

By the Committees on Fiscal Policy; and Health Policy; and
Senator Garcia

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1 A bill to be entitled
2 An act relating to office surgeries; amending ss.
3 458.328 and 459.0138, F.S.; revising the types of
4 procedures for which a medical office must register
5 with the Department of Health to perform office
6 surgeries; specifying inspection procedures for such
7 offices seeking registration with the department;
8 requiring that certain offices seeking registration
9 provide proof to the department that they have met
10 specified requirements and rules; requiring the
11 department to inspect such offices to ensure that
12 certain equipment and procedures are present or in
13 place; requiring the department to notify the Agency
14 for Health Care Administration if an applicant is
15 unable to provide certain proof to the department and
16 to request that the agency inspect and consult with
17 the office; deleting obsolete language; providing that
18 the department may not register and must seek an
19 emergency suspension of an office under specified
20 circumstances; requiring that each office, as a
21 condition of registration, list certain medical
22 personnel and thereafter notify the department of the
23 addition or termination of such personnel within a
24 specified timeframe; providing for disciplinary action
25 for failure to comply; revising the materials that the
26 department must review when inspecting a registered
27 office; requiring offices already registered with the
28 department as of a specified date to provide a
29 registration update within a specified timeframe;

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30 specifying requirements for such registration update
31 process; revising requirements for the standards of
32 practice for office surgeries; providing an
33 administrative penalty; revising rulemaking
34 requirements; creating ss. 458.3281 and 459.0139,
35 F.S.; providing construction; defining terms;
36 specifying general requirements for office surgeries;
37 specifying standards of practice for office surgeries,
38 delineated by the level of surgery being performed;
39 providing an exemption; authorizing the Board of
40 Medicine and the Board of Osteopathic Medicine, as
41 applicable, to adopt additional standards of practice
42 by rule; amending s. 456.074, F.S.; correcting a
43 cross-reference; providing an effective date.

44
45 Be It Enacted by the Legislature of the State of Florida:

46
47 Section 1. Section 458.328, Florida Statutes, is amended to
48 read:

49 458.328 Office surgeries.—

50 (1) REGISTRATION.—

51 (a) ~~1.~~ An office in which a physician performs or intends to
52 perform a liposuction procedure in which more than 1,000 cubic
53 centimeters of supernatant fat is temporarily or permanently
54 removed, a liposuction procedure during which the patient is
55 rotated between the supine, lateral, and prone positions, a
56 Level II office surgery, or a Level III office surgery must
57 register with the department. ~~unless the office is licensed as A~~
58 facility licensed under chapter 390 or chapter 395 may not be

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59 registered under this section.

60 ~~(b)2.~~ The department must complete an inspection of any
61 office seeking registration under this section before the office
62 may be registered.

63 1. The inspection of the office seeking registration under
64 this section must include inspection for compliance with the
65 standards of practice set out in this section and s. 458.3281
66 and any applicable board rules for the levels of office surgery
67 and procedures listed on the application which any physician
68 practicing at the office performs or intends to perform. The
69 application must be updated within 10 calendar days before any
70 additional surgical procedures or levels of office surgery are
71 to be performed at the office. Failure to timely update the
72 application for any such additional surgical procedures or
73 levels of office surgery is a violation of this section and
74 subject to discipline under ss. 456.072 and 458.331.

75 2. The department must immediately suspend the registration
76 process of an office that refuses an inspection under
77 subparagraph 1., and the applicant must be required to reapply
78 for registration.

79 3. If the department determines that an office seeking
80 registration under this section is one in which a physician may
81 perform, or intends to perform, liposuction procedures that
82 include a patient being rotated between the supine, lateral, and
83 prone positions during the procedure, or in which a physician
84 may perform, or intends to perform, gluteal fat grafting
85 procedures, the office must provide proof to the department that
86 it has met the applicable requirements of s. 469 of the Florida
87 Building Code, relating to office surgery suites, and s.

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88 458.3281 and the applicable rules adopted thereunder, and the
89 department must inspect the office to ensure that all of the
90 following are present or in place:

91 a. Equipment and a procedure for measuring and documenting
92 in a log the amount of supernatant fat removed, both temporarily
93 and permanently, from a particular patient, including tissue
94 disposal procedures.

95 b. A procedure for measuring and documenting the amount of
96 lidocaine injected for tumescent liposuction, if used.

97 c. Working ultrasound guidance equipment or other guidance
98 technology authorized under board rule which equals or exceeds
99 the quality of ultrasound guidance.

100 d. The office procedure for obtaining blood products.

101 e. Documentation on file at the office demonstrating that
102 any physician performing these procedures has privileges to
103 perform such procedures in a hospital no more than 30 minutes
104 away.

105 f. Procedures for emergency resuscitation and transport to
106 a hospital.

107 g. Procedures for anesthesia and surgical recordkeeping.

108 h. Any additional inspection requirements, as set by board
109 rule.

110 4. If an applicant is required under subparagraph 3. to
111 provide proof to the department that the office is in compliance
112 with the applicable requirements of s. 469 of the Florida
113 Building Code, relating to office surgery suites, or s. 458.3281
114 and the applicable rules adopted thereunder, but is unable to
115 provide such proof, the department must notify the Agency for
116 Health Care Administration and request the agency to inspect the

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117 office and consult with the office about the process to apply
118 for ambulatory surgical center licensure under chapter 395 and
119 how the office may seek qualification for such licensure,
120 notwithstanding the office's failure to meet all requirements
121 associated with such licensure at the time of inspection and
122 notwithstanding any pertinent exceptions provided under s.
123 395.002 (3).

124 (c)(b) To be ~~By January 1, 2020,~~ each office registered
125 under this section or s. 459.0138, an office must, at the time
126 of application, list a designated ~~designate~~ a physician who is
127 responsible for the office's compliance with the office health
128 and safety requirements of this section and rules adopted
129 hereunder. A designated physician must have a full, active, and
130 unencumbered license under this chapter or chapter 459 and shall
131 practice at the office for which he or she has assumed
132 responsibility. Within 10 calendar days after the termination of
133 a designated physician relationship, the office must notify the
134 department of the designation of another physician to serve as
135 the designated physician. The department may not register an
136 office if the office fails to comply with this requirement at
137 the time of application and must seek an emergency suspension of
138 ~~suspend~~ the registration of an office pursuant to s. 456.074(6)
139 if the office fails to timely notify the department of its new
140 designated physician within 10 calendar days after the
141 termination of the previous designated physician relationship
142 ~~comply with the requirements of this paragraph.~~

143 (d) As a condition of registration, each office must, at
144 the time of application, list all medical personnel who will be
145 practicing at the office, including all of the following:

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146 1. Physicians who intend to practice surgery or assist in
147 surgery at the office seeking registration, including their
148 respective license numbers and practice addresses.

