

By Senator Flores

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1 A bill to be entitled
2 An act relating to office surgery; amending s.
3 395.002, F.S.; revising the definition of the term
4 "ambulatory surgical center" to remove the exclusion
5 of physician offices; amending ss. 458.309 and
6 459.005, F.S.; deleting provisions related to the
7 registration and inspection of certain offices by the
8 Department of Health and the payment for such
9 registration and inspection, for the purpose of
10 relocating the requirements; creating ss. 458.3266 and
11 459.0138, F.S.; defining terms; relocating the
12 requirements that a person who seeks to operate an
13 office surgery center must register with the
14 department and pay registration costs; providing an
15 exception; requiring each office surgery center to
16 identify to the department a designated physician upon
17 registration or within a specified timeframe after the
18 resignation or termination of a designated physician;
19 authorizing the department to suspend a center's
20 certificate of registration under certain
21 circumstances; requiring the department to issue a
22 certificate of registration to qualified applicants
23 and prohibiting the department from issuing a
24 certificate to certain centers; requiring the
25 department to revoke a certificate upon making a
26 certain determination; requiring a designated
27 physician of a center to perform certain actions upon
28 the revocation or suspension of the center's
29 certificate and providing for the disposition of

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30 medicinal drugs; authorizing the department to
31 prescribe a certain period of suspension when
32 suspending the certificate of an office surgery
33 center; prohibiting persons named in the registration
34 documents of a center whose certificate was revoked
35 from applying to operate a center for a specified
36 time; prohibiting a registration from being
37 transferred to a new owner and requiring a new owner
38 to register the center with the department before
39 beginning operation under the new ownership;
40 prohibiting a physician from practicing medicine in a
41 center that is not registered with the department;
42 prohibiting a physician from performing certain
43 procedures in a facility or office surgery center;
44 requiring a physician who practices in a center to
45 immediately notify the department of certain
46 noncompliance; requiring a physician to notify the
47 Board of Medicine or Board of Osteopathic Medicine,
48 respectively, within a specified timeframe after
49 beginning or ending his or her practice at a center;
50 providing for disciplinary action; providing
51 requirements for designated physicians; providing
52 facility and infection control requirements for
53 centers; specifying health and safety requirements;
54 prohibiting performance of a level III procedure in a
55 center unless an anesthesiologist is present and
56 available; specifying that level III procedures may be
57 performed only in a center on patients who meet
58 certain conditions; establishing requirements for a

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59 surgeon to perform a level III procedure in a center;
60 relocating the requirement that the department inspect
61 each center for compliance annually unless the center
62 is accredited by certain organizations; relocating the
63 requirement that the person who registered and
64 operates the center pay costs of inspection; requiring
65 the Department of Health to attempt to resolve
66 violations during the inspection of a center;
67 requiring the owner or designated physician to
68 document actions taken to resolve violations;
69 requiring the department to verify correction of the
70 violation during a subsequent inspection; authorizing
71 the department to revoke a center's certificate of
72 registration and prohibit associated physicians from
73 practicing at the center for failure to comply with
74 certain provisions; authorizing the department to
75 impose an administrative fine on a center for
76 violations of specified provisions; requiring the
77 department to consider specified factors in
78 determining whether to impose a penalty or determining
79 the amount of a fine to be imposed on a center;
80 providing that each day a violation continues after
81 the department orders its correction constitutes an
82 additional violation; requiring the department to
83 impose specified fines on an owner or a designated
84 physician for operating an unregistered center;
85 authorizing the department to adopt rules relating to
86 the registration, inspection, and safety of centers;
87 requiring the board to adopt rules specifying training

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88 requirements for certain center practitioners;
89 republishing ss. 458.351 and 459.026, F.S., relating
90 to reports of adverse incidents in office practice
91 settings; providing an effective date.
92

93 Be It Enacted by the Legislature of the State of Florida:
94

95 Section 1. Subsection (3) of section 395.002, Florida
96 Statutes, is amended to read:

97 395.002 Definitions.—As used in this chapter:

98 (3) "Ambulatory surgical center" means a facility the
99 primary purpose of which is to provide elective surgical care,
100 in which the patient is admitted to and discharged from such
101 facility within the same working day and is not permitted to
102 stay overnight, and which is not part of a hospital. However, a
103 facility existing for the primary purpose of performing
104 terminations of pregnancy, ~~an office maintained by a physician~~
105 ~~for the practice of medicine,~~ or an office maintained for the
106 practice of dentistry may not be construed to be an ambulatory
107 surgical center, provided that any facility or office which is
108 certified or seeks certification as a Medicare ambulatory
109 surgical center shall be licensed as an ambulatory surgical
110 center pursuant to s. 395.003.

111 Section 2. Subsection (3) of section 458.309, Florida
112 Statutes, is amended to read:

113 458.309 Rulemaking authority.—

114 ~~(3) A physician who performs liposuction procedures in~~
115 ~~which more than 1,000 cubic centimeters of supernatant fat is~~
116 ~~removed, level 2 procedures lasting more than 5 minutes, and all~~

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117 ~~level 3 surgical procedures in an office setting must register~~
118 ~~the office with the department unless that office is licensed as~~
119 ~~a facility under chapter 395. The department shall inspect the~~
120 ~~physician's office annually unless the office is accredited by a~~
121 ~~nationally recognized accrediting agency or an accrediting~~
122 ~~organization subsequently approved by the Board of Medicine. The~~
123 ~~actual costs for registration and inspection or accreditation~~
124 ~~shall be paid by the person seeking to register and operate the~~
125 ~~office setting in which office surgery is performed.~~

126 Section 3. Section 458.3266, Florida Statutes, is created
127 to read:

128 458.3266 Office surgery centers.-

129 (1) DEFINITIONS.-As used in this section, the term:

130 (a) "Deep sedation with analgesia" means a drug-induced
131 depression of consciousness during which all of the following
132 apply:

133 1. The patient cannot be easily aroused but responds
134 purposefully following repeated or painful stimulation.

135 2. The patient's ability to independently maintain
136 ventilatory function may be impaired.

137 3. The patient may require assistance in maintaining a
138 patent airway, and spontaneous ventilation may be inadequate.

139 4. The patient's cardiovascular function is usually
140 maintained.

141 5. The patient's reflex withdrawal from painful stimulus is
142 not considered a purposeful response.

143 (b) "Designated physician" means a physician licensed under
144 this chapter or chapter 459 who practices at an office surgery
145 center and who has assumed responsibility for the center's

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146 compliance with this section and related board rules.

147 (c) "General anesthesia" means a drug-induced loss of
148 consciousness administered by an anesthesiologist or a certified
149 registered nurse anesthetist during which all of the following
150 apply:

151 1. The patient is not able to be aroused, even by painful
152 stimulation.

153 2. The patient's ability to independently maintain
154 ventilatory function is often impaired.

155 3. The patient has a level of depressed neuromuscular
156 function.

