

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 in which certain
6 procedures or office surgeries are performed under
7 certain circumstances; providing applicability;
8 authorizing the department to deny certain persons
9 associated with a facility of which the registration
10 was revoked from registering another facility to
11 perform certain procedures or office surgeries;
12 amending s. 456.074, F.S.; authorizing the department
13 to issue an emergency order suspending or restricting
14 the registration of certain facilities upon specified
15 findings; amending s. 458.305, F.S.; providing
16 definitions; amending s. 458.309, F.S.; requiring a
17 physician who performs certain procedures or office
18 surgeries and the office in which the procedures or
19 office surgeries are performed to maintain specified
20 levels of financial responsibility; authorizing the
21 Department of Health to adopt rules to administer the
22 registration, inspection, and safety of offices in
23 which certain procedures or office surgeries are
24 performed; requiring the Board of Medicine to adopt
25 rules governing the standards of practice for

26 | physicians practicing in such offices and to impose a
27 | specified fine on physicians who perform certain
28 | procedures or office surgeries in an unregistered
29 | office; amending s. 458.331, F.S.; providing that a
30 | physician performing certain procedures or office
31 | surgeries in an unregistered office constitutes
32 | grounds for denial of a license or disciplinary
33 | action; amending s. 459.003, F.S.; providing
34 | definitions; amending s. 459.005, F.S.; requiring a
35 | physician who performs certain procedures or office
36 | surgeries and the office in which the procedures or
37 | office surgeries are performed to maintain specified
38 | levels of financial responsibility; authorizing the
39 | Department of Health to adopt rules to administer the
40 | registration, inspection, and safety of offices in
41 | which certain procedures or office surgeries are
42 | performed; requiring the Board of Osteopathic Medicine
43 | to adopt rules governing the standards of practice for
44 | physicians practicing in such offices and to impose a
45 | specified fine on physicians who perform certain
46 | procedures or office surgeries in an unregistered
47 | office; amending s. 459.015, F.S.; providing that a
48 | physician performing certain procedures or office
49 | surgeries in an unregistered office constitutes
50 | grounds for denial of a license or disciplinary

51 action; amending s. 766.101, F.S.; conforming a cross-
52 reference; providing an effective date.

53

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

55

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

58 456.004 Department; powers and duties.—The department, for
59 the professions under its jurisdiction, shall:

60 (12) Deny or revoke the registration of, or impose any
61 penalty set forth in s. 456.072(2) against, any facility in
62 which office surgery, as defined in ss. 458.305(8) and
63 459.003(9), is performed for failure of any of its physicians,
64 owners, or operators to comply with rules adopted under ss.
65 458.309(3) and 459.005(2). Section 456.073 applies to
66 enforcement actions brought against such facilities. If a
67 facility's registration is revoked, the department may deny any
68 person named in the registration documents of the facility,
69 including the persons who own or operate the facility,
70 individually or as part of a group, from registering a facility
71 to perform surgical procedures pursuant to s. 458.309(3) or s.
72 459.005(2) for 5 years after the revocation date.

73 Section 2. Subsection (6) is added to section 456.074,
74 Florida Statutes, to read:

75 456.074 Certain health care practitioners; immediate

76 suspension of license.—

77 (6) The department may issue an emergency order suspending
 78 or restricting the registration of a facility in which
 79 liposuction procedures in which more than 1,000 cubic
 80 centimeters of supernatant fat is removed, Level II office
 81 surgery, or Level III office surgery, as those terms are defined
 82 in ss. 458.305(8) and 459.003(9), are performed upon a finding
 83 of probable cause that the facility or its surgeons are not in
 84 compliance with the standards of practice for office surgery
 85 adopted by the boards pursuant to s. 458.309(4) or s.
 86 459.005(3), as applicable, or are in violation of s.
 87 458.331(1)(v) or s. 459.015(1)(z) and that such noncompliance
 88 constitutes an immediate danger to the public.

89 Section 3. Section 458.305, Florida Statutes, is amended
 90 to read:

91 458.305 Definitions.—As used in this chapter, the term:

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

93 (2) "Deep sedation and analgesia" means a drug-induced
 94 depression of consciousness during which all of the following
 95 apply:

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

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

100 (c) The patient may require assistance in maintaining a

101 patent airway, and spontaneous ventilation may be inadequate.

102 (d) The patient's cardiovascular function is usually
103 maintained.

