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LEGISLATIVE ACTION

Senate

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House

Appropriations Subcommittee on Health and Human Services
(Flores) recommended the following:

1 **Senate Substitute for Amendment (359744) (with title**
2 **amendment)**

3
4 Delete everything after the enacting clause
5 and insert:

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

8 456.004 Department; powers and duties.—The department, for
9 the professions under its jurisdiction, shall:

10 (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
12 office surgery, as defined in ss. 458.305(8) and 459.003(9), is
13 performed for failure of any of its physicians, owners, or
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
21 procedures pursuant to s. 458.309(3) or s. 459.005(2) for 5
22 years after the revocation date.

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

25 456.074 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



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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.



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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.

86 (d) Reflex withdrawal from a painful stimulus is not
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
90 chapter 390 or chapter 395.

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

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

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



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

102 (10)-~~(3)~~ "Practice of medicine" means the diagnosis,
103 treatment, operation, or prescription for any human disease,
104 pain, injury, deformity, or other physical or mental condition.

105 (11) "Spinal anesthesia" means anesthesia produced by the
106 injection of an anesthetic agent into the subarachnoid space of
107 the spinal cord.

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

109 (13) "Surgery" means any manual or operative procedure,
110 including the use of lasers, performed upon the body of a living
111 human being for the purposes of preserving health, diagnosing or
112 curing disease, repairing injury, correcting deformity or
113 defects, prolonging life, or relieving suffering or any elective
114 procedure for aesthetic, reconstructive, or cosmetic purposes,
115 including, but not limited to: incision or curettage of tissue
116 or an organ; suture or other repair of tissue or organ,
117 including a closed as well as an open reduction of a fracture;
118 extraction of tissue including premature extraction of the
119 products of conception from the uterus; insertion of natural or
120 artificial implants; or an endoscopic procedure with use of
121 local or general anesthetic.

122 (9)-~~(4)~~ "Physician" means a person who is licensed to
123 practice medicine in this state.

124 Section 4. Subsection (3) of section 458.309, Florida
125 Statutes, is amended and subsection (4) is added to that
126 section, to read:



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127 458.309 Rulemaking authority.—

128 (3) A physician who performs any liposuction procedure
129 ~~procedures~~ in which more than 1,000 cubic centimeters of
130 supernatant fat is removed, any Level II office surgery level 2
131 ~~procedures lasting more than 5 minutes, or any Level III office~~
132 surgery and all level 3 surgical procedures in an office setting
133 must register the office with the department unless that office
134 is licensed as a facility under chapter 395. The department
135 shall inspect the physician's office annually unless the office
136 is accredited by a nationally recognized accrediting agency or
137 an accrediting organization ~~subsequently~~ approved by the Board
138 of Medicine. The actual costs for registration and inspection or
139 accreditation shall be paid by the person seeking to register
140 and operate the office setting in which office surgery is
141 performed. As a condition of registration, a physician who
142 performs such surgical procedures in an office setting, and the
143 office itself if it is a separate legal entity from the
144 physician, must maintain the same levels of financial
145 responsibility required in s. 458.320.

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

149 (b) As a part of registration, such an office must
150 designate a physician who is responsible for the office's
151 compliance with this section and the rules adopted hereunder.
152 Within 10 days after termination of the designated physician,
153 the office must notify the department of the identity of another
154 designated physician for that office. The designated physician
155 must have a full, active, and unencumbered license under this



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

160 (c) The department shall inspect the office at least
161 annually, including a review of patient records, to ensure that
162 it complies with this section and rules adopted hereunder unless
163 the office is accredited by a nationally recognized accrediting
164 agency approved by the board. The inspection may be unannounced,
165 except for the inspection of a physician's office that meets the
166 description of a clinic specified in s. 458.3265(1)(a)1.h.,
167 which must be announced.

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

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

175 458.331 Grounds for disciplinary action; action by the
176 board and department.—

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

179 (vv) Performing a liposuction procedure in which more than
180 1,000 cubic centimeters of supernatant fat is removed, a Level
181 II office surgery, or a Level III office surgery in an office
182 that is not registered with the department pursuant to s.
183 458.309(3).

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



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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 apply:

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)~~ (2) "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.



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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.

231 (d) Reflex withdrawal from a painful stimulus is not
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.

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



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

247 (11)-(3) "Practice of osteopathic medicine" means the
248 diagnosis, treatment, operation, or prescription for any human
249 disease, pain, injury, deformity, or other physical or mental
250 condition, which practice is based in part upon educational
251 standards and requirements which emphasize the importance of the
252 musculoskeletal structure and manipulative therapy in the
253 maintenance and restoration of health.

254 (12) "Spinal anesthesia" means anesthesia produced by the
255 injection of an anesthetic agent into the subarachnoid space of
256 the spinal cord.

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

258 (14) "Surgery" means any manual or operative procedure,
259 including the use of lasers, performed upon the body of a living
260 human being for the purposes of preserving health, diagnosing or
261 curing disease, repairing injury, correcting deformity or
262 defects, prolonging life, or relieving suffering or any elective
263 procedure for aesthetic, reconstructive, or cosmetic purposes,
264 including, but not limited to: incision or curettage of tissue
265 or an organ; suture or other repair of tissue or organ,
266 including a closed as well as an open reduction of a fracture;
267 extraction of tissue including premature extraction of the
268 products of conception from the uterus; insertion of natural or
269 artificial implants; or an endoscopic procedure with use of
270 local or general anesthetic.

271 (10)-(4) "Osteopathic physician" means a person who is



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272 licensed to practice osteopathic medicine in this state.

273 ~~(4)-(5)~~ "Doctor of Osteopathy" and "Doctor of Osteopathic
274 Medicine," when referring to degrees, shall be construed to be
275 equivalent and equal degrees.