157 4. The patient may require assistance in maintaining a
158 patent airway, and positive pressure ventilation is required.

159 5. The patient's cardiovascular function may be impaired.

160 (d) "Level I procedure" includes procedures in which the
161 patient's level of sedation is that of minimal sedation, and
162 controlled substances, as defined in ss. 893.02 and 893.03, are
163 limited to oral administration in doses appropriate for the
164 unsupervised treatment of insomnia, anxiety, or pain. The term
165 includes:

166 1. Minor procedures such as excision of skin lesions,
167 moles, warts, cysts, and lipomas; repair of lacerations; or
168 surgery limited to the skin and subcutaneous tissue performed
169 under topical or regional anesthesia not involving drug-induced
170 alteration of consciousness other than minimal preoperative
171 tranquilization of the patient.

172 2. The incision and drainage of superficial abscesses,
173 limited endoscopies such as proctoscopies, skin biopsies,
174 arthrocentesis, thoracentesis, paracentesis, dilation of

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175 urethra, cystoscopic procedures, and closed reduction of simple
176 fractures or small joint dislocations, including, but not
177 limited to, finger and toe joints.

178 (e) "Level II procedure" includes any surgery in which the
179 patient's level of sedation is that of moderate sedation and
180 analgesia or conscious sedation. The term includes, but is not
181 limited to: hemorrhoidectomy, hernia repair, large joint
182 dislocations, colonoscopy, and liposuction involving the removal
183 of up to 1,000 cubic centimeters of supernatant fat.

184 (f) "Level III procedure" includes any surgery in which the
185 patient's level of sedation is that of deep sedation with
186 analgesia, general anesthesia, and spinal, regional, or epidural
187 anesthesia.

188 (g) "Minimal sedation" includes anxiolysis and means a
189 drug-induced state during which all of the following apply:

- 190 1. The patient may respond normally to verbal commands.
- 191 2. The patient's cognitive function and physical
192 coordination may be impaired, while his or her airway reflexes,
193 ventilation, and cardiovascular functions are unaffected.

194 (h) "Moderate sedation with analgesia" or "conscious
195 sedation" are both drug-induced depressions of consciousness and
196 mean a state of consciousness during which all of the following
197 apply:

- 198 1. The patient responds purposefully to verbal commands,
199 either alone or accompanied by light tactile stimulation.
- 200 2. Interventions are not required to maintain a patent
201 airway, and spontaneous ventilation is adequate.
- 202 3. Cardiovascular function is maintained.
- 203 4. Reflex withdrawal from a painful stimulus is not

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204 considered a purposeful response.

205 (i) "Office surgery" means any manual or operative
206 procedure, including by use of lasers, performed upon the body
207 of a living human being for the purposes of preserving health,
208 diagnosing or curing disease, repairing injury, correcting
209 deformity or defects, prolonging life, or relieving suffering or
210 any elective procedure for aesthetic, reconstructive, or
211 cosmetic purposes, to include, but not be limited to: incision
212 or curettage of tissue or an organ; suture or other repair of
213 tissue or an organ, including both a closed and open reduction
214 of a fracture; extraction of tissue, including premature
215 extraction of the products of conception from the uterus;
216 insertion of natural or artificial implants; or an endoscopic
217 procedure with use of local or general anesthetic.

218 (j) "Office surgery center" means any facility or office
219 surgery setting, other than a facility licensed under chapter
220 390 or chapter 395, where a physician performs any of the
221 following surgical procedures:

- 222 1. A level I procedure;
223 2. A level II procedure lasting more than 5 minutes; or
224 3. A level III procedure.

225 (k) "Regional anesthesia" is a drug-induced loss of
226 sensation in a circumscribed region of the body, produced by the
227 application of a regional anesthetic, usually by injection. The
228 term includes, but is not limited to, spinal, epidural, and
229 specific nerve blocks.

230 (l) "Surgery" or "surgical" means any manual or operative
231 procedure, including the use of lasers, performed upon the body
232 of a living human being for the purposes of preserving health,

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233 diagnosing or curing disease, repairing injury, correcting
234 deformity or defects, prolonging life, or relieving suffering or
235 any elective procedure for aesthetic, reconstructive, or
236 cosmetic purposes. The term includes, but is not limited to, all
237 of the following: incision or curettage of tissue or an organ;
238 suture or other repair of tissue or an organ, including both a
239 closed and an open reduction of a fracture; extraction of
240 tissue, including premature extraction of the products of
241 conception from the uterus; insertion of natural or artificial
242 implants; or an endoscopic procedure with use of local,
243 regional, or general anesthetic.

244 (2) CERTIFICATE OF REGISTRATION.—

245 (a) A person who seeks to operate an office surgery center
246 must register the center with the department unless the center
247 is affiliated with an accredited medical school at which
248 training is provided for medical students, residents, or
249 fellows.

250 (b) Each office surgery center must be registered
251 separately, regardless of whether it is operated under the same
252 business name or management as another center. The actual costs
253 of registration, as determined by the department, must be paid
254 by the person seeking to register and operate the center.

255 (c) At the time of registration and thereafter, each office
256 surgery center shall identify to the department a designated
257 physician. Within 10 days after the resignation or termination
258 of its designated physician, a center shall identify to the
259 department the new designated physician. The department may
260 suspend a center's certificate of registration for failure to
261 comply with this paragraph.

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262 (d) The department shall issue a certificate of
263 registration to a qualified applicant who is required to
264 register under this section. The department may not issue a
265 certificate of registration to an office surgery center that is:

266 1. Not fully owned by a physician licensed under this
267 chapter or chapter 459 or a group of physicians licensed under
268 this chapter or chapter 459;

269 2. Not a health care center licensed under part X of
270 chapter 400; or

271 3. Owned by or in any contractual or employment
272 relationship with a physician licensed under this chapter or
273 chapter 459 who:

274 a. Has had his or her hospital privileges revoked in the
275 last 5 years;

276 b. Does not have a clear and active license with the
277 department; or

278 c. Has been the subject of disciplinary action in this
279 state or in another jurisdiction in the last 5 years for an
280 offense related to standard of care.

281 (e) If the department determines that an office surgery
282 center does not meet the requirements of paragraph (c) or is
283 owned, directly or indirectly, by a physician whose privileges,
284 license, or disciplinary status is identified in sub-
285 subparagraph (d)3.a., sub-subparagraph (d)3.b., or sub-
286 subparagraph (d)3.c., the department shall revoke the center's
287 certificate of registration.

288 (f) If the center's certificate of registration is revoked
289 or suspended, the designated physician of the center shall
290 ensure that, as appropriate, the owner or lessor of the center

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291 property, the manager, or the proprietor, as of the effective
292 date of the suspension or revocation:

293 1. Ceases to operate the facility as an office surgery
294 center; and

295 2. Removes any signs and symbols identifying the premises
296 as an office surgery center.

