maintain
66	ventilatory function is often impaired.
67	(c) The patient has a level of depressed neuromuscular
68	function.



69 (d) The patient may require assistance in maintaining a 70 patent airway, and positive pressure ventilation may be 71 required. 72 (e) The patient's cardiovascular function may be impaired. 73 (6) "Minimal sedation" means a drug-induced state during 74 which patients respond normally to verbal commands. Although 75 cognitive function and physical coordination may be impaired, 76 airway reflexes and respiratory and cardiovascular functions are 77 unaffected. 78 (7) "Moderate sedation and analgesia" or "conscious 79 sedation" means drug-induced depression of consciousness and a 80 state of consciousness during which all of the following apply: 81 (a) The patient responds purposefully to verbal commands, 82 either alone or accompanied by light tactile stimulation. 83 (b) Interventions are not required to maintain a patent 84 airway, and spontaneous ventilation is adequate. 85 (c) Cardiovascular function is maintained. (d) Reflex withdrawal from a painful stimulus is not 86 87 considered a purposeful response. 88 (8) "Office surgery" means a surgery that is performed in a 89 physician's office or any facility that is not licensed under chapter 390 or chapter 395. 90 91 (a) "Level I office surgery" includes any surgery that consists of only minor procedures and in which anesthesia is 92 93 limited to minimal sedation. 94 (b) "Level II office surgery" includes any surgery in which

the patient's level of sedation is that of moderate sedation and

(c) "Level III office surgery" includes any surgery in

analgesia or conscious sedation.

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which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

- (10) (3) "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.
- (11) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.
  - (12) "Surgeon" means a physician who performs surgery.
- (13) "Surgery" means 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, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.
- (9) (4) "Physician" means a person who is licensed to practice medicine in this state.
- Section 4. Subsection (3) of section 458.309, Florida Statutes, is amended and subsection (4) is added to that section, to read:

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458.309 Rulemaking authority.-

- (3) A physician who performs any liposuction procedure procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery level 2 procedures lasting more than 5 minutes, or any Level III office surgery and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 458.320.
- (4) (a) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery.
- (b) As a part of registration, such an office must designate a physician who is responsible for the office's compliance with this section and the rules adopted hereunder. Within 10 days after termination of the designated physician, the office must notify the department of the identity of another designated physician for that office. The designated physician must have a full, active, and unencumbered license under this

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chapter or chapter 459 and shall practice at the office for which he or she has assumed responsibility. The department may suspend a registration certificate for an office without a designated physician who practices at the office.

- (c) The department shall inspect the office at least annually, including a review of patient records, to ensure that it complies with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of a physician's office that meets the description of a clinic specified in s. 458.3265(1)(a)1.h., which must be announced.
- (d) The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of \$5,000 per day on a physician who performs a surgical procedure identified in subsection (3) in an office that is not registered with the department.

Section 5. Paragraph (vv) is added to subsection (1) of section 458.331, Florida Statutes, to read:

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

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (vv) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is removed, a Level II office surgery, or a Level III office surgery in an office that is not registered with the department pursuant to s. 458.309(3).

Section 6. Section 459.003, Florida Statutes, is amended to



185	read:
186	459.003 Definitions.—As used in this chapter, the term:
187	(1) "Board" means the Board of Osteopathic Medicine.
188	(2) "Deep sedation and analgesia" means a drug-induced
189	depression of consciousness during which all of the following
190	<pre>apply:</pre>
191	(a) The patient cannot be easily aroused but responds by
192	purposefully following repeated or painful stimulation.
193	(b) The patient's ability to independently maintain
194	ventilatory function may be impaired.
195	(c) The patient may require assistance in maintaining a
196	patent airway, and spontaneous ventilation may be inadequate.
197	(d) The patient's cardiovascular function is usually
198	maintained.
199	(e) The patient's reflex withdrawal from painful stimulus
200	is not considered a purposeful response.
201	(3) "Department" means the Department of Health.
202	(5) "Epidural anesthesia" means anesthesia produced by the
203	injection of an anesthetic agent into the space on or around the
204	dura mater of the spinal cord.
205	(6) "General anesthesia" means a drug-induced loss of
206	consciousness administered by a qualified general anesthesia
207	provider during which all of the following apply:
208	(a) The patient is not able to be aroused, even by painful
209	stimulation.
210	(b) The patient's ability to independently maintain
211	ventilatory function is often impaired.
212	(c) The patient has a level of depressed neuromuscular
213	function.



