

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
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34 | documents of a center whose certificate was revoked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
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
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~~
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
142 is not considered a purposeful response.

143 (b) "Designated physician" means a physician licensed
144 under this chapter or chapter 459 who practices at an office
145 surgery center and who has assumed responsibility for the
146 center's 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
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
185 the 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
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 (1) "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,
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
256 office surgery center shall identify to the department a
257 designated physician. Within 10 days after the resignation or
258 termination of its designated physician, a center shall identify
259 to the department the new designated physician. The department
260 may suspend a center's certificate of registration for failure
261 to comply with this paragraph.

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
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
309 revoked, any person named in the registration documents of the
310 center, including the persons who own or operate the center, may
311 not apply, individually or as part of a group, to operate an
312 office surgery center for a period of 5 years after the
313 revocation 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
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
337 center determines that the center is not in compliance with
338 subsection (4), he or she must immediately notify the department
339 of such 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
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,
365 or 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
373 surgery 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
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
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
419 emergency. The procedures must provide for the evacuation of
420 patients with 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;

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-
462 tidal CO2 monitor, pulse oximeter, emergency intubation
463 equipment, and a temperature monitoring device.

464 6. Have at least one table capable of trendelenburg,
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
480 have admitting privileges at a hospital within reasonable
481 proximity 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
487 undergoing a level III office surgery procedure shall have a
488 complete medical workup performed by the surgeon before the
489 performance of level III surgery. If the patient has a cardiac
490 history or has other complicating health conditions, he or she
491 must have a preoperative EKG and be referred to an appropriate
492 consultant for medical optimization of the complicating
493 conditions. The referral to a consultant may be waived after
494 evaluation by the anesthesiologist to administer or supervise
495 the patient's 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
505 center annually, including a review of patient records, to
506 ensure that the center complies with this section and board
507 rule, unless the center is accredited by a nationally recognized
508 accrediting agency or an accrediting organization subsequently
509 approved by the board. The department also may inspect an office
510 surgery 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
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
538 office surgery center, and in determining the amount of any
539 fine, the department shall consider all of the following
540 factors:

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

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

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

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

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

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

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

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

569 (7) RULEMAKING.—

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

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

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

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

580 (1) Any adverse incident that occurs on or after January
581 1, 2000, in any office maintained by a physician for the
582 practice of medicine which is not licensed under chapter 395
583 must be reported to the department in accordance with the
584 provisions of this section.

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

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

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

- 601 (a) The death of a patient.
- 602 (b) Brain or spinal damage to a patient.
- 603 (c) The performance of a surgical procedure on the wrong
604 patient.
- 605 (d)1. The performance of a wrong-site surgical procedure;
606 2. The performance of a wrong surgical procedure; or
607 3. The surgical repair of damage to a patient resulting
608 from a planned surgical procedure where the damage is not a
609 recognized specific risk as disclosed to the patient and
610 documented through the informed-consent process
611
- 612 if it results in: death; brain or spinal damage; permanent
613 disfigurement not to include the incision scar; fracture or
614 dislocation of bones or joints; a limitation of neurological,
615 physical, or sensory function; or any condition that required
616 the transfer of the patient.
- 617 (e) A procedure to remove unplanned foreign objects
618 remaining from a surgical procedure.
- 619 (f) Any condition that required the transfer of a patient
620 to a hospital licensed under chapter 395 from an ambulatory
621 surgical center licensed under chapter 395 or any facility or
622 any office maintained by a physician for the practice of
623 medicine which is not licensed under chapter 395.
- 624 (5) The department shall review each incident and
625 determine whether it potentially involved conduct by a health

626 care professional who is subject to disciplinary action, in
627 which case s. 456.073 applies. Disciplinary action, if any,
628 shall be taken by the board under which the health care
629 professional is licensed.

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

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

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

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

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

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651 rebuttable presumption that the physician properly disclosed the
652 risks.

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

654 Section 5. Section 459.005, Florida Statutes, is amended
655 to read:

656 459.005 Rulemaking authority.—

657 ~~(1)~~ The board has authority to adopt rules pursuant to ss.
658 120.536(1) and 120.54 to implement the provisions of this
659 chapter conferring duties upon it.