297 (g) Upon the effective date of the suspension or
298 revocation, the designated physician of the office surgery
299 center shall advise the department of the disposition of the
300 medicinal drugs located on the premises. Such disposition is
301 subject to the supervision and approval of the department.
302 Medicinal drugs that are purchased or held by a center that is
303 not registered may be deemed adulterated for purposes of s.
304 499.006.

305 (h) When the department suspends the registration of an
306 office surgery center, it shall prescribe an appropriate period
307 of suspension, not to exceed 2 years.

308 (i) If the office surgery center's registration is revoked,
309 any person named in the registration documents of the center,
310 including the persons who own or operate the center, may not
311 apply, individually or as part of a group, to operate an office
312 surgery center for a period of 5 years after the revocation
313 date.

314 (j) An office surgery center registration may not be
315 transferred to a new owner. If the ownership of a registered
316 office surgery center changes, the new owner must register the
317 center with the department before beginning operation under the
318 new ownership.

319 (3) OFFICE SURGERY CENTER PHYSICIANS; DESIGNATED

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320 PHYSICIANS; PROHIBITION; REQUIREMENTS.—

321 (a)1. A physician may not practice medicine in an office
322 surgery center that is not registered with the department in
323 compliance with this section.

324 2. A physician may not perform surgical procedures in an
325 office surgery center which may:

326 a. Result in blood loss of more than 10 percent of
327 estimated blood volume in a patient having a normal hemoglobin
328 level;

329 b. Require major or prolonged intracranial, intrathoracic,
330 abdominal, or major joint replacement procedures, except for
331 laparoscopic procedures; or

332 c. Involve major blood vessels, when such procedure is
333 performed with direct visualization by open exposure of the
334 major vessel, except for percutaneous endovascular intervention;
335 or are generally emergent or life threatening in nature.

336 3. If a physician who practices in an office surgery center
337 determines that the center is not in compliance with subsection
338 (4), he or she must immediately notify the department of such
339 noncompliance.

340 4. A physician who practices in an office surgery center
341 shall notify the board in writing within 10 days after beginning
342 or ending his or her practice at the office surgery center.

343
344 A physician who violates this paragraph is subject to
345 disciplinary action by the board.

346 (b) The designated physician of an office surgery center
347 shall:

348 1. Ensure that the center maintains an ongoing quality

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349 assurance program that objectively and systematically monitors
350 and evaluates the quality and appropriateness of patient care,
351 evaluates methods to improve patient care, identifies and
352 corrects deficiencies at the facility, alerts the designated
353 physician to identify and resolve recurring problems, and
354 provides opportunities for the center to improve its performance
355 and enhance and improve the quality of care provided to the
356 public.

357 2. Establish and document compliance with the quality
358 assurance program which includes at least the following
359 components:

360 a. Identification, investigation, and analysis of the
361 frequency and causes of incidents;

362 b. Identification of trends or patterns of adverse
363 incidents; and

364 c. Development of measures to correct, reduce, minimize, or
365 eliminate the risk of adverse incidents to patients.

366 3. Review, at least quarterly, the quality assurance
367 program.

368 4. Report all adverse incidents to the department as
369 provided in s. 458.351.

370 5. Notify the applicable board in writing of his or her
371 termination of employment within 10 days after such termination.

372 (4) OFFICE SURGERY CENTERS; REQUIREMENTS.—An office surgery
373 center must comply with the following requirements:

374 (a) Facility requirements.—The office surgery center must:

375 1. Be located and operated at a publicly accessible, fixed
376 location.

377 2. Display a sign that clearly identifies the name, hours

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378 of operation, and street address of the center. The sign must be
379 prominently displayed in public view.

380 3. Maintain and publicly list a telephone number.

381 4. Provide emergency lighting and for emergency
382 communications.

383 5. Have a reception and waiting area.

384 6. Have a restroom.

385 7. Have an administrative area, including room for storage
386 of medical records, supplies, and equipment.

387 8. Have private patient examination rooms.

388 9. Have treatment rooms, if treatment is being provided to
389 the patients.

390 10. Publicly display a visible printed sign in a
391 conspicuous place in each waiting room which includes the name
392 and contact information of the center's designated physician and
393 the names of all physicians practicing at the center.

394 11. Comply with ss. 499.0121 and 893.07, if the center
395 stores and dispenses prescription drugs.

396 (b) Infection control requirements.—The center must:

397 1. Maintain equipment and supplies to support infection
398 prevention and control.

399 2. Identify infection risks based on the following:

400 a. Geographic location, community, and population served.

401 b. The nature of the provided care, treatments, and
402 services.

403 c. An analysis of the center's infection surveillance and
404 control data.

405 3. Maintain written infection prevention policies and
406 procedures that address prioritized risks and limit the

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407 following:

408 a. Unprotected exposure to pathogens.

409 b. The transmission of infections associated with
410 procedures performed at the center.

411 c. The transmission of infections associated with the
412 center's use of medical equipment, devices, and supplies.

413 (c) Health and safety requirements.—The center must:

414 1. Maintain its structurally sound buildings and keep its
415 grounds free from health and safety hazards.

416 2. Keep its furniture, appliances, and equipment clean,
417 safe, and in good repair.

418 3. Have evacuation procedures in the event of an emergency.
419 The procedures must provide for the evacuation of patients with
420 disabilities and center employees.

421 4. Have a written facility-specific disaster plan that
422 specifies actions to be taken in the event of the center closing
423 due to unforeseen disasters. The plan must provide for the
424 protection of medical records and any controlled substances.

425 5. Have at least one employee on the premises during
426 patient care hours who is certified in basic life support and
427 trained in reacting to accidents and medical emergencies.

428 6. Have written emergency policies and procedures related
429 to serious anesthesia complications which must be formulated,
430 reviewed annually, practiced, updated, and posted in a
431 conspicuous location. Such procedures must address all of the
432 following conditions:

433 a. Airway blockage and foreign body obstruction;

434 b. Allergic reactions;

435 c. Bradycardia;

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- 436 d. Bronchospasm;
437 e. Cardiac arrest;
438 f. Chest pain;
439 g. Hypoglycemia;
440 h. Hypotension;
441 i. Hypoventilation;
442 j. Laryngospasm;
443 k. Local anesthetic toxicity reaction; and
444 l. Malignant hyperthermia.
- 445 (d) Equipment and supplies.—The center must:
- 446 1. Have the equipment and medications to properly manage
447 and treat a cardiac incident or arrest, including a full and
448 current crash cart with a defibrillator, and, at a minimum, the
449 intravenous or inhaled medications recommended by the American
450 Heart Association Guidelines for CPR & Emergency Cardiovascular
451 Care, as published November 2018, at the location where the
452 anesthetizing is being carried out.
- 453 2. Store medicines per the manufacturer's recommendations
454 and note the date on multidose vials once they are opened.
- 455 3. Maintain dantrolene on site if halogenated anesthetics
456 or succinylcholine are used.
- 457 4. In terms of general preparation, equipment, and
458 supplies, be comparable to a freestanding ambulatory surgical
459 center, including, but not limited to, patient recovery
460 capability and provisions for proper recordkeeping.
- 461 5. Have blood pressure monitoring equipment, EKG, end-tidal
462 CO2 monitor, pulse oximeter, emergency intubation equipment, and
463 a temperature monitoring device.
- 464 6. Have at least one table capable of trendelenburg,

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465 lithotomy, and other positions necessary to facilitate the
466 surgical procedure.