214 (d) The patient may require assistance in maintaining a 215 patent airway, and positive pressure ventilation may be 216 required. 217 (e) The patient's cardiovascular function may be impaired. 218 (7) "Minimal sedation" means a drug-induced state during 219 which patients respond normally to verbal commands. Although 220 cognitive function and physical coordination may be impaired, 221 airway reflexes, and respiratory and cardiovascular functions 222 are unaffected. 223 (8) "Moderate sedation and analgesia" or "conscious 224 sedation" means drug-induced depression of consciousness and a 225 state of consciousness during which all of the following apply: 226 (a) The patient responds purposefully to verbal commands, 227 either alone or accompanied by light tactile stimulation. 228 (b) Interventions are not required to maintain a patent 229 airway, and spontaneous ventilation is adequate. 230 (c) Cardiovascular function is maintained. (d) Reflex withdrawal from a painful stimulus is not 231 232 considered a purposeful response. 233 (9) "Office surgery" means a surgery that is performed in a 234 physician's office or any facility that is not licensed under 235 chapter 390 or chapter 395. 236 (a) "Level I office surgery" includes any surgery that 237 consists of only minor procedures and in which anesthesia is 238 limited to minimal sedation. 239 (b) "Level II office surgery" includes any surgery in which 240 the patient's level of sedation is that of moderate sedation and 241 analgesia or conscious sedation.

(c) "Level III office surgery" includes any surgery in

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which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The term includes any surgery that includes the use of spinal anesthesia or epidural anesthesia.

- (11) (3) "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.
- (12) "Spinal anesthesia" means anesthesia produced by the injection of an anesthetic agent into the subarachnoid space of the spinal cord.
  - (13) "Surgeon" means a physician who performs surgery.
- (14) "Surgery" means 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, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, including, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.
  - (10) (4) "Osteopathic physician" means a person who is

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licensed to practice osteopathic medicine in this state.

(4) <del>(5)</del> "Doctor of Osteopathy" and "Doctor of Osteopathic Medicine," when referring to degrees, shall be construed to be equivalent and equal degrees.

Section 7. Subsection (2) of section 459.005, Florida Statutes, is amended and subsection (3) is added to that section, to read:

459.005 Rulemaking authority.-

- (2) A physician who performs any liposuction procedure procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, any Level II office surgery level 2 procedures lasting more than 5 minutes, or any Level III office surgery and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility under chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed. As a condition of registration, a physician who performs such surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in s. 459.0085.
- (3) (a) The board may adopt rules to administer the registration, inspection, and safety of offices in which a physician performs office surgery.

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- (b) As a part of registration, such an office must designate a physician who is responsible for the office's compliance with this section and the rules adopted hereunder. Within 10 days after termination of the designated physician, the office must notify the department of the identity of another designated physician for that office. The designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. The department may suspend a registration certificate for an office without a designated physician who practices at the office. (c) The department shall inspect the office at least
- annually, including a review of patient records, to ensure that it complies with this section and rules adopted hereunder unless the office is accredited by a nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of a physician's office that meets the description of a clinic specified in s. 459.0137(1)(a)1.h., which must be announced.
- (d) The board shall adopt by rule standards of practice for physicians who perform office surgery. The board shall impose a fine of \$5,000 per day on a physician who performs a surgical procedure identified in subsection (2) in an office that is not registered with the department.
- Section 8. Paragraph (xx) is added to subsection (1) of section 459.015, Florida Statutes, to read:
- 459.015 Grounds for disciplinary action; action by the board and department.-
  - (1) The following acts constitute grounds for denial of a



