

By the Committees on Appropriations; and Health Policy; and
Senator Flores

576-04628-19

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1 A bill to be entitled
2 An act relating to clinics and office surgery;
3 amending s. 456.004, F.S.; requiring the Department of
4 Health to deny or revoke the registration of or impose
5 certain penalties against a facility where certain
6 office surgeries are performed under certain
7 circumstances; specifying provisions that apply
8 enforcement actions against such facilities;
9 authorizing the department to deny certain persons
10 associated with an office of which the registration
11 was revoked from registering a new office to perform
12 certain office surgery; amending s. 456.074, F.S.;
13 authorizing the department to issue an emergency order
14 suspending or restricting the registration of a
15 certain office if it makes certain findings; amending
16 s. 458.305, F.S.; defining terms; amending s. 458.309,
17 F.S.; requiring a physician who performs certain
18 office surgery and the office in which the surgery is
19 performed to maintain specified levels of financial
20 responsibility; authorizing the Board of Medicine to
21 adopt rules to administer the registration,
22 inspection, and safety of offices that perform certain
23 office surgery; requiring such an office to designate
24 a certain physician responsible for the office's
25 compliance with specified provisions; authorizing the
26 department to suspend an office's registration
27 certificate under certain circumstances; requiring the
28 department to conduct certain inspections; providing
29 an exception; requiring the board to adopt rules

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30 governing the standard of care for physicians
31 practicing in such offices; requiring the board to
32 impose a specified fine on physicians who perform
33 certain office surgeries in an unregistered office;
34 amending s. 458.331, F.S.; providing that a physician
35 performing certain office surgeries in an unregistered
36 office constitutes grounds for denial of a license or
37 disciplinary action; amending s. 459.003, F.S.;

38 defining terms; amending s. 459.005, F.S.; requiring a
39 physician who performs certain office surgery and the
40 office in which the surgery is performed to maintain
41 specified levels of financial responsibility;
42 authorizing the Board of Osteopathic Medicine to adopt
43 rules to administer the registration, inspection, and
44 safety of offices that perform certain office surgery;
45 requiring such an office to designate a certain
46 physician responsible for the office's compliance with
47 specified provisions; authorizing the department to
48 suspend an office's registration certificate under
49 certain circumstances; requiring the department to
50 conduct certain inspections; providing an exception;
51 requiring the board to adopt rules governing the
52 standard of care for physicians practicing in such
53 offices; requiring the board to impose a specified
54 fine on physicians who perform certain office
55 surgeries in an unregistered office; amending s.
56 459.015, F.S.; providing that a physician performing
57 certain office surgeries in an unregistered office
58 constitutes grounds for denial of a license or

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59 disciplinary action; amending s. 766.101, F.S.;

60 conforming a cross-reference; providing an effective

61 date.

62

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

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65 Section 1. Subsection (12) is added to section 456.004,

66 Florida Statutes, to read:

67 456.004 Department; powers and duties.—The department, for

68 the professions under its jurisdiction, shall:

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

70 penalty set forth in s. 456.072(2) against, any facility where

71 office surgery, as defined in ss. 458.305(8) and 459.003(9), is

72 performed for failure of any of its physicians, owners, or

73 operators to comply with rules adopted under ss. 458.309(3) and

74 459.005(2). Section 456.073 applies to enforcement actions

75 brought against such facilities. If a facility's registration is

76 revoked, the department may deny any person named in the

77 registration documents of the facility, including the persons

78 who own or operate the facility, individually or as part of a

79 group, from registering a facility to perform surgical

80 procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5

81 years after the revocation date.

82 Section 2. Subsection (6) is added to section 456.074,

83 Florida Statutes, to read:

84 456.074 Certain health care practitioners; immediate

85 suspension of license.—

86 (6) The department may issue an emergency order suspending

87 or restricting the registration of a facility in which

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88 liposuction procedures in which more than 1,000 cubic
89 centimeters of supernatant fat is removed, Level II office
90 surgery, or Level III office surgery as those terms are defined
91 in ss. 458.305(8) and 459.003(9), are performed upon a finding
92 of probable cause that the facility or its surgeons are not in
93 compliance with the standards of practice for office surgery
94 adopted by the boards pursuant to s. 458.309(4) or s.
95 459.005(3), as applicable, or are in violation of s.
96 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance
97 constitutes an immediate danger to the public.