149 2. Anesthesia providers, including their license numbers.

150 3. Nursing personnel licensed under chapter 464, including
151 their license numbers unless already provided under subparagraph
152 2.

153 4. Physician assistants, including their respective license
154 numbers and supervising physicians.

155
156 The office must notify the department of the addition or
157 termination of any of the types of medical personnel specified
158 under this paragraph within 10 calendar days before such
159 addition or after such termination. Failure to timely notify the
160 department of such addition or termination is a violation of
161 this section and subject to discipline under ss. 456.072 and
162 458.331.

163 (e)~~(e)~~ As a condition of registration, each office must
164 establish financial responsibility by demonstrating that it has
165 met and continues to maintain, at a minimum, the same
166 requirements applicable to physicians in ss. 458.320 and
167 459.0085. Each physician practicing at an office registered
168 under this section or s. 459.0138 must meet the financial
169 responsibility requirements under s. 458.320 or s. 459.0085, as
170 applicable.

171 (f)~~(d)~~ Each physician practicing or intending to practice
172 at an office registered under this section or s. 459.0138 must
173 shall advise the board, in writing, within 10 calendar days
174 before ~~after~~ beginning or after ending his or her practice at a

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175 registered office, as applicable.

176 (g)~~(e)~~¹. The department shall inspect a registered office
177 at least annually, including a review of patient records,
178 anesthesia logs, surgery logs, and liposuction logs, to ensure
179 that the office is in compliance with this section and rules
180 adopted hereunder unless the office is accredited in office-
181 based surgery by the Joint Commission or other a nationally
182 recognized accrediting agency approved by the board. The
183 inspection may be unannounced, except for the inspection of an
184 office that meets the description of a clinic specified in s.
185 458.3265(1)(a)3.h., and those wholly owned and operated
186 physician offices described in s. 458.3265(1)(a)3.g. which
187 perform procedures referenced in s. 458.3265(1)(a)3.h., which
188 must be announced.

189 (h)². The department must immediately suspend the
190 registration of a registered office that refuses an inspection
191 under paragraph (g) ~~subparagraph 1~~. The office must close during
192 such suspension. The suspension must remain in effect for at
193 least 14 consecutive days and may not terminate until the
194 department issues a written declaration that the office may
195 reopen following the department's completion of an inspection of
196 the office.

197 (i)~~(f)~~. The department may suspend or revoke the
198 registration of an office in which a procedure or surgery
199 identified in paragraph (a) is performed for failure of any of
200 its physicians, owners, or operators to comply with this section
201 and rules adopted hereunder or s. 459.0138 and rules adopted
202 thereunder. If an office's registration is revoked for any
203 reason, the department may deny any person named in the

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204 registration documents of the office, including the persons who
205 own or operate the office, individually or as part of a group,
206 from registering an office to perform procedures or office
207 surgeries pursuant to this section or s. 459.0138 for 5 years
208 after the revocation date.

209 ~~(j)~~^(j) The department may impose any penalty set forth in
210 s. 456.072(2) against the designated physician for failure of
211 the office to operate in compliance with the office health and
212 safety requirements of this section and rules adopted hereunder
213 or s. 459.0138 and rules adopted thereunder.

214 ~~(h) A physician may only perform a procedure or surgery~~
215 ~~identified in paragraph (a) in an office that is registered with~~
216 ~~the department. The board shall impose a fine of \$5,000 per day~~
217 ~~on a physician who performs a procedure or surgery in an office~~
218 ~~that is not registered with the department.~~

219 ~~(k)~~⁽ⁱ⁾ The actual costs of registration and inspection or
220 accreditation must ~~shall~~ be paid by the person seeking to
221 register and operate the office in which a procedure or surgery
222 identified in paragraph (a) will be performed.

223 (2) REGISTRATION UPDATE.—

224 (a) An office that registered under this section before
225 July 1, 2024, in which a physician performs liposuction
226 procedures that include a patient being rotated between the
227 supine, lateral, and prone positions during the procedure or in
228 which a physician performs gluteal fat grafting procedures must
229 provide a registration update to the department consistent with
230 the requirements of the initial registration under subsection
231 (1) no later than 30 days before the office surgery's next
232 annual inspection.

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233 (b) Registration update inspections required under
234 subsection (1) must be performed by the department on the date
235 of the office surgery's next annual inspection.

236 (c) During the registration update process, the office
237 surgery may continue to operate under the original registration.

238 (d) In order to provide an office surgery time to update to
239 the requirements of subsection (1) and s. 458.3281, effective
240 July 1, 2024, and the applicable provisions of s. 469 of the
241 Florida Building Code, relating to office surgery suites, any
242 office surgery registered under this section before July 1,
243 2024, whose annual inspection is due in July or August 2024, may
244 request from the department, in writing, a 60-day postponement
245 of the required annual inspection, which postponement must be
246 granted.

247 (e) All other requests to the department for a postponement
248 of the registration update inspection required under this
249 registration update process must be in writing and be approved
250 by the chair of the Board of Medicine for good cause shown, and
251 such postponement may not exceed 30 days.

252 (3) STANDARDS OF PRACTICE.—

253 (a) A physician performing a procedure or surgery in an
254 office registered under this section must comply with the
255 applicable provisions of s. 469 of the Florida Building Code,
256 relating to office surgery suites, and the standards of practice
257 for office surgery set forth in this section and s. 458.3281 and
258 any applicable rules adopted thereunder.

259 (b) A physician may not perform any surgery or procedure
260 identified in paragraph (1)(a) in a setting other than an office
261 registered under this section or a facility licensed under

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262 chapter 390 or chapter 395, as applicable. The board shall
263 impose a fine of \$5,000 per incident on a physician who violates
264 this paragraph performing a gluteal fat grafting procedure in an
265 office surgery setting shall adhere to standards of practice
266 pursuant to this subsection and rules adopted by the board.