467 (e) Level III office surgery requirements.-

468 1. A level III procedure may not be performed in an office
469 surgery center unless an anesthesiologist, as defined in s.
470 458.3475 or s. 459.023, is physically present at the center and
471 available at the time of the procedure.

472 2. For a center in which level III procedures are
473 performed, either:

474 a. The center must have a written patient transfer
475 agreement with a hospital within reasonable proximity to the
476 center which includes the transfer of the patient's medical
477 records held by the center and the treating physician to the
478 licensed hospital; or

479 b. The surgeon performing the level III procedure must have
480 admitting privileges at a hospital within reasonable proximity
481 to the center.

482 3. Level III procedures may be performed only on a patient
483 who is classified under the American Society of
484 Anesthesiologists' (ASA) Physical Status Classification System,
485 as approved on October 15, 2014, as Class I or II.

486 4. All ASA Class II patients above the age of 50 undergoing
487 a level III office surgery procedure shall have a complete
488 medical workup performed by the surgeon before the performance
489 of level III surgery. If the patient has a cardiac history or
490 has other complicating health conditions, he or she must have a
491 preoperative EKG and be referred to an appropriate consultant
492 for medical optimization of the complicating conditions. The
493 referral to a consultant may be waived after evaluation by the

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494 anesthesiologist to administer or supervise the patient's
495 anesthesia.

496 5. To perform a level III procedure in an office surgery
497 center, the surgeon must have staff privileges at a licensed
498 hospital to perform the same level III procedure in the hospital
499 or must be able to document satisfactory completion of training,
500 such as board certification or board qualification by a board
501 approved by the American Board of Medical Specialties or any
502 other board approved by the Board of Medicine.

503 (5) INSPECTION.—

504 (a) The department shall inspect each office surgery center
505 annually, including a review of patient records, to ensure that
506 the center complies with this section and board rule, unless the
507 center is accredited by a nationally recognized accrediting
508 agency or an accrediting organization subsequently approved by
509 the board. The department also may inspect an office surgery
510 center as necessary to investigate a notification of
511 noncompliance made by a physician pursuant to subparagraph

512 (3) (a) 3.

513 (b) The actual costs of inspection must be paid by the
514 person who registered and operates the office surgery center.

515 (c) During an onsite inspection, the department shall make
516 a reasonable attempt to resolve each violation with the owner or
517 designated physician of the office surgery center before issuing
518 a formal written notification.

519 (d) Any action taken to resolve a violation must be
520 documented in writing by the owner or designated physician of
521 the office surgery center and submitted to the department. The
522 department must verify any correction of the violation in a

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523 subsequent inspection.

524 (6) ENFORCEMENT.—

525 (a) The department may revoke an office surgery center's
526 certificate of registration and prohibit all physicians
527 associated with the center from practicing at the center for
528 failure to comply with this section and rules adopted hereunder.

529 (b) The department may impose an administrative fine of up
530 to \$5,000 per violation on an office surgery center for
531 violations of this section; chapter 499, the Florida Drug and
532 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
533 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
534 Abuse Prevention and Control Act; chapter 893, the Florida
535 Comprehensive Drug Abuse Prevention and Control Act; or
536 department rule.

537 (c) In determining whether to impose a penalty on an office
538 surgery center, and in determining the amount of any fine, the
539 department shall consider all of the following factors:

540 1. The gravity of the violation, including the probability
541 that death or serious physical or emotional harm to a patient
542 has resulted, or could have resulted, from the center's actions
543 or the actions of the physician; the gravity of the action or
544 potential harm; and the nature of the violations of applicable
545 laws or rules.

546 2. Any actions taken by the owner or designated physician
547 to correct the violation.

548 3. Whether any previous violations were committed at the
549 center.

550 4. Any financial benefits derived by the center from
551 committing or continuing to commit the violation.

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552 (d) Each day a violation continues after the date on which
553 the department orders a correction of the violation constitutes
554 an additional, separate, and distinct violation.

555 (e) The department may impose a fine and, in the case of an
556 owner-operated office surgery center, revoke or deny a center's
557 registration if the center's designated physician knowingly and
558 intentionally misrepresents actions taken to correct a
559 violation.

560 (f) The department shall impose a fine of \$5,000 per day on
561 an owner or designated physician of an office surgery center
562 registered under this section who concurrently operates an
563 unregistered center.

564 (g) The department shall impose a fine of \$10,000 on a new
565 owner of an office surgery center that requires registration who
566 fails to register the center upon the change of ownership and
567 who operates the unregistered center.

568 (7) RULEMAKING.—

569 (a) The department may adopt rules to administer the
570 registration, inspection, and safety of office surgery centers.

571 (b) The board shall adopt rules specifying training
572 requirements for all licensed or certified office surgery center
573 health care practitioners and other health care practitioners
574 who are not regulated by any board.

575 Section 4. Section 458.351, Florida Statutes, is
576 republished to read:

577 458.351 Reports of adverse incidents in office practice
578 settings.—

579 (1) Any adverse incident that occurs on or after January 1,
580 2000, in any office maintained by a physician for the practice

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581 of medicine which is not licensed under chapter 395 must be
582 reported to the department in accordance with the provisions of
583 this section.

584 (2) Any physician or other licensee under this chapter
585 practicing in this state must notify the department if the
586 physician or licensee was involved in an adverse incident that
587 occurred on or after January 1, 2000, in any office maintained
588 by a physician for the practice of medicine which is not
589 licensed under chapter 395.

590 (3) The required notification to the department must be
591 submitted in writing by certified mail and postmarked within 15
592 days after the occurrence of the adverse incident.

593 (4) For purposes of notification to the department pursuant
594 to this section, the term "adverse incident" means an event over
595 which the physician or licensee could exercise control and which
596 is associated in whole or in part with a medical intervention,
597 rather than the condition for which such intervention occurred,
598 and which results in the following patient injuries:

599 (a) The death of a patient.

600 (b) Brain or spinal damage to a patient.

601 (c) The performance of a surgical procedure on the wrong
602 patient.

603 (d)1. The performance of a wrong-site surgical procedure;

604 2. The performance of a wrong surgical procedure; or

605 3. The surgical repair of damage to a patient resulting

606 from a planned surgical procedure where the damage is not a

607 recognized specific risk as disclosed to the patient and

608 documented through the informed-consent process

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610 if it results in: death; brain or spinal damage; permanent
611 disfigurement not to include the incision scar; fracture or
612 dislocation of bones or joints; a limitation of neurological,
613 physical, or sensory function; or any condition that required
614 the transfer of the patient.