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

106 (3)~~(2)~~ "Department" means the Department of Health.

107 (4) "Epidural anesthesia" means anesthesia produced by the
108 injection of an anesthetic agent into the space on or around the
109 dura mater of the spinal cord.

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

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

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

117 (c) The patient has depressed neuromuscular function.

118 (d) The patient may require assistance in maintaining a
119 patent airway, and positive pressure ventilation may be
120 required.

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

122 (6) "Minimal sedation" means a drug-induced state during
123 which patients respond normally to verbal commands. Although
124 cognitive function and physical coordination may be impaired,
125 airway reflexes and respiratory and cardiovascular functions are

126 unaffected.

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

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

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

134 (c) Cardiovascular function is maintained.

135 (d) Reflex withdrawal from a painful stimulus is not
136 considered a purposeful response.

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

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

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

146 (c) "Level III office surgery" includes any surgery in
147 which the patient's level of sedation is that of deep sedation
148 and analgesia or general anesthesia. The term includes any
149 surgery that includes the use of spinal anesthesia or epidural
150 anesthesia.

151 ~~(9)-(4)~~ "Physician" means a person who is licensed to
152 practice medicine in this state.

153 ~~(10)-(3)~~ "Practice of medicine" means the diagnosis,
154 treatment, operation, or prescription for any human disease,
155 pain, injury, deformity, or other physical or mental condition.

156 (11) "Spinal anesthesia" means anesthesia produced by the
157 injection of an anesthetic agent into the subarachnoid space of
158 the spinal cord.

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

160 (13) "Surgery" means any manual or operative procedure,
161 including the use of lasers, performed upon the body of a living
162 human being for the purposes of preserving health, diagnosing or
163 curing disease, repairing injury, correcting deformity or
164 defects, prolonging life, or relieving suffering or any elective
165 procedure for aesthetic, reconstructive, or cosmetic purposes,
166 including, but not limited to: incision or curettage of tissue
167 or an organ; suture or other repair of tissue or an organ,
168 including a closed as well as an open reduction of a fracture;
169 extraction of tissue, including premature extraction of the
170 products of conception from the uterus; insertion of natural or
171 artificial implants; or an endoscopic procedure with use of
172 local or general anesthetic.

173 Section 4. Subsection (3) of section 458.309, Florida
174 Statutes, is amended, and subsection (4) is added to that
175 section, to read:

176 458.309 Rulemaking authority.—

177 (3) A physician who performs any liposuction procedure
178 ~~procedures~~ in which more than 1,000 cubic centimeters of
179 supernatant fat is removed, any Level II office surgery level 2
180 ~~procedures lasting more than 5 minutes, or any Level III office~~
181 surgery and all level 3 surgical procedures in an office setting
182 must register the office with the department unless that office
183 is licensed as a facility under chapter 395. The department
184 shall inspect the physician's office annually unless the office
185 is accredited by a nationally recognized accrediting agency or
186 an accrediting organization ~~subsequently~~ approved by the Board
187 of Medicine. The actual costs for registration and inspection or
188 accreditation shall be paid by the person seeking to register
189 and operate the office setting in which office surgery is
190 performed. As a condition of registration, a physician who
191 performs surgical procedures in an office setting, and the
192 office itself if it is a separate legal entity from the
193 physician, must maintain the same levels of financial
194 responsibility required in s. 458.320.

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

198 (b) As a part of registration, such an office must
199 designate a physician who is responsible for the office's
200 compliance with this section and the rules adopted hereunder.

201 Within 10 days after termination of the designated physician,
202 the office must notify the department of the identity of another
203 designated physician for that office. The designated physician
204 must have a full, active, and unencumbered license under this
205 chapter or chapter 459 and shall practice at the office for
206 which he or she has assumed responsibility. The department may
207 suspend a registration certificate for an office without a
208 designated physician who practices at the office.

209 (c) The department shall inspect the office at least
210 annually, including a review of patient records, to ensure that
211 it complies with this section and rules adopted hereunder unless
212 the office is accredited by a nationally recognized accrediting
213 agency approved by the board. The inspection may be unannounced,
214 except for the inspection of a physician's office that meets the
215 description of a clinic specified in s. 458.3265(1)(a)3.h.,
216 which must be announced.