267 (c) ~~(b)~~ Office surgeries may not:

268 1. Be a type of surgery that generally results in blood
269 loss of more than 10 percent of estimated blood volume in a
270 patient with a normal hemoglobin level;

271 2. Require major or prolonged intracranial, intrathoracic,
272 abdominal, or joint replacement procedures, except for
273 laparoscopic procedures;

274 3. Involve major blood vessels and be performed with direct
275 visualization by open exposure of the major blood vessel, except
276 for percutaneous endovascular intervention; or

277 4. Be emergent or life threatening.

278 (d) ~~(e)~~ A physician performing a gluteal fat grafting
279 procedure in an office surgery setting must comply with the
280 applicable provisions of s. 469 of the Florida Building Code,
281 relating to office surgery suites, and the standards of practice
282 under this subsection and s. 458.3281, and applicable rules
283 adopted thereunder, including, but not limited to, all of the
284 following standards of practice:

285 1. The ~~A~~ physician performing the ~~a~~ gluteal fat grafting
286 procedure must conduct an in-person examination of the patient
287 while physically present in the same room as the patient no
288 later than the day before the procedure.

289 2. Before a physician may delegate any duties during a
290 gluteal fat grafting procedure, the patient must provide

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291 written, informed consent for such delegation. Any duty
292 delegated by a physician during a gluteal fat grafting procedure
293 must be performed under the direct supervision of the physician
294 performing such procedure. Fat extraction and gluteal fat
295 injections must be performed by the physician and may not be
296 delegated.

297 3. Fat may only be injected into the subcutaneous space of
298 the patient and may not cross the fascia overlying the gluteal
299 muscle. Intramuscular or submuscular fat injections are
300 prohibited.

301 4. When the physician performing a gluteal fat grafting
302 procedure injects fat into the subcutaneous space of the
303 patient, the physician must use ultrasound guidance, or guidance
304 with other technology authorized under board rule which equals
305 or exceeds the quality of ultrasound, during the placement and
306 navigation of the cannula to ensure that the fat is injected
307 into the subcutaneous space of the patient above the fascia
308 overlying the gluteal muscle. Such guidance with the use of
309 ultrasound or other technology is not required for other
310 portions of such procedure.

311 5. An office in which a physician performs gluteal fat
312 grafting procedures shall at all times maintain a ratio of one
313 physician to one patient during all phases of the procedure,
314 beginning with the administration of anesthesia to the patient
315 and concluding with the extubation of the patient. After a
316 physician has commenced, and while he or she is engaged in, a
317 gluteal fat grafting procedure, the physician may not commence
318 or engage in another gluteal fat grafting procedure or any other
319 procedure with another patient at the same time.

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320 ~~(e)(d)~~ If a procedure in an office surgery setting results
321 in hospitalization, the incident must be reported as an adverse
322 incident pursuant to s. 458.351.

323 ~~(e) An office in which a physician performs gluteal fat~~
324 ~~grafting procedures must at all times maintain a ratio of one~~
325 ~~physician to one patient during all phases of the procedure,~~
326 ~~beginning with the administration of anesthesia to the patient~~
327 ~~and concluding with the extubation of the patient. After a~~
328 ~~physician has commenced, and while he or she is engaged in, a~~
329 ~~gluteal fat grafting procedure, the physician may not commence~~
330 ~~or engage in another gluteal fat grafting procedure or any other~~
331 ~~procedure with another patient at the same time.~~

332 ~~(4)(3)~~ RULEMAKING.—

333 (a) The board may ~~shall~~ adopt by rule additional standards
334 of practice for physicians who perform office procedures or
335 ~~office~~ surgeries under ~~pursuant to~~ this section, as warranted
336 for patient safety and by the evolution of technology and
337 medical practice.

338 (b) The board may adopt rules to administer the
339 registration, registration update, inspection, and safety of
340 offices in which a physician performs office procedures or
341 ~~office~~ surgeries under ~~pursuant to~~ this section.

342 Section 2. Section 458.3281, Florida Statutes, is created
343 to read:

344 458.3281 Standard of practice for office surgery.—

345 (1) CONSTRUCTION.—This section does not relieve a physician
346 performing a procedure or surgery from the responsibility of
347 making the medical determination of whether an office is an
348 appropriate setting in which to perform that particular

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349 procedure or surgery, taking into consideration the particular
350 patient on which the procedure or surgery is to be performed.

351 (2) DEFINITIONS.—As used in this section, the term:

352 (a) "Certified in advanced cardiac life support" means a
353 person holds a current certification in an advanced cardiac life
354 support course with didactic and skills components, approved by
355 the American Heart Association, the American Safety and Health
356 Institute, the American Red Cross, Pacific Medical Training, or
357 the Advanced Cardiovascular Life Support (ACLS) Certification
358 Institute.

359 (b) "Certified in basic life support" means a person holds
360 a current certification in a basic life support course with
361 didactic and skills components, approved by the American Heart
362 Association, the American Safety and Health Institute, the
363 American Red Cross, Pacific Medical Training, or the ACLS
364 Certification Institute.

365 (c) "Certified in pediatric advanced life support" means a
366 person holds a current certification in a pediatric advanced
367 life support course with didactic and skills components approved
368 by the American Heart Association, the American Safety and
369 Health Institute, or Pacific Medical Training.

370 (d) "Continual monitoring" means monitoring that is
371 repeated regularly and frequently in steady, rapid succession.

372 (e) "Continuous" means monitoring that is prolonged without
373 any interruption at any time.

374 (f) "Equipment" means a medical device, instrument, or tool
375 used to perform specific actions or take certain measurements
376 during, or while a patient is recovering from, a procedure or
377 surgery which must meet current performance standards according

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378 to its manufacturer's guidelines for the specific device,
379 instrument, or tool, as applicable.

380 (g) "Major blood vessels" means a group of critical
381 arteries and veins, including the aorta, coronary arteries,
382 pulmonary arteries, superior and inferior vena cava, pulmonary
383 veins, and any intra-cerebral artery or vein.

384 (h) "Office surgery" means a physician's office in which
385 surgical procedures are performed by a physician for the
386 practice of medicine as authorized by this section and board
387 rule. The office must be an office at which a physician
388 regularly performs consultations with surgical patients,
389 preoperative examinations, and postoperative care, as
390 necessitated by the standard of care related to the surgeries
391 performed at the physician's office, and at which patient
392 records are readily maintained and available. The types of
393 procedures or surgeries performed in an office surgery are those
394 which need not be performed in a facility licensed under chapter
395 390 or chapter 395, and are not of the type that:

396 1. Generally result in blood loss of more than 10 percent
397 of estimated blood volume in a patient with a normal hemoglobin
398 count;

399 2. Require major or prolonged intracranial, intrathoracic,
400 abdominal, or major joint replacement procedures, except for
401 laparoscopic procedures;

402 3. Involve major blood vessels and are performed with
403 direct visualization by open exposure of the major vessel,
404 except for percutaneous endovascular intervention; or

405 4. Are generally emergent or life threatening in nature.