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

673 Section 6. Section 459.0138, Florida Statutes, is created
674 to read:

675 459.0138 Office surgery centers.—

- 676 (1) DEFINITIONS.—As used in this section, the term:
- 677 (a) "Deep sedation with analgesia" means a drug-induced
- 678 depression of consciousness during which all of the following
- 679 apply:
- 680 1. The patient cannot be easily aroused but responds
- 681 purposefully following repeated or painful stimulation.
- 682 2. The patient's ability to independently maintain
- 683 ventilatory function may be impaired.
- 684 3. The patient may require assistance in maintaining a
- 685 patent airway, and spontaneous ventilation may be inadequate.
- 686 4. The patient's cardiovascular function is usually
- 687 maintained.
- 688 5. The patient's reflex withdrawal from painful stimulus
- 689 is not considered a purposeful response.
- 690 (b) "Designated physician" means a physician licensed
- 691 under this chapter or chapter 458 who practices at an office
- 692 surgery center and who has assumed responsibility for the
- 693 center's compliance with this section and related board rules.
- 694 (c) "General anesthesia" means a drug-induced loss of
- 695 consciousness administered by an anesthesiologist or a certified
- 696 registered nurse anesthetist during which all of the following
- 697 apply:
- 698 1. The patient is not able to be aroused, even by painful
- 699 stimulation.
- 700 2. The patient's ability to independently maintain

701 ventilatory function is often impaired.

702 3. The patient has a level of depressed neuromuscular
703 function.

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

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

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

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

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

725 (e) "Level II procedure" includes any surgery in which the

726 patient's level of sedation is that of moderate sedation and
727 analgesia or conscious sedation. The term includes, but is not
728 limited to: hemorrhoidectomy, hernia repair, large joint
729 dislocations, colonoscopy, and liposuction involving the removal
730 of up to 1,000 cubic centimeters of supernatant fat.

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

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

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

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

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

751 considered a purposeful response.

752 (i) "Office surgery" means any manual or operative
753 procedure, including by use of lasers, performed upon the body
754 of a living human being for the purposes of preserving health,
755 diagnosing or curing disease, repairing injury, correcting
756 deformity or defects, prolonging life, or relieving suffering or
757 any elective procedure for aesthetic, reconstructive, or
758 cosmetic purposes, to include, but not be limited to: incision
759 or curettage of tissue or an organ; suture or other repair of
760 tissue or an organ, including both a closed and open reduction
761 of a fracture; extraction of tissue, including premature
762 extraction of the products of conception from the uterus;
763 insertion of natural or artificial implants; or an endoscopic
764 procedure with use of local or general anesthetic.

765 (j) "Office surgery center" means any facility or office
766 surgery setting, other than a facility licensed under chapter
767 390 or chapter 395, where a physician performs any of the
768 following surgical procedures:

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

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

776 specific nerve blocks.

777 (1) "Surgery" or "surgical" means any manual or operative
778 procedure, including the use of lasers, performed upon the body
779 of a living human being for the purposes of preserving health,
780 diagnosing or curing disease, repairing injury, correcting
781 deformity or defects, prolonging life, or relieving suffering or
782 any elective procedure for aesthetic, reconstructive, or
783 cosmetic purposes. The term includes, but is not limited to, all
784 of the following: incision or curettage of tissue or an organ;
785 suture or other repair of tissue or an organ, including both a
786 closed and an open reduction of a fracture; extraction of
787 tissue, including premature extraction of the products of
788 conception from the uterus; insertion of natural or artificial
789 implants; or an endoscopic procedure with use of local,
790 regional, or general anesthetic.

791 (2) CERTIFICATE OF REGISTRATION.—

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

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

801 by the person seeking to register and operate the center.

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

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

813 1. Not fully owned by a physician licensed under this
814 chapter or chapter 458 or a group of physicians licensed under
815 this chapter or chapter 458;

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

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

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

823 b. Does not have a clear and active license with the
824 department; or

825 c. Has been the subject of disciplinary action in this

826 state or in another jurisdiction in the last 5 years for an
827 offense related to standard of care.

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

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

840 1. Ceases to operate the facility as an office surgery
841 center; and

842 2. Removes any signs and symbols identifying the premises
843 as an office surgery center.

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

851 499.006.