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

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

224 458.331 Grounds for disciplinary action; action by the
225 board and department.—

226 (1) The following acts constitute grounds for denial of a
 227 license or disciplinary action, as specified in s. 456.072(2):
 228 (vv) Performing a liposuction procedure in which more than
 229 1,000 cubic centimeters of supernatant fat is removed, a Level
 230 II office surgery, or a Level III office surgery in an office
 231 that is not registered with the department pursuant to s.
 232 458.309(3).

233 Section 6. Section 459.003, Florida Statutes, is amended
 234 to read:

235 459.003 Definitions.—As used in this chapter, the term:

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

237 (2) "Deep sedation and analgesia" means a drug-induced
 238 depression of consciousness during which all of the following
 239 apply:

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

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

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

246 (d) The patient's cardiovascular function is usually
 247 maintained.

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

250 (3)~~(2)~~ "Department" means the Department of Health.

251 (4)-(5) "Doctor of Osteopathy" and "Doctor of Osteopathic
252 Medicine," when referring to degrees, shall be construed to be
253 equivalent and equal degrees.

254 (5) "Epidural anesthesia" means anesthesia produced by the
255 injection of an anesthetic agent into the space on or around the
256 dura mater of the spinal cord.

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

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

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

264 (c) The patient has a level of depressed neuromuscular
265 function.

266 (d) The patient may require assistance in maintaining a
267 patent airway, and positive pressure ventilation may be
268 required.

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

270 (7) "Minimal sedation" means a drug-induced state during
271 which patients respond normally to verbal commands. Although
272 cognitive function and physical coordination may be impaired,
273 airway reflexes and respiratory and cardiovascular functions are
274 unaffected.

275 (8) "Moderate sedation and analgesia" or "conscious

276 sedation" means a drug-induced depression of consciousness and a
277 state of consciousness during which all of the following apply:

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

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

282 (c) Cardiovascular function is maintained.

283 (d) Reflex withdrawal from a painful stimulus is not
284 considered a purposeful response.

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

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

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

294 (c) "Level III office surgery" includes any surgery in
295 which the patient's level of sedation is that of deep sedation
296 and analgesia or general anesthesia. The term includes any
297 surgery that includes the use of spinal anesthesia or epidural
298 anesthesia.

299 (10)-(4) "Osteopathic physician" means a person who is
300 licensed to practice osteopathic medicine in this state.

301 ~~(11)(3)~~ "Practice of osteopathic medicine" means the
302 diagnosis, treatment, operation, or prescription for any human
303 disease, pain, injury, deformity, or other physical or mental
304 condition, which practice is based in part upon educational
305 standards and requirements which emphasize the importance of the
306 musculoskeletal structure and manipulative therapy in the
307 maintenance and restoration of health.

308 (12) "Spinal anesthesia" means anesthesia produced by the
309 injection of an anesthetic agent into the subarachnoid space of
310 the spinal cord.

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

312 (14) "Surgery" means any manual or operative procedure,
313 including the use of lasers, performed upon the body of a living
314 human being for the purposes of preserving health, diagnosing or
315 curing disease, repairing injury, correcting deformity or
316 defects, prolonging life, or relieving suffering or any elective
317 procedure for aesthetic, reconstructive, or cosmetic purposes,
318 including, but not limited to: incision or curettage of tissue
319 or an organ; suture or other repair of tissue or an organ,
320 including a closed as well as an open reduction of a fracture;
321 extraction of tissue, including premature extraction of the
322 products of conception from the uterus; insertion of natural or
323 artificial implants; or an endoscopic procedure with use of
324 local or general anesthetic.

325 Section 7. Subsection (2) of section 459.005, Florida

326 Statutes, is amended, and subsection (3) is added to that
 327 section, to read:

328 459.005 Rulemaking authority.—

329 (2) A physician who performs any liposuction procedure
 330 ~~procedures~~ in which more than 1,000 cubic centimeters of
 331 supernatant fat is removed, any Level II office surgery ~~level 2~~
 332 ~~procedures lasting more than 5 minutes, or any Level III office~~
 333 surgery and all level 3 surgical procedures in an office setting
 334 must register the office with the department unless that office
 335 is licensed as a facility under chapter 395. The department
 336 shall inspect the physician's office annually unless the office
 337 is accredited by a nationally recognized accrediting agency or
 338 an accrediting organization ~~subsequently~~ approved by the Board
 339 of Osteopathic Medicine. The actual costs for registration and
 340 inspection or accreditation shall be paid by the person seeking
 341 to register and operate the office setting in which office
 342 surgery is performed. As a condition of registration, a
 343 physician who performs such surgical procedure in an office
 344 setting, and the office itself if it is a separate legal entity
 345 from the physician, must maintain the same levels of financial
 346 responsibility required in s. 459.0085.