406 (i) "Pediatric patient" means a patient who is 13 years of

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407 age or younger.

408 (j) "Percutaneous endovascular intervention" means a
409 procedure performed without open direct visualization of the
410 target vessel and which requires only needle puncture of an
411 artery or vein followed by insertion of catheters, wires, or
412 similar devices that are then advanced through the blood vessels
413 using imaging guidance. Once the catheter reaches the intended
414 location, various maneuvers to address the diseased area may be
415 performed, including, but not limited to, injection of contrast
416 medium for imaging; treatment of vessels with angioplasty;
417 atherectomy; covered or uncovered stenting; embolization or
418 intentionally occluding vessels or organs; and delivering
419 medications or radiation or other energy, such as laser,
420 radiofrequency, or cryo.

421 (k) "Reasonable proximity" means a distance that does not
422 exceed 30 minutes of transport time to the hospital.

423 (l) "Surgery" means any manual or operative procedure
424 performed upon the body of a living human being, including, but
425 not limited to, those performed with the use of lasers, for the
426 purposes of preserving health, diagnosing or curing disease,
427 repairing injury, correcting a deformity or defect, prolonging
428 life, or relieving suffering, or any elective procedure for
429 aesthetic, reconstructive, or cosmetic purposes. The term
430 includes, but is not limited to, incision or curettage of tissue
431 or an organ; suture or other repair of tissue or an organ,
432 including a closed as well as an open reduction of a fracture;
433 extraction of tissue, including premature extraction of the
434 products of conception from the uterus; insertion of natural or
435 artificial implants; or an endoscopic procedure with use of

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436 local or general anesthetic.

437 (3) GENERAL REQUIREMENTS FOR OFFICE SURGERY.—

438 (a) The physician performing the surgery must examine the
439 patient immediately before the surgery to evaluate the risk of
440 anesthesia and of the surgical procedure to be performed. The
441 physician performing the surgery may delegate the preoperative
442 heart and lung evaluation to a qualified anesthesia provider
443 within the scope of the provider's practice and, if applicable,
444 protocol.

445 (b) The physician performing the surgery shall maintain
446 complete patient records of each surgical procedure performed,
447 which must include all of the following:

448 1. The patient's name, patient number, preoperative
449 diagnosis, postoperative diagnosis, surgical procedure,
450 anesthetic, anesthesia records, recovery records, and
451 complications, if any.

452 2. The name of each member of the surgical team, including
453 the surgeon, first assistant, anesthesiologist, nurse
454 anesthetist, anesthesiologist assistant, circulating nurse, and
455 operating room technician, as applicable.

456 (c) Each office surgery's designated physician shall ensure
457 that the office surgery has procedures in place to verify that
458 all of the following have occurred before any surgery is
459 performed:

460 1. The patient has signed the informed consent form for the
461 procedure reflecting the patient's knowledge of identified risks
462 of the procedure, consent to the procedure, the type of
463 anesthesia and anesthesia provider to be used during the
464 procedure, and the fact that the patient may choose the type of

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465 anesthesia provider for the procedure, such as an
466 anesthesiologist, a certified registered nurse anesthetist, a
467 physician assistant, an anesthesiologist assistant, or another
468 appropriately trained physician as provided by board rule.

469 2. The patient's identity has been verified.

470 3. The operative site has been verified.

471 4. The operative procedure to be performed has been
472 verified with the patient.

473 5. All of the information and actions required to be
474 verified under this paragraph are documented in the patient's
475 medical record.

476 (d) With respect to the requirements set forth in paragraph
477 (c), written informed consent is not necessary for minor Level I
478 procedures limited to the skin and mucosa.

479 (e) The physician performing the surgery shall maintain a
480 log of all liposuction procedures performed at the office
481 surgery where more than 1,000 cubic centimeters of supernatant
482 fat is temporarily or permanently removed and where Level II and
483 Level III surgical procedures are performed. The log must, at a
484 minimum, include all of the following:

485 1. A confidential patient identifier.

486 2. Time of arrival in the operating suite.

487 3. The name of the physician performing the procedure.

488 4. The patient's diagnosis, CPT codes used for the
489 procedure, the patient's classification for risk with anesthesia
490 according to the American Society of Anesthesiologists' physical
491 status classification system, and the type of procedure and
492 level of surgery performed.

493 5. Documentation of completion of the medical clearance

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494 performed by the anesthesiologist or the physician performing
495 the surgery.

496 6. The name and provider type of the anesthesia provider
497 and the type of anesthesia used.

498 7. The duration of the procedure.

499 8. Any adverse incidents as identified in s. 458.351.

500 9. The type of postoperative care, duration of recovery,
501 disposition of the patient upon discharge, including the address
502 of where the patient is being discharged, discharge
503 instructions, and list of medications used during surgery and
504 recovery.

505
506 All surgical and anesthesia logs must be kept at the office
507 surgery and maintained for 6 years after the date of last
508 patient contact and must be provided to department investigators
509 upon request.

510 (f) For any liposuction procedure, the physician performing
511 the surgery is responsible for determining the appropriate
512 amount of supernatant fat to be removed from a particular
513 patient. A maximum of 4,000 cubic centimeters of supernatant fat
514 may be removed by liposuction in the office surgery setting. A
515 maximum of 50mg/kg of lidocaine may be injected for tumescent
516 liposuction in the office surgery setting.

517 (g)1. Liposuction may be performed in combination with
518 another separate surgical procedure during a single Level II or
519 Level III surgical procedure only in the following
520 circumstances:

521 a. When combined with an abdominoplasty, liposuction may
522 not exceed 1,000 cubic centimeters of supernatant fat.

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523 b. When liposuction is associated and directly related to
524 another procedure, the liposuction may not exceed 1,000 cubic
525 centimeters of supernatant fat.

526 2. Major liposuction in excess of 1,000 cubic centimeters
527 of supernatant fat may not be performed on a patient's body in a
528 location that is remote from the site of another procedure being
529 performed on that patient.