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

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

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

866 (3) OFFICE SURGERY CENTER PHYSICIANS; DESIGNATED
867 PHYSICIANS; PROHIBITION; REQUIREMENTS.—

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

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

873 a. Result in blood loss of more than 10 percent of
874 estimated blood volume in a patient having a normal hemoglobin
875 level;

876 b. Require major or prolonged intracranial, intrathoracic,
877 abdominal, or major joint replacement procedures, except for
878 laparoscopic procedures; or

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

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

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

890

891 A physician who violates this paragraph is subject to
892 disciplinary action by the board.

893 (b) The designated physician of an office surgery center
894 shall:

895 1. Ensure that the center maintains an ongoing quality
896 assurance program that objectively and systematically monitors
897 and evaluates the quality and appropriateness of patient care,
898 evaluates methods to improve patient care, identifies and
899 corrects deficiencies at the facility, alerts the designated
900 physician to identify and resolve recurring problems, and

901 provides opportunities for the center to improve its performance
 902 and enhance and improve the quality of care provided to the
 903 public.

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

907 a. Identification, investigation, and analysis of the
 908 frequency and causes of incidents;

909 b. Identification of trends or patterns of adverse
 910 incidents; and

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

913 3. Review, at least quarterly, the quality assurance
 914 program.

915 4. Report all adverse incidents to the department as
 916 provided in s. 459.026.

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

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

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

922 1. Be located and operated at a publicly accessible, fixed
 923 location.

924 2. Display a sign that clearly identifies the name, hours
 925 of operation, and street address of the center. The sign must be

- 926 | prominently displayed in public view.
- 927 | 3. Maintain and publicly list a telephone number.
- 928 | 4. Provide emergency lighting and for emergency
929 | communications.
- 930 | 5. Have a reception and waiting area.
- 931 | 6. Have a restroom.
- 932 | 7. Have an administrative area, including room for storage
933 | of medical records, supplies, and equipment.
- 934 | 8. Have private patient examination rooms.
- 935 | 9. Have treatment rooms, if treatment is being provided to
936 | the patients.
- 937 | 10. Publicly display a visible printed sign in a
938 | conspicuous place in each waiting room which includes the name
939 | and contact information of the center's designated physician and
940 | the names of all physicians practicing at the center.
- 941 | 11. Comply with ss. 499.0121 and 893.07, if the center
942 | stores and dispenses prescription drugs.
- 943 | (b) Infection control requirements.—The center must:
- 944 | 1. Maintain equipment and supplies to support infection
945 | prevention and control.
- 946 | 2. Identify infection risks based on the following:
- 947 | a. Geographic location, community, and population served.
- 948 | b. The nature of the provided care, treatments, and
949 | services.
- 950 | c. An analysis of the center's infection surveillance and

951 control data.

952 3. Maintain written infection prevention policies and
953 procedures that address prioritized risks and limit the
954 following:

955 a. Unprotected exposure to pathogens.

956 b. The transmission of infections associated with
957 procedures performed at the center.

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

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

961 1. Maintain its structurally sound buildings and keep its
962 grounds free from health and safety hazards.

963 2. Keep its furniture, appliances, and equipment clean,
964 safe, and in good repair.

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

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

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

975 6. Have written emergency policies and procedures related

976 to serious anesthesia complications which must be formulated,
 977 reviewed annually, practiced, updated, and posted in a
 978 conspicuous location. Such procedures must address all of the
 979 following conditions:

- 980 a. Airway blockage and foreign body obstruction;
- 981 b. Allergic reactions;
- 982 c. Bradycardia;
- 983 d. Bronchospasm;
- 984 e. Cardiac arrest;
- 985 f. Chest pain;
- 986 g. Hypoglycemia;
- 987 h. Hypotension;
- 988 i. Hypoventilation;
- 989 j. Laryngospasm;
- 990 k. Local anesthetic toxicity reaction; and
- 991 l. Malignant hyperthermia.

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

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

- 1000 2. Store medicines per the manufacturer's recommendations

1001 and note the date on multidose vials once they are opened.

1002 3. Maintain dantrolene on site if halogenated anesthetics
1003 or succinylcholine are used.

1004 4. In terms of general preparation, equipment, and
1005 supplies, be comparable to a freestanding ambulatory surgical
1006 center, including, but not limited to, patient recovery
1007 capability and provisions for proper recordkeeping.

1008 5. Have blood pressure monitoring equipment, EKG, end-
1009 tidal CO2 monitor, pulse oximeter, emergency intubation
1010 equipment, and a temperature monitoring device.

1011 6. Have at least one table capable of trendelenburg,
1012 lithotomy, and other positions necessary to facilitate the
1013 surgical procedure.

1014 (e) Level III office surgery requirements.—

1015 1. A level III procedure may not be performed in an office
1016 surgery center unless an anesthesiologist, as defined in s.
1017 458.3475 or s. 459.023, is physically present at the center and
1018 available at the time of the procedure.