98 Section 3. Section 458.305, Florida Statutes, is amended to
99 read:

100 458.305 Definitions.—As used in this chapter, the term:

101 (1) "Board" means the Board of Medicine.

102 (2) "Deep sedation and analgesia" means a drug-induced
103 depression of consciousness during which all of the following
104 apply:

105 (a) The patient cannot be easily aroused but responds by
106 purposefully following repeated or painful stimulation.

107 (b) The patient's ability to independently maintain
108 ventilatory function may be impaired.

109 (c) The patient may require assistance in maintaining a
110 patent airway, and spontaneous ventilation may be inadequate.

111 (d) The patient's cardiovascular function is usually
112 maintained.

113 (e) The patient's reflex withdrawal from painful stimulus
114 is not considered a purposeful response.

115 (3)~~(2)~~ "Department" means the Department of Health.

116 (4) "Epidural anesthesia" means anesthesia produced by the

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117 injection of an anesthetic agent into the space on or around the
118 dura mater of the spinal cord.

119 (5) "General anesthesia" means a drug-induced loss of
120 consciousness administered by a qualified general anesthesia
121 provider during which all of the following apply:

122 (a) The patient is not able to be aroused, even by painful
123 stimulation.

124 (b) The patient's ability to independently maintain
125 ventilatory function is often impaired.

126 (c) The patient has a level of depressed neuromuscular
127 function.

128 (d) The patient may require assistance in maintaining a
129 patent airway, and positive pressure ventilation may be
130 required.

131 (e) The patient's cardiovascular function may be impaired.

132 (6) "Minimal sedation" means a drug-induced state during
133 which patients respond normally to verbal commands. Although
134 cognitive function and physical coordination may be impaired,
135 airway reflexes and respiratory and cardiovascular functions are
136 unaffected.

137 (7) "Moderate sedation and analgesia" or "conscious
138 sedation" means drug-induced depression of consciousness and a
139 state of consciousness during which all of the following apply:

140 (a) The patient responds purposefully to verbal commands,
141 either alone or accompanied by light tactile stimulation.

142 (b) Interventions are not required to maintain a patent
143 airway, and spontaneous ventilation is adequate.

144 (c) Cardiovascular function is maintained.

145 (d) Reflex withdrawal from a painful stimulus is not

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146 considered a purposeful response.

147 (8) "Office surgery" means a surgery that is performed in a
148 physician's office or any facility that is not licensed under
149 chapter 390 or chapter 395.

150 (a) "Level I office surgery" includes any surgery that
151 consists of only minor procedures and in which anesthesia is
152 limited to minimal sedation.

153 (b) "Level II office surgery" includes any surgery in which
154 the patient's level of sedation is that of moderate sedation and
155 analgesia or conscious sedation.

156 (c) "Level III office surgery" includes any surgery in
157 which the patient's level of sedation is that of deep sedation
158 and analgesia or general anesthesia. The term includes any
159 surgery that includes the use of spinal anesthesia or epidural
160 anesthesia.

161 (10) ~~(3)~~ "Practice of medicine" means the diagnosis,
162 treatment, operation, or prescription for any human disease,
163 pain, injury, deformity, or other physical or mental condition.

164 (11) "Spinal anesthesia" means anesthesia produced by the
165 injection of an anesthetic agent into the subarachnoid space of
166 the spinal cord.

167 (12) "Surgeon" means a physician who performs surgery.

168 (13) "Surgery" means any manual or operative procedure,
169 including the use of lasers, performed upon the body of a living
170 human being for the purposes of preserving health, diagnosing or
171 curing disease, repairing injury, correcting deformity or
172 defects, prolonging life, or relieving suffering or any elective
173 procedure for aesthetic, reconstructive, or cosmetic purposes,
174 including, but not limited to: incision or curettage of tissue

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175 or an organ; suture or other repair of tissue or organ,
176 including a closed as well as an open reduction of a fracture;
177 extraction of tissue including premature extraction of the
178 products of conception from the uterus; insertion of natural or
179 artificial implants; or an endoscopic procedure with use of
180 local or general anesthetic.

181 (9)~~(4)~~ "Physician" means a person who is licensed to
182 practice medicine in this state.