530 (h) For elective cosmetic and plastic surgery procedures
531 performed in a physician's office, the maximum planned duration
532 of all surgical procedures combined may not exceed 8 hours.
533 Except for elective cosmetic and plastic surgery, the physician
534 performing the surgery may not keep patients past midnight in a
535 physician's office. For elective cosmetic and plastic surgical
536 procedures, the patient must be discharged within 24 hours after
537 presenting to the office for surgery. However, an overnight stay
538 is allowed in the office if the total time the patient is at the
539 office does not exceed 23 hours and 59 minutes, including the
540 surgery time. An overnight stay in a physician's office for
541 elective cosmetic and plastic surgery must be strictly limited
542 to the physician's office. If the patient has not recovered
543 sufficiently to be safely discharged within the timeframes set
544 forth, the patient must be transferred to a hospital for
545 continued postoperative care.

546 (i) The American Society of Anesthesiologists Standards for
547 Basic Anesthetic Monitoring are hereby adopted and incorporated
548 by reference as the standards for anesthetic monitoring by any
549 qualified anesthesia provider under this section.

550 1. These standards apply to general anesthetics, regional
551 anesthetics, and monitored Level II and III anesthesia care.

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552 However, in emergency circumstances, appropriate life support
553 measures take priority. These standards may be exceeded at any
554 time based on the judgment of the responsible supervising
555 physician or anesthesiologist. While these standards are
556 intended to encourage quality patient care, observing them does
557 not guarantee any specific patient outcome. This set of
558 standards addresses only the issue of basic anesthesia
559 monitoring, which is only one component of anesthesia care.

560 2. In certain rare or unusual circumstances, some of these
561 methods of monitoring may be clinically impractical, and
562 appropriate use of the described monitoring methods may fail to
563 detect adverse clinical developments. In such cases, a brief
564 interruption of continual monitoring may be unavoidable and does
565 not by itself constitute a violation of the standards of
566 practice of this section.

567 3. Under extenuating circumstances, the physician
568 performing the surgery or the anesthesiologist may waive the
569 following requirements:

570 a. The use of an oxygen analyzer with a low oxygen
571 concentration limit alarm, or other technology authorized under
572 board rule which equals or exceeds the quality of the oxygen
573 analyzer, during the administration of general anesthesia with
574 an anesthesia machine.

575 b. The use of pulse oximetry with a variable pitch pulse
576 tone and an audible low threshold alarm, or other technology
577 authorized under board rule which equals or exceeds the quality
578 of a pulse oximeter, and the use of adequate illumination and
579 exposure of the patient to assess color.

580 c. The use of capnography, capnometry, or mass

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581 spectroscopy, or other technology authorized under board rule
582 which equals or exceeds the quality of capnography, capnometry,
583 or mass spectroscopy, as a quantitative method of analyzing the
584 end-tidal carbon dioxide for continual monitoring for the
585 presence of expired carbon dioxide during ventilation, from the
586 time of the endotracheal tube or supraglottic airway placement
587 until extubation or removal or initiating transfer of the
588 patient to a postoperative care location.

589 d. The use of continuous electrocardiogram display, or
590 other technology authorized under board rule which equals or
591 exceeds the quality of electrocardiogram display, from the
592 beginning of anesthesia until preparing to leave the
593 anesthetizing location.

594 e. The measuring of arterial blood pressure and heart rate
595 evaluated at least every 5 minutes during anesthesia.

596
597 When any of the monitoring is waived for extenuating
598 circumstances under this subparagraph, it must be documented in
599 a note in the patient's medical record, including the reasons
600 for the need to waive the requirement. These standards are not
601 intended for the application to the care of an obstetrical
602 patient in labor or in the conduct of pain management.

603 (j)1. Because of the rapid changes in patient status during
604 anesthesia, qualified anesthesia personnel must be continuously
605 present in the room to provide anesthesia care for the entire
606 duration of all general anesthetics, regional anesthetics, and
607 monitored anesthesia care conducted on the patient. In the event
608 that there is a direct known hazard, such as radiation, to the
609 anesthesia personnel which might require intermittent remote

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610 observation of the patient, some provision for monitoring the
611 patient must be made. In the event that an emergency requires
612 the temporary absence of the person primarily responsible for
613 the anesthesia, the best judgment of the supervising physician
614 or anesthesiologist shall be exercised in comparing the
615 emergency with the anesthetized patient's condition and in the
616 selection of the person left responsible for the anesthesia
617 during the temporary absence.

618 2. During all anesthesia, the patient's oxygenation,
619 ventilation, circulation, and temperature must be continually
620 evaluated to ensure adequate oxygen concentration in the
621 inspired gas and the blood.

622 a. During all general anesthesia using an anesthesia
623 machine, the concentration of oxygen in the patient's breathing
624 system must be measured by an oxygen analyzer with a low oxygen
625 concentration limit alarm used to measure blood oxygenation.

626 b. During all anesthesia, a quantitative method of
627 assessing oxygenation, such as pulse oximetry, must be employed.
628 When a pulse oximeter is used, the variable pitch pulse tone and
629 the low threshold alarm must be audible to the qualified
630 anesthesia provider. Adequate illumination and exposure of the
631 patient are necessary to assess color.

632 c. During all anesthesia, every patient must have the
633 adequacy of his or her ventilation continually evaluated,
634 including, but not limited to, the evaluation of qualitative
635 clinical signs, such as chest excursion, observation of the
636 reservoir breathing bag, and auscultation of breath sounds.
637 Continual monitoring for the presence of expired carbon dioxide
638 must be performed unless invalidated by the nature of the

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639 patient's condition, the procedure, or the equipment.
640 Quantitative monitoring of the volume of expired gas must also
641 be performed.

642 d. When an endotracheal tube or supraglottic airway is
643 inserted, its correct positioning must be verified by clinical
644 assessment and by identification of carbon dioxide in the
645 expired gas. Continual end-tidal carbon dioxide analysis, in use
646 from the time of endotracheal tube or supraglottic airway
647 placement until extubation or removal or initiating transfer of
648 the patient to a postoperative care location, must be performed
649 using a quantitative method, such as capnography, capnometry, or
650 mass spectroscopy, or other technology authorized under board
651 rule which equals or exceeds the quality of capnography,
652 capnometry, or mass spectroscopy. When capnography or capnometry
653 is used, the end-tidal carbon dioxide alarm must be audible to
654 the qualified anesthesia provider.