1019 2. For a center in which level III procedures are
1020 performed, either:

1021 a. The center must have a written patient transfer
1022 agreement with a hospital within reasonable proximity to the
1023 center which includes the transfer of the patient's medical
1024 records held by the center and the treating physician to the
1025 licensed hospital; or

1026 b. The surgeon performing the level III procedure must
1027 have admitting privileges at a hospital within reasonable
1028 proximity to the center.

1029 3. Level III procedures may be performed only on a patient
1030 who is classified under the American Society of
1031 Anesthesiologists' (ASA) Physical Status Classification System,
1032 as approved on October 15, 2014, as Class I or II.

1033 4. All ASA Class II patients above the age of 50
1034 undergoing a level III office surgery procedure shall have a
1035 complete medical workup performed by the surgeon before the
1036 performance of level III surgery. If the patient has a cardiac
1037 history or has other complicating health conditions, he or she
1038 must have a preoperative EKG and be referred to an appropriate
1039 consultant for medical optimization of the complicating
1040 conditions. The referral to a consultant may be waived after
1041 evaluation by the anesthesiologist to administer or supervise
1042 the patient's anesthesia.

1043 5. To perform a level III procedure in an office surgery
1044 center, the surgeon must have staff privileges at a licensed
1045 hospital to perform the same level III procedure in the hospital
1046 or must be able to document satisfactory completion of training,
1047 such as board certification or board qualification by a board
1048 approved by the American Board of Medical Specialties or any
1049 other board approved by the Board of Medicine.

1050 (5) INSPECTION.—

1051 (a) The department shall inspect each office surgery
1052 center annually, including a review of patient records, to
1053 ensure that the center complies with this section and board
1054 rule, unless the center is accredited by a nationally recognized
1055 accrediting agency or an accrediting organization subsequently
1056 approved by the board. The department also may inspect an office
1057 surgery center as necessary to investigate a notification of
1058 noncompliance made by a physician pursuant to subparagraph
1059 (3) (a) 3.

1060 (b) The actual costs of inspection must be paid by the
1061 person who registered and operates the office surgery center.

1062 (c) During an onsite inspection, the department shall make
1063 a reasonable attempt to resolve each violation with the owner or
1064 designated physician of the office surgery center before issuing
1065 a formal written notification.

1066 (d) Any action taken to resolve a violation must be
1067 documented in writing by the owner or designated physician of
1068 the office surgery center and submitted to the department. The
1069 department must verify any correction of the violation in a
1070 subsequent inspection.

1071 (6) ENFORCEMENT.—

1072 (a) The department may revoke an office surgery center's
1073 certificate of registration and prohibit all physicians
1074 associated with the center from practicing at the center for
1075 failure to comply with this section and rules adopted hereunder.

1076 (b) The department may impose an administrative fine of up
1077 to \$5,000 per violation on an office surgery center for
1078 violations of this section; chapter 499, the Florida Drug and
1079 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
1080 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
1081 Abuse Prevention and Control Act; chapter 893, the Florida
1082 Comprehensive Drug Abuse Prevention and Control Act; or
1083 department rule.

1084 (c) In determining whether to impose a penalty on an
1085 office surgery center, and in determining the amount of any
1086 fine, the department shall consider all of the following
1087 factors:

1088 1. The gravity of the violation, including the probability
1089 that death or serious physical or emotional harm to a patient
1090 has resulted, or could have resulted, from the center's actions
1091 or the actions of the physician; the gravity of the action or
1092 potential harm; and the nature of the violations of applicable
1093 laws or rules.

1094 2. Any actions taken by the owner or designated physician
1095 to correct the violation.

1096 3. Whether any previous violations were committed at the
1097 center.

1098 4. Any financial benefits derived by the center from
1099 committing or continuing to commit the violation.

1100 (d) Each day a violation continues after the date on which

1101 the department orders a correction of the violation constitutes
1102 an additional, separate, and distinct violation.

1103 (e) The department may impose a fine and, in the case of
1104 an owner-operated office surgery center, revoke or deny a
1105 center's registration if the center's designated physician
1106 knowingly and intentionally misrepresents actions taken to
1107 correct a violation.

1108 (f) The department shall impose a fine of \$5,000 per day
1109 on an owner or designated physician of an office surgery center
1110 registered under this section who concurrently operates an
1111 unregistered center.