183 Section 4. Subsection (3) of section 458.309, Florida
184 Statutes, is amended and subsection (4) is added to that
185 section, to read:

186 458.309 Rulemaking authority.—

187 (3) A physician who performs any liposuction procedure
188 ~~procedures~~ in which more than 1,000 cubic centimeters of
189 supernatant fat is removed, any Level II office surgery level 2
190 ~~procedures lasting more than 5 minutes,~~ or any Level III office
191 surgery and all level 3 surgical procedures in an office setting
192 must register the office with the department unless that office
193 is licensed as a facility under chapter 395. The department
194 shall inspect the physician's office annually unless the office
195 is accredited by a nationally recognized accrediting agency or
196 an accrediting organization ~~subsequently~~ approved by the Board
197 of Medicine. The actual costs for registration and inspection or
198 accreditation shall be paid by the person seeking to register
199 and operate the office setting in which office surgery is
200 performed. As a condition of registration, a physician who
201 performs such surgical procedures in an office setting, and the
202 office itself if it is a separate legal entity from the
203 physician, must maintain the same levels of financial

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204 responsibility required in s. 458.320.

205 (4) (a) The board may adopt rules to administer the
206 registration, inspection, and safety of offices in which a
207 physician performs office surgery.

208 (b) As a part of registration, such an office must
209 designate a physician who is responsible for the office's
210 compliance with this section and the rules adopted hereunder.
211 Within 10 days after termination of the designated physician,
212 the office must notify the department of the identity of another
213 designated physician for that office. The designated physician
214 must have a full, active, and unencumbered license under this
215 chapter or chapter 459 and shall practice at the office for
216 which he or she has assumed responsibility. The department may
217 suspend a registration certificate for an office without a
218 designated physician who practices at the office.

219 (c) The department shall inspect the office at least
220 annually, including a review of patient records, to ensure that
221 it complies with this section and rules adopted hereunder unless
222 the office is accredited by a nationally recognized accrediting
223 agency approved by the board. The inspection may be unannounced,
224 except for the inspection of a physician's office that meets the
225 description of a clinic specified in s. 458.3265(1)(a)3.g. and
226 h., which must be announced.

227 (d) The board shall adopt by rule standards of practice for
228 physicians who perform office surgery. The board shall impose a
229 fine of \$5,000 per day on a physician who performs a surgical
230 procedure identified in subsection (3) in an office that is not
231 registered with the department.

232 Section 5. Paragraph (vv) is added to subsection (1) of

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233 section 458.331, Florida Statutes, to read:

234 458.331 Grounds for disciplinary action; action by the
235 board and department.—

236 (1) The following acts constitute grounds for denial of a
237 license or disciplinary action, as specified in s. 456.072(2):

238 (vv) Performing a liposuction procedure in which more than
239 1,000 cubic centimeters of supernatant fat is removed, a Level
240 II office surgery, or a Level III office surgery in an office
241 that is not registered with the department pursuant to s.
242 458.309(3).

243 Section 6. Section 459.003, Florida Statutes, is amended to
244 read:

245 459.003 Definitions.—As used in this chapter, the term:

246 (1) "Board" means the Board of Osteopathic Medicine.

247 (2) "Deep sedation and analgesia" means a drug-induced
248 depression of consciousness during which all of the following
249 apply:

250 (a) The patient cannot be easily aroused but responds by
251 purposefully following repeated or painful stimulation.

252 (b) The patient's ability to independently maintain
253 ventilatory function may be impaired.

254 (c) The patient may require assistance in maintaining a
255 patent airway, and spontaneous ventilation may be inadequate.

256 (d) The patient's cardiovascular function is usually
257 maintained.

258 (e) The patient's reflex withdrawal from painful stimulus
259 is not considered a purposeful response.

260 (3)-(2) "Department" means the Department of Health.

261 (5) "Epidural anesthesia" means anesthesia produced by the

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262 injection of an anesthetic agent into the space on or around the
263 dura mater of the spinal cord.

264 (6) "General anesthesia" means a drug-induced loss of
265 consciousness administered by a qualified general anesthesia
266 provider during which all of the following apply:

267 (a) The patient is not able to be aroused, even by painful
268 stimulation.

269 (b) The patient's ability to independently maintain
270 ventilatory function is often impaired.

271 (c) The patient has a level of depressed neuromuscular
272 function.