655 e. When ventilation is controlled by a mechanical
656 ventilator, there must be in continuous use a device capable of
657 detecting disconnection of components of the breathing system.
658 The device must give an audible signal when its alarm threshold
659 is exceeded.

660 f. During regional anesthesia without sedation or local
661 anesthesia with no sedation, the adequacy of ventilation must be
662 evaluated by continual observation of qualitative clinical
663 signs. During moderate or deep sedation, the adequacy of
664 ventilation must be evaluated by continual observation of
665 qualitative clinical signs. Monitoring for the presence of
666 exhaled carbon dioxide is recommended.

667 g. Every patient receiving anesthesia must have the

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668 electrocardiogram or other technology authorized under board
669 rule which equals or exceeds the quality of electrocardiogram
670 continuously displayed from the beginning of anesthesia until
671 preparing to leave the anesthetizing location.

672 h. Every patient receiving anesthesia must have arterial
673 blood pressure and heart rate determined and evaluated at least
674 every 5 minutes.

675 i. Every patient receiving general anesthesia must have
676 circulatory function continually evaluated by at least one of
677 the following methods:

678 (I) Palpation of a pulse.

679 (II) Auscultation of heart sounds.

680 (III) Monitoring of a tracing of intra-arterial pressure.

681 (IV) Ultrasound peripheral pulse monitoring.

682 (V) Pulse plethysmography or oximetry.

683 (VI) Other technology authorized under board rule which
684 equals or exceeds the quality of any of the methods listed in
685 sub-sub-subparagraphs (I)-(V).

686 j. Every patient receiving anesthesia must have his or her
687 temperature monitored when clinically significant changes in
688 body temperature are intended, anticipated, or suspected.

689 (k)1. The physician performing the surgery shall ensure
690 that the postoperative care arrangements made for the patient
691 are adequate for the procedure being performed, as required by
692 board rule.

693 2. Management of postoperative care is the responsibility
694 of the physician performing the surgery and may be delegated as
695 determined by board rule. If the physician performing the
696 surgery is unavailable to provide postoperative care, the

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697 physician performing the surgery must notify the patient of his
698 or her unavailability for postoperative care before the
699 procedure.

700 3. If there is an overnight stay at the office in relation
701 to any surgical procedure:

702 a. The office must provide at least two persons to act as
703 monitors, one of whom must be certified in advanced cardiac life
704 support, and maintain a monitor-to-patient ratio of at least one
705 monitor to two patients.

706 b. Once the physician performing the surgery has signed a
707 timed and dated discharge order, the office may provide only one
708 monitor to monitor the patient. The monitor must be qualified by
709 licensure and training to administer all of the medications
710 required on the crash cart and must be certified in advanced
711 cardiac life support.

712 c. A complete and current crash cart must be present in the
713 office surgery and immediately accessible for the monitors.

714 4. The physician performing the surgery must be reachable
715 by telephone and readily available to return to the office if
716 needed.

717 5. A policy and procedures manual must be maintained in the
718 office at which Level II and Level III procedures are performed.
719 The manual must be updated and implemented annually. The policy
720 and procedures manual must provide for all of the following:

721 a. Duties and responsibilities of all personnel.

722 b. A quality assessment and improvement system designed to
723 objectively and systematically monitor and evaluate the quality
724 and appropriateness of patient care and opportunities to improve
725 performance.

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- 726 c. Cleaning procedures and protocols.
- 727 d. Sterilization procedures.
- 728 e. Infection control procedures and personnel
- 729 responsibilities.
- 730 f. Emergency procedures.
- 731 6. The designated physician shall establish a risk
- 732 management program that includes all of the following
- 733 components:
- 734 a. The identification, investigation, and analysis of the
- 735 frequency and causes of adverse incidents.
- 736 b. The identification of trends or patterns of adverse
- 737 incidents.
- 738 c. The development of appropriate measures to correct,
- 739 reduce, minimize, or eliminate the risk of adverse incidents.
- 740 d. The documentation of such functions and periodic review
- 741 of such information at least quarterly by the designated
- 742 physician.
- 743 7. The designated physician shall report to the department
- 744 any adverse incidents that occur within the scope of office
- 745 surgeries. This report must be made within 15 days after the
- 746 occurrence of an incident as required by s. 458.351.
- 747 8. The designated physician is responsible for prominently
- 748 posting a sign in the office which states that the office is a
- 749 doctor's office regulated under this section and ss. 458.328,
- 750 458.3281, and 459.0138 and the applicable rules of the Board of
- 751 Medicine and the Board of Osteopathic Medicine as set forth in
- 752 rules 64B8 and 64B15, Florida Administrative Code. This notice
- 753 must also appear prominently within the required patient
- 754 informed consent form.

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755 9. All physicians performing surgery at the office surgery
756 must be qualified by education, training, and experience to
757 perform any procedure the physician performs in the office
758 surgery.

759 10. When Level II, Level II-A, or Level III procedures are
760 performed in an office surgery setting, the physician performing
761 the surgery is responsible for providing the patient, in
762 writing, before the procedure, with the name and location of the
763 hospital where the physician performing the surgery has
764 privileges to perform the same procedure as the one being
765 performed in the office surgery setting or the name and location
766 of the hospital with which the physician performing the surgery
767 has a transfer agreement in the event of an emergency.

768 (4) LEVEL I OFFICE SURGERY.-

769 (a) Scope.-Level I office surgery includes the following:

770 1. Minor procedures such as excision of skin lesions,
771 moles, warts, cysts, or lipomas and repair of lacerations or
772 surgery limited to the skin and subcutaneous tissue which are
773 performed under topical or local anesthesia not involving drug-
774 induced alteration of consciousness other than minimal pre-
775 operative tranquilization of the patient.

776 2. Liposuction involving the removal of less than 4,000
777 cubic centimeters of supernatant fat.

778 3. Incision and drainage of superficial abscesses; limited
779 endoscopies, such as proctoscopies, skin biopsies,
780 arthrocentesis, thoracentesis, paracentesis, dilation of the
781 urethra, cystoscopic procedures, and closed reduction of simple
782 fractures; or small joint dislocations, such as in the finger or
783 toe joints.