330 license or disciplinary action, as specified in s. 456.072(2): 331 (xx) Performing a liposuction procedure in which more than 1,000 cubic centimeters of supernatant <u>fat is removed</u>, a <u>Level</u> 332 333 II office surgery, or a Level III office surgery in an office 334 that is not registered with the department pursuant to s. 335 459.005(2). 336 Section 9. Paragraph (a) of subsection (1) of section 337 766.101, Florida Statutes, is amended to read: 338 766.101 Medical review committee, immunity from liability. 339 (1) As used in this section: 340 (a) The term "medical review committee" or "committee" 341 means: 342 1.a. A committee of a hospital or ambulatory surgical 343 center licensed under chapter 395 or a health maintenance 344 organization certificated under part I of chapter 641; 345 b. A committee of a physician-hospital organization, a 346 provider-sponsored organization, or an integrated delivery 347 system; 348 c. A committee of a state or local professional society of 349 health care providers; 350 d. A committee of a medical staff of a licensed hospital or 351 nursing home, provided the medical staff operates pursuant to 352 written bylaws that have been approved by the governing board of 353 the hospital or nursing home; 354 e. A committee of the Department of Corrections or the 355 Correctional Medical Authority as created under s. 945.602, or 356 employees, agents, or consultants of either the department or 357 the authority or both;

f. A committee of a professional service corporation formed

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under chapter 621 or a corporation organized under part I of chapter 607 or chapter 617, which is formed and operated for the practice of medicine as defined in s.  $458.305 \cdot \frac{458.305(3)}{5}$ , and which has at least 25 health care providers who routinely provide health care services directly to patients;

- q. A committee of the Department of Children and Families which includes employees, agents, or consultants to the department as deemed necessary to provide peer review, utilization review, and mortality review of treatment services provided pursuant to chapters 394, 397, and 916;
- h. A committee of a mental health treatment facility licensed under chapter 394 or a community mental health center as defined in s. 394.907, provided the quality assurance program operates pursuant to the guidelines that have been approved by the governing board of the agency;
- i. A committee of a substance abuse treatment and education prevention program licensed under chapter 397 provided the quality assurance program operates pursuant to the quidelines that have been approved by the governing board of the agency;
- j. A peer review or utilization review committee organized under chapter 440;
- k. A committee of the Department of Health, a county health department, healthy start coalition, or certified rural health network, when reviewing quality of care, or employees of these entities when reviewing mortality records; or
- 1. A continuous quality improvement committee of a pharmacy licensed pursuant to chapter 465,

which committee is formed to evaluate and improve the quality of



health care rendered by providers of health service, to determine that health services rendered were professionally indicated or were performed in compliance with the applicable standard of care, or that the cost of health care rendered was considered reasonable by the providers of professional health services in the area; or

2. A committee of an insurer, self-insurer, or joint underwriting association of medical malpractice insurance, or other persons conducting review under s. 766.106.

Section 10. This act shall take effect upon becoming a law.

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========== T I T L E A M E N D M E N T ============= And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to clinics and office surgery; amending s. 456.004, F.S.; requiring the Department of Health to deny or revoke the registration of or impose certain penalties against a facility where certain office surgeries are performed under certain circumstances; specifying provisions that apply enforcement actions against such facilities; authorizing the department to deny certain persons associated with an office of which the registration was revoked from registering a new office to perform certain office surgery; amending s. 456.074, F.S.; authorizing the department to issue an emergency order suspending or restricting the registration of a

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certain office if it makes certain findings; amending s. 458.305, F.S.; defining terms; amending s. 458.309, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the Board of Medicine to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery; requiring such an office to designate a certain physician responsible for the office's compliance with specified provisions; authorizing the department to suspend an office's registration certificate under certain circumstances; requiring the department to conduct certain inspections; providing an exception; requiring the board to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 458.331, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 459.003, F.S.; defining terms; amending s. 459.005, F.S.; requiring a physician who performs certain office surgery and the office in which the surgery is performed to maintain specified levels of financial responsibility; authorizing the Board of Osteopathic Medicine to adopt rules to administer the registration, inspection, and

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safety of offices that perform certain office surgery; requiring such an office to designate a certain physician responsible for the office's compliance with specified provisions; authorizing the department to suspend an office's registration certificate under certain circumstances; requiring the department to conduct certain inspections; providing an exception; requiring the board to adopt rules governing the standard of care for physicians practicing in such offices; requiring the board to impose a specified fine on physicians who perform certain office surgeries in an unregistered office; amending s. 459.015, F.S.; providing that a physician performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action; amending s. 766.101, F.S.; conforming a cross-reference; providing an effective date.