273 (d) The patient may require assistance in maintaining a
274 patent airway, and positive pressure ventilation may be
275 required.

276 (e) The patient's cardiovascular function may be impaired.

277 (7) "Minimal sedation" means a drug-induced state during
278 which patients respond normally to verbal commands. Although
279 cognitive function and physical coordination may be impaired,
280 airway reflexes, and respiratory and cardiovascular functions
281 are unaffected.

282 (8) "Moderate sedation and analgesia" or "conscious
283 sedation" means drug-induced depression of consciousness and a
284 state of consciousness during which all of the following apply:

285 (a) The patient responds purposefully to verbal commands,
286 either alone or accompanied by light tactile stimulation.

287 (b) Interventions are not required to maintain a patent
288 airway, and spontaneous ventilation is adequate.

289 (c) Cardiovascular function is maintained.

290 (d) Reflex withdrawal from a painful stimulus is not

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291 considered a purposeful response.

292 (9) "Office surgery" means a surgery that is performed in a
293 physician's office or any facility that is not licensed under
294 chapter 390 or chapter 395.

295 (a) "Level I office surgery" includes any surgery that
296 consists of only minor procedures and in which anesthesia is
297 limited to minimal sedation.

298 (b) "Level II office surgery" includes any surgery in which
299 the patient's level of sedation is that of moderate sedation and
300 analgesia or conscious sedation.

301 (c) "Level III office surgery" includes any surgery in
302 which the patient's level of sedation is that of deep sedation
303 and analgesia or general anesthesia. The term includes any
304 surgery that includes the use of spinal anesthesia or epidural
305 anesthesia.

306 (11) ~~(3)~~ "Practice of osteopathic medicine" means the
307 diagnosis, treatment, operation, or prescription for any human
308 disease, pain, injury, deformity, or other physical or mental
309 condition, which practice is based in part upon educational
310 standards and requirements which emphasize the importance of the
311 musculoskeletal structure and manipulative therapy in the
312 maintenance and restoration of health.

313 (12) "Spinal anesthesia" means anesthesia produced by the
314 injection of an anesthetic agent into the subarachnoid space of
315 the spinal cord.

316 (13) "Surgeon" means a physician who performs surgery.

317 (14) "Surgery" means any manual or operative procedure,
318 including the use of lasers, performed upon the body of a living
319 human being for the purposes of preserving health, diagnosing or

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320 curing disease, repairing injury, correcting deformity or
321 defects, prolonging life, or relieving suffering or any elective
322 procedure for aesthetic, reconstructive, or cosmetic purposes,
323 including, but not limited to: incision or curettage of tissue
324 or an organ; suture or other repair of tissue or organ,
325 including a closed as well as an open reduction of a fracture;
326 extraction of tissue including premature extraction of the
327 products of conception from the uterus; insertion of natural or
328 artificial implants; or an endoscopic procedure with use of
329 local or general anesthetic.

330 (10)~~(4)~~ "Osteopathic physician" means a person who is
331 licensed to practice osteopathic medicine in this state.

332 (4)~~(5)~~ "Doctor of Osteopathy" and "Doctor of Osteopathic
333 Medicine," when referring to degrees, shall be construed to be
334 equivalent and equal degrees.

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

338 459.005 Rulemaking authority.—

339 (2) A physician who performs any liposuction procedure
340 ~~procedures~~ in which more than 1,000 cubic centimeters of
341 supernatant fat is removed, any Level II office surgery level 2
342 ~~procedures lasting more than 5 minutes, or any Level III office~~
343 surgery and all level 3 surgical procedures in an office setting
344 must register the office with the department unless that office
345 is licensed as a facility under chapter 395. The department
346 shall inspect the physician's office annually unless the office
347 is accredited by a nationally recognized accrediting agency or
348 an accrediting organization ~~subsequently~~ approved by the Board

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349 of Osteopathic Medicine. The actual costs for registration and
350 inspection or accreditation shall be paid by the person seeking
351 to register and operate the office setting in which office
352 surgery is performed. As a condition of registration, a
353 physician who performs such surgical procedures in an office
354 setting, and the office itself if it is a separate legal entity
355 from the physician, must maintain the same levels of financial
356 responsibility required in s. 459.0085.

357 (3) (a) The board may adopt rules to administer the
358 registration, inspection, and safety of offices in which a
359 physician performs office surgery.