615 (e) A procedure to remove unplanned foreign objects
616 remaining from a surgical procedure.

617 (f) Any condition that required the transfer of a patient
618 to a hospital licensed under chapter 395 from an ambulatory
619 surgical center licensed under chapter 395 or any facility or
620 any office maintained by a physician for the practice of
621 medicine which is not licensed under chapter 395.

622 (5) The department shall review each incident and determine
623 whether it potentially involved conduct by a health care
624 professional who is subject to disciplinary action, in which
625 case s. 456.073 applies. Disciplinary action, if any, shall be
626 taken by the board under which the health care professional is
627 licensed.

628 (6) (a) The board shall adopt rules establishing a standard
629 informed consent form that sets forth the recognized specific
630 risks related to cataract surgery. The board must propose such
631 rules within 90 days after the effective date of this
632 subsection.

633 (b) Before formally proposing the rule, the board must
634 consider information from physicians licensed under this chapter
635 or chapter 459 regarding recognized specific risks related to
636 cataract surgery and the standard informed consent forms adopted
637 for use in the medical field by other states.

638 (c) A patient's informed consent is not executed until the

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639 patient, or a person authorized by the patient to give consent,
640 and a competent witness sign the form adopted by the board.

641 (d) An incident resulting from recognized specific risks
642 described in the signed consent form is not considered an
643 adverse incident for purposes of s. 395.0197 and this section.

644 (e) In a civil action or administrative proceeding against
645 a physician based on his or her alleged failure to properly
646 disclose the risks of cataract surgery, a patient's informed
647 consent executed as provided in paragraph (c) on the form
648 adopted by the board is admissible as evidence and creates a
649 rebuttable presumption that the physician properly disclosed the
650 risks.

651 (7) The board may adopt rules to administer this section.

652 Section 5. Section 459.005, Florida Statutes, is amended to
653 read:

654 459.005 Rulemaking authority.—

655 ~~(1)~~ The board has authority to adopt rules pursuant to ss.
656 120.536(1) and 120.54 to implement the provisions of this
657 chapter conferring duties upon it.

658 ~~(2) A physician who performs liposuction procedures in~~
659 ~~which more than 1,000 cubic centimeters of supernatant fat is~~
660 ~~removed, level 2 procedures lasting more than 5 minutes, and all~~
661 ~~level 3 surgical procedures in an office setting must register~~
662 ~~the office with the department unless that office is licensed as~~
663 ~~a facility under chapter 395. The department shall inspect the~~
664 ~~physician's office annually unless the office is accredited by a~~
665 ~~nationally recognized accrediting agency or an accrediting~~
666 ~~organization subsequently approved by the Board of Osteopathic~~
667 ~~Medicine. The actual costs for registration and inspection or~~

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668 ~~accreditation shall be paid by the person seeking to register~~
669 ~~and operate the office setting in which office surgery is~~
670 ~~performed.~~

671 Section 6. Section 459.0138, Florida Statutes, is created
672 to read:

673 459.0138 Office surgery centers.—

674 (1) DEFINITIONS.—As used in this section, the term:

675 (a) "Deep sedation with analgesia" means a drug-induced
676 depression of consciousness during which all of the following
677 apply:

678 1. The patient cannot be easily aroused but responds
679 purposefully following repeated or painful stimulation.

680 2. The patient's ability to independently maintain
681 ventilatory function may be impaired.

682 3. The patient may require assistance in maintaining a
683 patent airway, and spontaneous ventilation may be inadequate.

684 4. The patient's cardiovascular function is usually
685 maintained.

686 5. The patient's reflex withdrawal from painful stimulus is
687 not considered a purposeful response.

688 (b) "Designated physician" means a physician licensed under
689 this chapter or chapter 458 who practices at an office surgery
690 center and who has assumed responsibility for the center's
691 compliance with this section and related board rules.

692 (c) "General anesthesia" means a drug-induced loss of
693 consciousness administered by an anesthesiologist or a certified
694 registered nurse anesthetist during which all of the following
695 apply:

696 1. The patient is not able to be aroused, even by painful

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697 stimulation.

698 2. The patient's ability to independently maintain
699 ventilatory function is often impaired.

700 3. The patient has a level of depressed neuromuscular
701 function.

702 4. The patient may require assistance in maintaining a
703 patent airway, and positive pressure ventilation is required.

704 5. The patient's cardiovascular function may be impaired.

705 (d) "Level I procedure" includes procedures in which the
706 patient's level of sedation is that of minimal sedation, and
707 controlled substances, as defined in ss. 893.02 and 893.03, are
708 limited to oral administration in doses appropriate for the
709 unsupervised treatment of insomnia, anxiety, or pain. The term
710 includes:

711 1. Minor procedures such as excision of skin lesions,
712 moles, warts, cysts, and lipomas; repair of lacerations; or
713 surgery limited to the skin and subcutaneous tissue performed
714 under topical or regional anesthesia not involving drug-induced
715 alteration of consciousness other than minimal preoperative
716 tranquilization of the patient.

717 2. The incision and drainage of superficial abscesses,
718 limited endoscopies such as proctoscopies, skin biopsies,
719 arthrocentesis, thoracentesis, paracentesis, dilation of
720 urethra, cystoscopic procedures, and closed reduction of simple
721 fractures or small joint dislocations, including, but not
722 limited to, finger and toe joints.

723 (e) "Level II procedure" includes any surgery in which the
724 patient's level of sedation is that of moderate sedation and
725 analgesia or conscious sedation. The term includes, but is not

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726 limited to: hemorrhoidectomy, hernia repair, large joint
727 dislocations, colonoscopy, and liposuction involving the removal
728 of up to 1,000 cubic centimeters of supernatant fat.

729 (f) "Level III procedure" includes any surgery in which the
730 patient's level of sedation is that of deep sedation with
731 analgesia, general anesthesia, and spinal, regional, or epidural
732 anesthesia.

733 (g) "Minimal sedation" includes anxiolysis and means a
734 drug-induced state during which all of the following apply:

- 735 1. The patient may respond normally to verbal commands.
736 2. The patient's cognitive function and physical
737 coordination may be impaired, while his or her airway reflexes,
738 ventilation, and cardiovascular functions are unaffected.

739 (h) "Moderate sedation with analgesia" or "conscious
740 sedation" are both drug-induced depressions of consciousness and
741 mean a state of consciousness during which all of the following
742 apply:

- 743 1. The patient responds purposefully to verbal commands,
744 either alone or accompanied by light tactile stimulation.
745 2. Interventions are not required to maintain a patent
746 airway, and spontaneous ventilation is adequate.
747 3. Cardiovascular function is maintained.
748 4. Reflex withdrawal from a painful stimulus is not
749 considered a purposeful response.