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784 4. Procedures in which anesthesia is limited to minimal
785 sedation. The patient's level of sedation must be that of
786 minimal sedation and anxiolysis, and the chances of
787 complications requiring hospitalization must be remote. As used
788 in this sub-subparagraph, the term "minimal sedation and
789 anxiolysis" means a drug-induced state during which patients
790 respond normally to verbal commands, and although cognitive
791 function and physical coordination may be impaired, airway
792 reflexes and ventilatory and cardiovascular functions remain
793 unaffected. Controlled substances, as defined in ss. 893.02 and
794 893.03, must be limited to oral administration in doses
795 appropriate for the unsupervised treatment of insomnia, anxiety,
796 or pain.

797 5. Procedures for which chances of complications requiring
798 hospitalization are remote as specified in board rule.

799 (b) Standards of practice.—Standards of practice for Level
800 I office surgery include all of the following:

801 1. The medical education, training, and experience of the
802 physician performing the surgery must include training on proper
803 dosages and management of toxicity or hypersensitivity to
804 regional anesthetic drugs, and the physician must be certified
805 in advanced cardiac life support.

806 2. At least one operating assistant must be certified in
807 basic life support.

808 3. Intravenous access supplies, oxygen, oral airways, and a
809 positive pressure ventilation device must be available in the
810 office surgery, along with the following medications, stored per
811 the manufacturer's recommendation:

812 a. Atropine, 3 mg.

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- 813 b. Diphenhydramine, 50 mg.
814 c. Epinephrine, 1 mg in 10 ml.
815 d. Epinephrine, 1 mg in 1 ml vial, 3 vials total.
816 e. Hydrocortisone, 100 mg.
817 f. If a benzodiazepine is administered, flumazenil, 0.5 mg
818 in 5 ml vial, 2 vials total.
819 g. If an opiate is administered, naloxone, 0.4 mg in 1 ml
820 vial, 2 vials total.
821 4. When performing minor procedures, such as excision of
822 skin lesions, moles, warts, cysts, or lipomas and repair of
823 lacerations or surgery limited to the skin and subcutaneous
824 tissue performed under topical or local anesthesia in an office
825 surgery setting, physicians performing the procedure are exempt
826 from subparagraphs 1.-3. Current certification in basic life
827 support is recommended but not required.
828 5. A physician performing the surgery need not have an
829 assistant during the procedure unless the specific procedure
830 being performed requires an assistant.
831 (5) LEVEL II OFFICE SURGERY.-
832 (a) Scope.-Level II office surgery includes, but is not
833 limited to, all of the following procedures:
834 1. Hemorrhoidectomy.
835 2. Hernia repair.
836 3. Large joint dislocations.
837 4. Colonoscopy.
838 5. Liposuction involving the removal of up to 4,000 cubic
839 centimeters of supernatant fat.
840 6. Any other procedure the board designates by rule as a
841 Level II office surgery.

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842 7. Surgeries in which the patient's level of sedation is
843 that of moderate sedation and analgesia or conscious sedation.
844 As used in this subparagraph, the term "moderate sedation and
845 analgesia or conscious sedation" is a drug-induced depression of
846 consciousness during which patients respond purposefully to
847 verbal commands, either alone or accompanied by light tactile
848 stimulation; interventions are not required to maintain a patent
849 airway; spontaneous ventilation is adequate; and cardiovascular
850 function is maintained. For purposes of this term, reflex
851 withdrawal from a painful stimulus is not considered a
852 purposeful response.

853 (b) Standards of practice.—Standards of practice for Level
854 II office surgery include, but are not limited to, the
855 following:

856 1. The physician performing the surgery, or the office
857 where the procedure is being performed, must have a transfer
858 agreement with a licensed hospital within reasonable proximity
859 if the physician performing the procedure does not have staff
860 privileges to perform the same procedure as that being performed
861 in the office surgery setting at a licensed hospital within
862 reasonable proximity. The transfer agreement required by this
863 section must be current and have been entered into no more than
864 5 years before the date of the office's most recent annual
865 inspection under s. 458.328. A transfer agreement must
866 affirmatively disclose an effective date and a termination date.

867 2. The physician performing the surgery must have staff
868 privileges at a licensed hospital to perform the same procedure
869 in that hospital as that being performed in the office surgery
870 setting or must be able to document satisfactory completion of

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871 training, such as board certification or board eligibility by a
872 board approved by the American Board of Medical Specialties or
873 any other board approved by the Board of Medicine or Board of
874 Osteopathic Medicine, as applicable, or must be able to
875 establish comparable background, training, and experience. Such
876 board certification or comparable background, training, and
877 experience must also be directly related to and include the
878 procedures being performed by the physician in the office
879 surgery facility.

880 3. One assistant must be currently certified in basic life
881 support.

882 4. The physician performing the surgery must be currently
883 certified in advanced cardiac life support.

884 5. A complete and current crash cart must be available at
885 all times at the location where the anesthesia is being
886 administered. The designated physician of an office surgery is
887 responsible for ensuring that the crash cart is replenished
888 after each use, the expiration dates for the crash cart's
889 medications are checked weekly, and crash cart events are
890 documented in the cart's logs. Medicines must be stored per the
891 manufacturer's recommendations, and multidose vials must be
892 dated once opened and checked daily for expiration. The crash
893 cart must, at a minimum, include the following intravenous or
894 inhaled medications:

895 a. Adenosine, 18 mg.

896 b. Albuterol, 2.5 mg with a small volume nebulizer.

897 c. Amiodarone, 300 mg.

898 d. Atropine, 3 mg.

899 e. Calcium chloride, 1 gram.

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- 900 f. Dextrose, 50 percent; 50 ml.
- 901 g. Diphenhydramine, 50 mg.
- 902 h. Dopamine, 200 mg, minimum.
- 903 i. Epinephrine, 1 mg, in 10 ml.
- 904 j. Epinephrine, 1 mg in 1 ml vial, 3 vials total.
- 905 k. Flumazenil, 1 mg.
- 906 l. Furosemide, 40 mg.
- 907 m. Hydrocortisone, 100 mg.
- 908 n. Lidocaine appropriate for cardiac administration, 100
- 909 mg.
- 910 o. Magnesium sulfate, 2 grams.
- 911 p. Naloxone, 1.2 mg.
- 912 q. A beta blocker class drug.
- 913 r. Sodium bicarbonate, 50 mEq/50 ml.
- 914 s. Paralytic agent that is appropriate for use in rapid
- 915 sequence intubation.
- 916 t. A calcium channel blocker class drug.
- 917 u. If nonneuraxial regional blocks are performed,
- 918 Intralipid, 20 percent, 500 ml solution.
- 919 v. Any additional medication the board determines by rule
- 920 is warranted for patient safety and by the evolution of
- 921 technology and medical practice.
- 922 6. In the event of a drug shortage, the designated
- 923 physician is authorized to substitute a therapeutically
- 924 equivalent drug that meets the prevailing practice standards.
- 925 7. The designated physician is responsible for ensuring
- 926 that the office maintains documentation of its unsuccessful
- 927 efforts to obtain the required drug.
- 928 8. The designated physician is responsible for ensuring