1112 (g) The department shall impose a fine of \$10,000 on a new
1113 owner of an office surgery center that requires registration who
1114 fails to register the center upon the change of ownership and
1115 who operates the unregistered center.

1116 (7) RULEMAKING.—

1117 (a) The department may adopt rules to administer the
1118 registration, inspection, and safety of office surgery centers.

1119 (b) The board shall adopt rules specifying training
1120 requirements for all licensed or certified office surgery center
1121 health care practitioners and other health care practitioners
1122 who are not regulated by any board.

1123 Section 7. Section 459.026, Florida Statutes, is
1124 republished to read:

1125 459.026 Reports of adverse incidents in office practice

1126 settings.—

1127 (1) Any adverse incident that occurs on or after January
 1128 1, 2000, in any office maintained by an osteopathic physician
 1129 for the practice of osteopathic medicine which is not licensed
 1130 under chapter 395 must be reported to the department in
 1131 accordance with the provisions of this section.

1132 (2) Any osteopathic physician or other licensee under this
 1133 chapter practicing in this state must notify the department if
 1134 the osteopathic physician or licensee was involved in an adverse
 1135 incident that occurred on or after January 1, 2000, in any
 1136 office maintained by an osteopathic physician for the practice
 1137 of osteopathic medicine which is not licensed under chapter 395.

1138 (3) The required notification to the department must be
 1139 submitted in writing by certified mail and postmarked within 15
 1140 days after the occurrence of the adverse incident.

1141 (4) For purposes of notification to the department
 1142 pursuant to this section, the term "adverse incident" means an
 1143 event over which the physician or licensee could exercise
 1144 control and which is associated in whole or in part with a
 1145 medical intervention, rather than the condition for which such
 1146 intervention occurred, and which results in the following
 1147 patient injuries:

- 1148 (a) The death of a patient.
- 1149 (b) Brain or spinal damage to a patient.
- 1150 (c) The performance of a surgical procedure on the wrong

1151 patient.

1152 (d)1. The performance of a wrong-site surgical procedure;

1153 2. The performance of a wrong surgical procedure; or

1154 3. The surgical repair of damage to a patient resulting

1155 from a planned surgical procedure where the damage is not a

1156 recognized specific risk as disclosed to the patient and

1157 documented through the informed-consent process

1158

1159 if it results in: death; brain or spinal damage; permanent

1160 disfigurement not to include the incision scar; fracture or

1161 dislocation of bones or joints; a limitation of neurological,

1162 physical, or sensory function; or any condition that required

1163 the transfer of the patient.

1164 (e) A procedure to remove unplanned foreign objects

1165 remaining from a surgical procedure.

1166 (f) Any condition that required the transfer of a patient

1167 to a hospital licensed under chapter 395 from an ambulatory

1168 surgical center licensed under chapter 395 or any facility or

1169 any office maintained by a physician for the practice of

1170 medicine which is not licensed under chapter 395.

1171 (5) The department shall review each incident and

1172 determine whether it potentially involved conduct by a health

1173 care professional who is subject to disciplinary action, in

1174 which case s. 456.073 applies. Disciplinary action, if any,

1175 shall be taken by the board under which the health care

1176 professional is licensed.

1177 (6) (a) The board shall adopt rules establishing a standard
1178 informed consent form that sets forth the recognized specific
1179 risks related to cataract surgery. The board must propose such
1180 rules within 90 days after the effective date of this
1181 subsection.

1182 (b) Before formally proposing the rule, the board must
1183 consider information from physicians licensed under chapter 458
1184 or this chapter regarding recognized specific risks related to
1185 cataract surgery and the standard informed consent forms adopted
1186 for use in the medical field by other states.

1187 (c) A patient's informed consent is not executed until the
1188 patient, or a person authorized by the patient to give consent,
1189 and a competent witness sign the form adopted by the board.

1190 (d) An incident resulting from recognized specific risks
1191 described in the signed consent form is not considered an
1192 adverse incident for purposes of s. 395.0197 and this section.

1193 (e) In a civil action or administrative proceeding against
1194 a physician based on his or her alleged failure to properly
1195 disclose the risks of cataract surgery, a patient's informed
1196 consent executed as provided in paragraph (c) on the form
1197 adopted by the board is admissible as evidence and creates a
1198 rebuttable presumption that the physician properly disclosed the
1199 risks.

1200 (7) The board may adopt rules to administer this section.

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1201 | Section 8. This act shall take effect July 1, 2019. |