750 (i) "Office surgery" means any manual or operative
751 procedure, including by use of lasers, performed upon the body
752 of a living human being for the purposes of preserving health,
753 diagnosing or curing disease, repairing injury, correcting
754 deformity or defects, prolonging life, or relieving suffering or

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755 any elective procedure for aesthetic, reconstructive, or
756 cosmetic purposes, to include, but not be limited to: incision
757 or curettage of tissue or an organ; suture or other repair of
758 tissue or an organ, including both a closed and open reduction
759 of a fracture; extraction of tissue, including premature
760 extraction of the products of conception from the uterus;
761 insertion of natural or artificial implants; or an endoscopic
762 procedure with use of local or general anesthetic.

763 (j) "Office surgery center" means any facility or office
764 surgery setting, other than a facility licensed under chapter
765 390 or chapter 395, where a physician performs any of the
766 following surgical procedures:

- 767 1. A level I procedure;
768 2. A level II procedure lasting more than 5 minutes; or
769 3. A level III procedure.

770 (k) "Regional anesthesia" is a drug-induced loss of
771 sensation in a circumscribed region of the body, produced by the
772 application of a regional anesthetic, usually by injection. The
773 term includes, but is not limited to, spinal, epidural, and
774 specific nerve blocks.

775 (l) "Surgery" or "surgical" means any manual or operative
776 procedure, including the use of lasers, performed upon the body
777 of a living human being for the purposes of preserving health,
778 diagnosing or curing disease, repairing injury, correcting
779 deformity or defects, prolonging life, or relieving suffering or
780 any elective procedure for aesthetic, reconstructive, or
781 cosmetic purposes. The term includes, but is not limited to, all
782 of the following: incision or curettage of tissue or an organ;
783 suture or other repair of tissue or an organ, including both a

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784 closed and an open reduction of a fracture; extraction of
785 tissue, including premature extraction of the products of
786 conception from the uterus; insertion of natural or artificial
787 implants; or an endoscopic procedure with use of local,
788 regional, or general anesthetic.

789 (2) CERTIFICATE OF REGISTRATION.—

790 (a) A person who seeks to operate an office surgery center
791 must register the center with the department unless the center
792 is affiliated with an accredited medical school at which
793 training is provided for medical students, residents, or
794 fellows.

795 (b) Each office surgery center must be registered
796 separately, regardless of whether it is operated under the same
797 business name or management as another center. The actual costs
798 of registration, as determined by the department, must be paid
799 by the person seeking to register and operate the center.

800 (c) At the time of registration and thereafter, each office
801 surgery center shall identify to the department a designated
802 physician. Within 10 days after the resignation or termination
803 of its designated physician, a center shall identify to the
804 department the new designated physician. The department may
805 suspend a center's certificate of registration for failure to
806 comply with this paragraph.

807 (d) The department shall issue a certificate of
808 registration to a qualified applicant who is required to
809 register under this section. The department may not issue a
810 certificate of registration to an office surgery center that is:

811 1. Not fully owned by a physician licensed under this
812 chapter or chapter 458 or a group of physicians licensed under

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813 this chapter or chapter 458;

814 2. Not a health care center licensed under part X of
815 chapter 400; or

816 3. Owned by or in any contractual or employment
817 relationship with a physician licensed under this chapter or
818 chapter 458 who:

819 a. Has had his or her hospital privileges revoked in the
820 last 5 years;

821 b. Does not have a clear and active license with the
822 department; or

823 c. Has been the subject of disciplinary action in this
824 state or in another jurisdiction in the last 5 years for an
825 offense related to standard of care.

826 (e) If the department determines that an office surgery
827 center does not meet the requirements of paragraph (c) or is
828 owned, directly or indirectly, by a physician whose privileges,
829 license, or disciplinary status is identified in sub-
830 paragraph (d)3.a., sub-paragraph (d)3.b., or sub-
831 paragraph (d)3.c., the department shall revoke the center's
832 certificate of registration.

833 (f) If the center's certificate of registration is revoked
834 or suspended, the designated physician of the center shall
835 ensure that, as appropriate, the owner or lessor of the center
836 property, the manager, or the proprietor, as of the effective
837 date of the suspension or revocation:

838 1. Ceases to operate the facility as an office surgery
839 center; and

840 2. Removes any signs and symbols identifying the premises
841 as an office surgery center.

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842 (g) Upon the effective date of the suspension or
843 revocation, the designated physician of the office surgery
844 center shall advise the department of the disposition of the
845 medicinal drugs located on the premises. Such disposition is
846 subject to the supervision and approval of the department.
847 Medicinal drugs that are purchased or held by a center that is
848 not registered may be deemed adulterated for purposes of s.
849 499.006.

850 (h) When the department suspends the registration of an
851 office surgery center, it shall prescribe an appropriate period
852 of suspension, not to exceed 2 years.

853 (i) If the office surgery center's registration is revoked,
854 any person named in the registration documents of the center,
855 including the persons who own or operate the center, may not
856 apply, individually or as part of a group, to operate an office
857 surgery center for a period of 5 years after the revocation
858 date.

859 (j) An office surgery center registration may not be
860 transferred to a new owner. If the ownership of a registered
861 office surgery center changes, the new owner must register the
862 center with the department before beginning operation under the
863 new ownership.

864 (3) OFFICE SURGERY CENTER PHYSICIANS; DESIGNATED
865 PHYSICIANS; PROHIBITION; REQUIREMENTS.—

866 (a)1. A physician may not practice medicine in an office
867 surgery center that is not registered with the department in
868 compliance with this section.

869 2. A physician may not perform surgical procedures in an
870 office surgery center which may:

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- 871 a. Result in blood loss of more than 10 percent of
872 estimated blood volume in a patient having a normal hemoglobin
873 level;
- 874 b. Require major or prolonged intracranial, intrathoracic,
875 abdominal, or major joint replacement procedures, except for
876 laparoscopic procedures; or
- 877 c. Involve major blood vessels, when such procedure is
878 performed with direct visualization by open exposure of the
879 major vessel, except for percutaneous endovascular intervention;
880 or are generally emergent or life threatening in nature.
- 881 3. If a physician who practices in an office surgery center
882 determines that the center is not in compliance with subsection
883 (4), he or she must immediately notify the department of such
884 noncompliance.
- 885 4. A physician who practices in an office surgery center
886 shall notify the board in writing within 10 days after beginning
887 or ending his or her practice at the office surgery center.
- 888
- 889 A physician who violates this paragraph is subject to
890 disciplinary action by the board.
- 891 (b) The designated physician of an office surgery center
892 shall:
- 893 1. Ensure that the center maintains an ongoing quality
894 assurance program that objectively and systematically monitors
895 and evaluates the quality and appropriateness of patient care,
896 evaluates methods to improve patient care, identifies and
897 corrects deficiencies at the facility, alerts the designated
898 physician to identify and resolve recurring problems, and
899 provides opportunities for the center to improve its performance

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900 and enhance and improve the quality of care provided to the
901 public.