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

279 459.005 Rulemaking authority.—

280 (2) A physician who performs any liposuction procedure
281 ~~procedures~~ in which more than 1,000 cubic centimeters of
282 supernatant fat is removed, any Level II office surgery level 2
283 ~~procedures lasting more than 5 minutes, or any Level III office~~
284 surgery and all level 3 surgical procedures in an office setting
285 must register the office with the department unless that office
286 is licensed as a facility under chapter 395. The department
287 shall inspect the physician's office annually unless the office
288 is accredited by a nationally recognized accrediting agency or
289 an accrediting organization ~~subsequently~~ approved by the Board
290 of Osteopathic Medicine. The actual costs for registration and
291 inspection or accreditation shall be paid by the person seeking
292 to register and operate the office setting in which office
293 surgery is performed. As a condition of registration, a
294 physician who performs such surgical procedures in an office
295 setting, and the office itself if it is a separate legal entity
296 from the physician, must maintain the same levels of financial
297 responsibility required in s. 459.0085.

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



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301 (b) As a part of registration, such an office must
302 designate a physician who is responsible for the office's
303 compliance with this section and the rules adopted hereunder.
304 Within 10 days after termination of the designated physician,
305 the office must notify the department of the identity of another
306 designated physician for that office. The designated physician
307 must have a full, active, and unencumbered license under this
308 chapter or chapter 458 and shall practice at the office for
309 which he or she has assumed responsibility. The department may
310 suspend a registration certificate for an office without a
311 designated physician who practices at the office.

312 (c) The department shall inspect the office at least
313 annually, including a review of patient records, to ensure that
314 it complies with this section and rules adopted hereunder unless
315 the office is accredited by a nationally recognized accrediting
316 agency approved by the board. The inspection may be unannounced,
317 except for the inspection of a physician's office that meets the
318 description of a clinic specified in s. 459.0137(1)(a)1.h.,
319 which must be announced.

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

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

327 459.015 Grounds for disciplinary action; action by the
328 board and department.—

329 (1) The following acts constitute grounds for denial of a



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330 license or disciplinary action, as specified in s. 456.072(2):
331 (xx) Performing a liposuction procedure in which more than
332 1,000 cubic centimeters of supernatant fat is removed, a Level
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;

358 f. A committee of a professional service corporation formed



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359 under chapter 621 or a corporation organized under part I of
360 chapter 607 or chapter 617, which is formed and operated for the
361 practice of medicine as defined in s. 458.305 ~~s. 458.305(3)~~, and
362 which has at least 25 health care providers who routinely
363 provide health care services directly to patients;

364 g. A committee of the Department of Children and Families
365 which includes employees, agents, or consultants to the
366 department as deemed necessary to provide peer review,
367 utilization review, and mortality review of treatment services
368 provided pursuant to chapters 394, 397, and 916;

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

374 i. A committee of a substance abuse treatment and education
375 prevention program licensed under chapter 397 provided the
376 quality assurance program operates pursuant to the guidelines
377 that have been approved by the governing board of the agency;

378 j. A peer review or utilization review committee organized
379 under chapter 440;

380 k. A committee of the Department of Health, a county health
381 department, healthy start coalition, or certified rural health
382 network, when reviewing quality of care, or employees of these
383 entities when reviewing mortality records; or

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

386
387 which committee is formed to evaluate and improve the quality of



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

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

397 Section 10. This act shall take effect upon becoming a law.
398

399 ===== T I T L E A M E N D M E N T =====

400 And the title is amended as follows:

401 Delete everything before the enacting clause
402 and insert:

403 A bill to be entitled

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



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417 certain office if it makes certain findings; amending
418 s. 458.305, F.S.; defining terms; amending s. 458.309,
419 F.S.; requiring a physician who performs certain
420 office surgery and the office in which the surgery is
421 performed to maintain specified levels of financial
422 responsibility; authorizing the Board of Medicine to
423 adopt rules to administer the registration,
424 inspection, and safety of offices that perform certain
425 office surgery; requiring such an office to designate
426 a certain physician responsible for the office's
427 compliance with specified provisions; authorizing the
428 department to suspend an office's registration
429 certificate under certain circumstances; requiring the
430 department to conduct certain inspections; providing
431 an exception; requiring the board to adopt rules
432 governing the standard of care for physicians
433 practicing in such offices; requiring the board to
434 impose a specified fine on physicians who perform
435 certain office surgeries in an unregistered office;
436 amending s. 458.331, F.S.; providing that a physician
437 performing certain office surgeries in an unregistered
438 office constitutes grounds for denial of a license or
439 disciplinary action; amending s. 459.003, F.S.;
440 defining terms; amending s. 459.005, F.S.; requiring a
441 physician who performs certain office surgery and the
442 office in which the surgery is performed to maintain
443 specified levels of financial responsibility;
444 authorizing the Board of Osteopathic Medicine to adopt
445 rules to administer the registration, inspection, and



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446 safety of offices that perform certain office surgery;
447 requiring such an office to designate a certain
448 physician responsible for the office's compliance with
449 specified provisions; authorizing the department to
450 suspend an office's registration certificate under
451 certain circumstances; requiring the department to
452 conduct certain inspections; providing an exception;
453 requiring the board to adopt rules governing the
454 standard of care for physicians practicing in such
455 offices; requiring the board to impose a specified
456 fine on physicians who perform certain office
457 surgeries in an unregistered office; amending s.
458 459.015, F.S.; providing that a physician performing
459 certain office surgeries in an unregistered office
460 constitutes grounds for denial of a license or
461 disciplinary action; amending s. 766.101, F.S.;
462 conforming a cross-reference; providing an effective
463 date.