360 (b) As a part of registration, such an office must
361 designate a physician who is responsible for the office's
362 compliance with this section and the rules adopted hereunder.
363 Within 10 days after termination of the designated physician,
364 the office must notify the department of the identity of another
365 designated physician for that office. The designated physician
366 must have a full, active, and unencumbered license under this
367 chapter or chapter 458 and shall practice at the office for
368 which he or she has assumed responsibility. The department may
369 suspend a registration certificate for an office without a
370 designated physician who practices at the office.

371 (c) The department shall inspect the office at least
372 annually, including a review of patient records, to ensure that
373 it complies with this section and rules adopted hereunder unless
374 the office is accredited by a nationally recognized accrediting
375 agency approved by the board. The inspection may be unannounced,
376 except for the inspection of a physician's office that meets the
377 description of a clinic specified in s. 459.0137(1) (a) 3.g. and

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378 h., which must be announced.

379 (d) The board shall adopt by rule standards of practice for
380 physicians who perform office surgery. The board shall impose a
381 fine of \$5,000 per day on a physician who performs a surgical
382 procedure identified in subsection (2) in an office that is not
383 registered with the department.

384 Section 8. Paragraph (xx) is added to subsection (1) of
385 section 459.015, Florida Statutes, to read:

386 459.015 Grounds for disciplinary action; action by the
387 board and department.—

388 (1) The following acts constitute grounds for denial of a
389 license or disciplinary action, as specified in s. 456.072(2):

390 (xx) Performing a liposuction procedure in which more than
391 1,000 cubic centimeters of supernatant fat is removed, a Level
392 II office surgery, or a Level III office surgery in an office
393 that is not registered with the department pursuant to s.
394 459.005(2).

395 Section 9. Paragraph (a) of subsection (1) of section
396 766.101, Florida Statutes, is amended to read:

397 766.101 Medical review committee, immunity from liability.—

398 (1) As used in this section:

399 (a) The term "medical review committee" or "committee"
400 means:

401 1.a. A committee of a hospital or ambulatory surgical
402 center licensed under chapter 395 or a health maintenance
403 organization certificated under part I of chapter 641;

404 b. A committee of a physician-hospital organization, a
405 provider-sponsored organization, or an integrated delivery
406 system;

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- 407 c. A committee of a state or local professional society of
408 health care providers;
- 409 d. A committee of a medical staff of a licensed hospital or
410 nursing home, provided the medical staff operates pursuant to
411 written bylaws that have been approved by the governing board of
412 the hospital or nursing home;
- 413 e. A committee of the Department of Corrections or the
414 Correctional Medical Authority as created under s. 945.602, or
415 employees, agents, or consultants of either the department or
416 the authority or both;
- 417 f. A committee of a professional service corporation formed
418 under chapter 621 or a corporation organized under part I of
419 chapter 607 or chapter 617, which is formed and operated for the
420 practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~, and
421 which has at least 25 health care providers who routinely
422 provide health care services directly to patients;
- 423 g. A committee of the Department of Children and Families
424 which includes employees, agents, or consultants to the
425 department as deemed necessary to provide peer review,
426 utilization review, and mortality review of treatment services
427 provided pursuant to chapters 394, 397, and 916;
- 428 h. A committee of a mental health treatment facility
429 licensed under chapter 394 or a community mental health center
430 as defined in s. 394.907, provided the quality assurance program
431 operates pursuant to the guidelines that have been approved by
432 the governing board of the agency;
- 433 i. A committee of a substance abuse treatment and education
434 prevention program licensed under chapter 397 provided the
435 quality assurance program operates pursuant to the guidelines

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436 that have been approved by the governing board of the agency;

437 j. A peer review or utilization review committee organized
438 under chapter 440;

439 k. A committee of the Department of Health, a county health
440 department, healthy start coalition, or certified rural health
441 network, when reviewing quality of care, or employees of these
442 entities when reviewing mortality records; or

443 l. A continuous quality improvement committee of a pharmacy
444 licensed pursuant to chapter 465,

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446 which committee is formed to evaluate and improve the quality of
447 health care rendered by providers of health service, to
448 determine that health services rendered were professionally
449 indicated or were performed in compliance with the applicable
450 standard of care, or that the cost of health care rendered was
451 considered reasonable by the providers of professional health
452 services in the area; or

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

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