902 2. Establish and document compliance with the quality
903 assurance program which includes at least the following
904 components:

905 a. Identification, investigation, and analysis of the
906 frequency and causes of incidents;

907 b. Identification of trends or patterns of adverse
908 incidents; and

909 c. Development of measures to correct, reduce, minimize, or
910 eliminate the risk of adverse incidents to patients.

911 3. Review, at least quarterly, the quality assurance
912 program.

913 4. Report all adverse incidents to the department as
914 provided in s. 459.026.

915 5. Notify the applicable board in writing of his or her
916 termination of employment within 10 days after such termination.

917 (4) OFFICE SURGERY CENTERS; REQUIREMENTS.—An office surgery
918 center must comply with the following requirements:

919 (a) Facility requirements.—The office surgery center must:

920 1. Be located and operated at a publicly accessible, fixed
921 location.

922 2. Display a sign that clearly identifies the name, hours
923 of operation, and street address of the center. The sign must be
924 prominently displayed in public view.

925 3. Maintain and publicly list a telephone number.

926 4. Provide emergency lighting and for emergency
927 communications.

928 5. Have a reception and waiting area.

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- 929 6. Have a restroom.
- 930 7. Have an administrative area, including room for storage
931 of medical records, supplies, and equipment.
- 932 8. Have private patient examination rooms.
- 933 9. Have treatment rooms, if treatment is being provided to
934 the patients.
- 935 10. Publicly display a visible printed sign in a
936 conspicuous place in each waiting room which includes the name
937 and contact information of the center's designated physician and
938 the names of all physicians practicing at the center.
- 939 11. Comply with ss. 499.0121 and 893.07, if the center
940 stores and dispenses prescription drugs.
- 941 (b) Infection control requirements.—The center must:
- 942 1. Maintain equipment and supplies to support infection
943 prevention and control.
- 944 2. Identify infection risks based on the following:
- 945 a. Geographic location, community, and population served.
- 946 b. The nature of the provided care, treatments, and
947 services.
- 948 c. An analysis of the center's infection surveillance and
949 control data.
- 950 3. Maintain written infection prevention policies and
951 procedures that address prioritized risks and limit the
952 following:
- 953 a. Unprotected exposure to pathogens.
- 954 b. The transmission of infections associated with
955 procedures performed at the center.
- 956 c. The transmission of infections associated with the
957 center's use of medical equipment, devices, and supplies.

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958 (c) Health and safety requirements.—The center must:

959 1. Maintain its structurally sound buildings and keep its
960 grounds free from health and safety hazards.

961 2. Keep its furniture, appliances, and equipment clean,
962 safe, and in good repair.

963 3. Have evacuation procedures in the event of an emergency.
964 The procedures must provide for the evacuation of patients with
965 disabilities and center employees.

966 4. Have a written facility-specific disaster plan that
967 specifies actions to be taken in the event of the center closing
968 due to unforeseen disasters. The plan must provide for the
969 protection of medical records and any controlled substances.

970 5. Have at least one employee on the premises during
971 patient care hours who is certified in basic life support and
972 trained in reacting to accidents and medical emergencies.

973 6. Have written emergency policies and procedures related
974 to serious anesthesia complications which must be formulated,
975 reviewed annually, practiced, updated, and posted in a
976 conspicuous location. Such procedures must address all of the
977 following conditions:

978 a. Airway blockage and foreign body obstruction;

979 b. Allergic reactions;

980 c. Bradycardia;

981 d. Bronchospasm;

982 e. Cardiac arrest;

983 f. Chest pain;

984 g. Hypoglycemia;

985 h. Hypotension;

986 i. Hypoventilation;

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987 j. Laryngospasm;

988 k. Local anesthetic toxicity reaction; and

989 l. Malignant hyperthermia.

990 (d) Equipment and supplies.—The center must:

991 1. Have the equipment and medications to properly manage
992 and treat a cardiac incident or arrest, including a full and
993 current crash cart with a defibrillator, and, at a minimum, the
994 intravenous or inhaled medications recommended by the American
995 Heart Association Guidelines for CPR & Emergency Cardiovascular
996 Care, as published November 2018, at the location where the
997 anesthetizing is being carried out.

998 2. Store medicines per the manufacturer's recommendations
999 and note the date on multidose vials once they are opened.

1000 3. Maintain dantrolene on site if halogenated anesthetics
1001 or succinylcholine are used.

1002 4. In terms of general preparation, equipment, and
1003 supplies, be comparable to a freestanding ambulatory surgical
1004 center, including, but not limited to, patient recovery
1005 capability and provisions for proper recordkeeping.

1006 5. Have blood pressure monitoring equipment, EKG, end-tidal
1007 CO2 monitor, pulse oximeter, emergency intubation equipment, and
1008 a temperature monitoring device.

1009 6. Have at least one table capable of trendelenburg,
1010 lithotomy, and other positions necessary to facilitate the
1011 surgical procedure.

1012 (e) Level III office surgery requirements.—

1013 1. A level III procedure may not be performed in an office
1014 surgery center unless an anesthesiologist, as defined in s.
1015 458.3475 or s. 459.023, is physically present at the center and

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1016 available at the time of the procedure.

1017 2. For a center in which level III procedures are
1018 performed, either:

1019 a. The center must have a written patient transfer
1020 agreement with a hospital within reasonable proximity to the
1021 center which includes the transfer of the patient's medical
1022 records held by the center and the treating physician to the
1023 licensed hospital; or

1024 b. The surgeon performing the level III procedure must have
1025 admitting privileges at a hospital within reasonable proximity
1026 to the center.

1027 3. Level III procedures may be performed only on a patient
1028 who is classified under the American Society of
1029 Anesthesiologists' (ASA) Physical Status Classification System,
1030 as approved on October 15, 2014, as Class I or II.

1031 4. All ASA Class II patients above the age of 50 undergoing
1032 a level III office surgery procedure shall have a complete
1033 medical workup performed by the surgeon before the performance
1034 of level III surgery. If the patient has a cardiac history or
1035 has other complicating health conditions, he or she must have a
1036 preoperative EKG and be referred to an appropriate consultant
1037 for medical optimization of the complicating conditions. The
1038 referral to a consultant may be waived after evaluation by the
1039 anesthesiologist to administer or supervise the patient's
1040 anesthesia.

1041 5. To perform a level III procedure in an office surgery
1042 center, the surgeon must have staff privileges at a licensed
1043 hospital to perform the same level III procedure in the hospital
1044 or must be able to document satisfactory completion of training,

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1045 such as board certification or board qualification by a board
1046 approved by the American Board of Medical Specialties or any
1047 other board approved by the Board of Medicine.

1048 (5) INSPECTION.—

1049 (a) The department shall inspect each office surgery center
1050 annually, including a review of patient records, to ensure that
1051 the center complies with this section and board rule, unless the
1052 center is accredited by a nationally recognized accrediting
1053 agency or an accrediting organization subsequently approved by
1054 the board. The department also may inspect an office surgery
1055 center as necessary to investigate a notification of
1056 noncompliance made by a physician pursuant to subparagraph
1057 (3) (a) 3.