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

350 (b) As a part of registration, such an office must

351 designate a physician who is responsible for the office's
352 compliance with this section and the rules adopted hereunder.
353 Within 10 days after termination of the designated physician,
354 the office must notify the department of the identity of another
355 designated physician for that office. The designated physician
356 must have a full, active, and unencumbered license under this
357 chapter or chapter 458 and shall practice at the office for
358 which he or she has assumed responsibility. The department may
359 suspend a registration certificate for an office without a
360 designated physician who practices at the office.

361 (c) The department shall inspect the office at least
362 annually, including a review of patient records, to ensure that
363 it complies with this section and rules adopted hereunder unless
364 the office is accredited by a nationally recognized accrediting
365 agency approved by the board. The inspection may be unannounced,
366 except for the inspection of a physician's office that meets the
367 description of a clinic specified in s. 459.0137(1)(a)3.h.,
368 which must be announced.

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

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

376 459.015 Grounds for disciplinary action; action by the
 377 board and department.—

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

380 (xx) Performing a liposuction procedure in which more than
 381 1,000 cubic centimeters of supernatant fat is removed, a Level
 382 II office surgery, or a Level III office surgery in an office
 383 that is not registered with the department pursuant to s.
 384 459.005(2).

385 Section 9. Paragraph (a) of subsection (1) of section
 386 766.101, Florida Statutes, is amended to read:

387 766.101 Medical review committee, immunity from
 388 liability.—

389 (1) As used in this section:

390 (a) The term "medical review committee" or "committee"
 391 means:

392 1.a. A committee of a hospital or ambulatory surgical
 393 center licensed under chapter 395 or a health maintenance
 394 organization certificated under part I of chapter 641;

395 b. A committee of a physician-hospital organization, a
 396 provider-sponsored organization, or an integrated delivery
 397 system;

398 c. A committee of a state or local professional society of
 399 health care providers;

400 d. A committee of a medical staff of a licensed hospital

401 or nursing home, provided the medical staff operates pursuant to
402 written bylaws that have been approved by the governing board of
403 the hospital or nursing home;

404 e. A committee of the Department of Corrections or the
405 Correctional Medical Authority as created under s. 945.602, or
406 employees, agents, or consultants of either the department or
407 the authority or both;

408 f. A committee of a professional service corporation
409 formed under chapter 621 or a corporation organized under part I
410 of chapter 607 or chapter 617, which is formed and operated for
411 the practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~,
412 and which has at least 25 health care providers who routinely
413 provide health care services directly to patients;

414 g. A committee of the Department of Children and Families
415 which includes employees, agents, or consultants to the
416 department as deemed necessary to provide peer review,
417 utilization review, and mortality review of treatment services
418 provided pursuant to chapters 394, 397, and 916;

419 h. A committee of a mental health treatment facility
420 licensed under chapter 394 or a community mental health center
421 as defined in s. 394.907, provided the quality assurance program
422 operates pursuant to the guidelines that have been approved by
423 the governing board of the agency;

424 i. A committee of a substance abuse treatment and
425 education prevention program licensed under chapter 397 provided

426 | the quality assurance program operates pursuant to the
 427 | guidelines that have been approved by the governing board of the
 428 | agency;

429 | j. A peer review or utilization review committee organized
 430 | under chapter 440;

431 | k. A committee of the Department of Health, a county
 432 | health department, healthy start coalition, or certified rural
 433 | health network, when reviewing quality of care, or employees of
 434 | these entities when reviewing mortality records; or

435 | 1. A continuous quality improvement committee of a
 436 | pharmacy licensed pursuant to chapter 465,

437 |
 438 | which committee is formed to evaluate and improve the quality of
 439 | health care rendered by providers of health service, to
 440 | determine that health services rendered were professionally
 441 | indicated or were performed in compliance with the applicable
 442 | standard of care, or that the cost of health care rendered was
 443 | considered reasonable by the providers of professional health
 444 | services in the area; or

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

448 | Section 10. This act shall take effect July 1, 2019.