1058 (b) The actual costs of inspection must be paid by the
1059 person who registered and operates the office surgery center.

1060 (c) During an onsite inspection, the department shall make
1061 a reasonable attempt to resolve each violation with the owner or
1062 designated physician of the office surgery center before issuing
1063 a formal written notification.

1064 (d) Any action taken to resolve a violation must be
1065 documented in writing by the owner or designated physician of
1066 the office surgery center and submitted to the department. The
1067 department must verify any correction of the violation in a
1068 subsequent inspection.

1069 (6) ENFORCEMENT.—

1070 (a) The department may revoke an office surgery center's
1071 certificate of registration and prohibit all physicians
1072 associated with the center from practicing at the center for
1073 failure to comply with this section and rules adopted hereunder.

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1074 (b) The department may impose an administrative fine of up
1075 to \$5,000 per violation on an office surgery center for
1076 violations of this section; chapter 499, the Florida Drug and
1077 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
1078 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
1079 Abuse Prevention and Control Act; chapter 893, the Florida
1080 Comprehensive Drug Abuse Prevention and Control Act; or
1081 department rule.

1082 (c) In determining whether to impose a penalty on an office
1083 surgery center, and in determining the amount of any fine, the
1084 department shall consider all of the following factors:

1085 1. The gravity of the violation, including the probability
1086 that death or serious physical or emotional harm to a patient
1087 has resulted, or could have resulted, from the center's actions
1088 or the actions of the physician; the gravity of the action or
1089 potential harm; and the nature of the violations of applicable
1090 laws or rules.

1091 2. Any actions taken by the owner or designated physician
1092 to correct the violation.

1093 3. Whether any previous violations were committed at the
1094 center.

1095 4. Any financial benefits derived by the center from
1096 committing or continuing to commit the violation.

1097 (d) Each day a violation continues after the date on which
1098 the department orders a correction of the violation constitutes
1099 an additional, separate, and distinct violation.

1100 (e) The department may impose a fine and, in the case of an
1101 owner-operated office surgery center, revoke or deny a center's
1102 registration if the center's designated physician knowingly and

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1103 intentionally misrepresents actions taken to correct a
1104 violation.

1105 (f) The department shall impose a fine of \$5,000 per day on
1106 an owner or designated physician of an office surgery center
1107 registered under this section who concurrently operates an
1108 unregistered center.

1109 (g) The department shall impose a fine of \$10,000 on a new
1110 owner of an office surgery center that requires registration who
1111 fails to register the center upon the change of ownership and
1112 who operates the unregistered center.

1113 (7) RULEMAKING.—

1114 (a) The department may adopt rules to administer the
1115 registration, inspection, and safety of office surgery centers.

1116 (b) The board shall adopt rules specifying training
1117 requirements for all licensed or certified office surgery center
1118 health care practitioners and other health care practitioners
1119 who are not regulated by any board.

1120 Section 7. Section 459.026, Florida Statutes, is
1121 republished to read:

1122 459.026 Reports of adverse incidents in office practice
1123 settings.—

1124 (1) Any adverse incident that occurs on or after January 1,
1125 2000, in any office maintained by an osteopathic physician for
1126 the practice of osteopathic medicine which is not licensed under
1127 chapter 395 must be reported to the department in accordance
1128 with the provisions of this section.

1129 (2) Any osteopathic physician or other licensee under this
1130 chapter practicing in this state must notify the department if
1131 the osteopathic physician or licensee was involved in an adverse

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1132 incident that occurred on or after January 1, 2000, in any
1133 office maintained by an osteopathic physician for the practice
1134 of osteopathic medicine which is not licensed under chapter 395.

1135 (3) The required notification to the department must be
1136 submitted in writing by certified mail and postmarked within 15
1137 days after the occurrence of the adverse incident.

1138 (4) For purposes of notification to the department pursuant
1139 to this section, the term "adverse incident" means an event over
1140 which the physician or licensee could exercise control and which
1141 is associated in whole or in part with a medical intervention,
1142 rather than the condition for which such intervention occurred,
1143 and which results in the following patient injuries:

1144 (a) The death of a patient.

1145 (b) Brain or spinal damage to a patient.

1146 (c) The performance of a surgical procedure on the wrong
1147 patient.

1148 (d) 1. The performance of a wrong-site surgical procedure;

1149 2. The performance of a wrong surgical procedure; or

1150 3. The surgical repair of damage to a patient resulting
1151 from a planned surgical procedure where the damage is not a
1152 recognized specific risk as disclosed to the patient and
1153 documented through the informed-consent process

1154
1155 if it results in: death; brain or spinal damage; permanent
1156 disfigurement not to include the incision scar; fracture or
1157 dislocation of bones or joints; a limitation of neurological,
1158 physical, or sensory function; or any condition that required
1159 the transfer of the patient.

1160 (e) A procedure to remove unplanned foreign objects

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1161 remaining from a surgical procedure.

1162 (f) Any condition that required the transfer of a patient
1163 to a hospital licensed under chapter 395 from an ambulatory
1164 surgical center licensed under chapter 395 or any facility or
1165 any office maintained by a physician for the practice of
1166 medicine which is not licensed under chapter 395.

1167 (5) The department shall review each incident and determine
1168 whether it potentially involved conduct by a health care
1169 professional who is subject to disciplinary action, in which
1170 case s. 456.073 applies. Disciplinary action, if any, shall be
1171 taken by the board under which the health care professional is
1172 licensed.

1173 (6) (a) The board shall adopt rules establishing a standard
1174 informed consent form that sets forth the recognized specific
1175 risks related to cataract surgery. The board must propose such
1176 rules within 90 days after the effective date of this
1177 subsection.

1178 (b) Before formally proposing the rule, the board must
1179 consider information from physicians licensed under chapter 458
1180 or this chapter regarding recognized specific risks related to
1181 cataract surgery and the standard informed consent forms adopted
1182 for use in the medical field by other states.

1183 (c) A patient's informed consent is not executed until the
1184 patient, or a person authorized by the patient to give consent,
1185 and a competent witness sign the form adopted by the board.

1186 (d) An incident resulting from recognized specific risks
1187 described in the signed consent form is not considered an
1188 adverse incident for purposes of s. 395.0197 and this section.

1189 (e) In a civil action or administrative proceeding against

39-00277A-19

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1190 a physician based on his or her alleged failure to properly
1191 disclose the risks of cataract surgery, a patient's informed
1192 consent executed as provided in paragraph (c) on the form
1193 adopted by the board is admissible as evidence and creates a
1194 rebuttable presumption that the physician properly disclosed the
1195 risks.

1196 (7) The board may adopt rules to administer this section.
1197 Section 8. This act shall take effect July 1, 2019.

1198