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- 929 that the following are present in the office surgery:
- 930 a. A benzodiazepine.
- 931 b. A positive pressure ventilation device, such as Ambu,
- 932 plus oxygen supply.
- 933 c. An end-tidal carbon dioxide detection device.
- 934 d. Monitors for blood pressure, electrocardiography, and
- 935 oxygen saturation.
- 936 e. Emergency intubation equipment that must, at a minimum,
- 937 include suction devices, endotracheal tubes, working
- 938 laryngoscopes, oropharyngeal airways, nasopharyngeal airways,
- 939 and bag valve mask apparatus that are sized appropriately for
- 940 the specific patient.
- 941 f. A working defibrillator with defibrillator pads or
- 942 defibrillator gel, or an automated external defibrillator unit.
- 943 g. Sufficient backup power to allow the physician
- 944 performing the surgery to safely terminate the procedure and to
- 945 allow the patient to emerge from the anesthetic, all without
- 946 compromising the sterility of the procedure or the environment
- 947 of care.
- 948 h. Working sterilization equipment cultured weekly.
- 949 i. Sufficient intravenous solutions and equipment for a
- 950 minimum of a week's worth of surgical cases.
- 951 j. Any other equipment required by board rule, as warranted
- 952 by the evolution of technology and medical practice.
- 953 9. The physician performing the surgery must be assisted by
- 954 a qualified anesthesia provider, which may include any of the
- 955 following types of providers:
- 956 a. An anesthesiologist.
- 957 b. A certified registered nurse anesthetist.

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958 c. A registered nurse, if the physician performing the
959 surgery is certified in advanced cardiac life support and the
960 registered nurse assists only with local anesthesia or conscious
961 sedation.

962

963 An anesthesiologist assistant may assist the anesthesiologist as
964 provided by board rule. An assisting anesthesia provider may not
965 function in any other capacity during the procedure.

966 10. If additional anesthesia assistance is required by the
967 specific procedure or patient circumstances, such assistance
968 must be provided by a physician, osteopathic physician,
969 registered nurse, licensed practical nurse, or operating room
970 technician.

971 11. The designated physician is responsible for ensuring
972 that each patient is monitored in the recovery room until the
973 patient is fully recovered from anesthesia. Such monitoring must
974 be provided by a licensed physician, physician assistant,
975 registered nurse with postanesthesia care unit experience, or
976 the equivalent who is currently certified in advanced cardiac
977 life support, or, in the case of pediatric patients, currently
978 certified in pediatric advanced life support.

979 (6) LEVEL II-A OFFICE SURGERY.—

980 (a) Scope.—Level II-A office surgeries are those Level II
981 office surgeries that have a maximum planned duration of 5
982 minutes or less and in which the chances of complications
983 requiring hospitalization are remote.

984 (b) Standards of practice.—

985 1. All practice standards for Level II office surgery set
986 forth in paragraph (5) (b) must be met for Level II-A office

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987 surgery except for the requirements set forth in subparagraph
988 (5)(b)9. regarding assistance by a qualified anesthesia
989 provider.

990 2. During the surgical procedure, the physician performing
991 the surgery must be assisted by a licensed physician, physician
992 assistant, registered nurse, or licensed practical nurse.

993 3. Additional assistance may be required by specific
994 procedure or patient circumstances.

995 4. Following the procedure, a licensed physician, physician
996 assistant, or registered nurse must be available to monitor the
997 patient in the recovery room until the patient is recovered from
998 anesthesia. The monitoring provider must be currently certified
999 in advanced cardiac life support, or, in the case of pediatric
1000 patients, currently certified in pediatric advanced life
1001 support.

1002 (7) LEVEL III OFFICE SURGERY.—

1003 (a) Scope.—

1004 1. Level III office surgery includes those types of surgery
1005 during which the patient's level of sedation is that of deep
1006 sedation and analgesia or general anesthesia. As used in this
1007 subparagraph, the term:

1008 a. "Deep sedation and analgesia" means a drug-induced
1009 depression of consciousness during which:

1010 (I) Patients cannot be easily aroused but respond
1011 purposefully following repeated or painful stimulation;

1012 (II) The ability to independently maintain ventilatory
1013 function may be impaired;

1014 (III) Patients may require assistance in maintaining a
1015 patent airway and spontaneous ventilation may be inadequate; and

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1016 (IV) Cardiovascular function is usually maintained.

1017
1018 For purposes of this sub-subparagraph, reflex withdrawal from a
1019 painful stimulus is not considered a purposeful response.

1020 b. "General anesthesia" means a drug-induced loss of
1021 consciousness during which:

1022 (I) Patients are not arousable, even by painful
1023 stimulation;

1024 (II) The ability to independently maintain ventilatory
1025 function is often impaired;

1026 (III) Patients often require assistance in maintaining a
1027 patent airway and positive pressure ventilation may be required
1028 because of depressed spontaneous ventilation or drug-induced
1029 depression of neuromuscular function; and

1030 (IV) Cardiovascular function may be impaired.

1031 2. The use of spinal or epidural anesthesia for a procedure
1032 requires that the procedure be considered a Level III office
1033 surgery.

1034 3. Only patients classified under the American Society of
1035 Anesthesiologists' (ASA) risk classification criteria as Class I
1036 or Class II are appropriate candidates for a Level III office
1037 surgery.

1038 a. All Level III office surgeries on patients classified as
1039 ASA III or higher must be performed only in a hospital or
1040 ambulatory surgical center.

1041 b. For all ASA II patients above the age of 50, the
1042 physician performing the surgery must obtain a complete workup
1043 performed before the performance of a Level III office surgery
1044 in the office surgery setting.

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1045 c. If the patient has a cardiac history or is deemed to be
1046 a complicated medical patient, the patient must have a
1047 preoperative electrocardiogram and be referred to an appropriate
1048 consultant for medical optimization. The referral to a
1049 consultant may be waived after evaluation by the patient's
1050 anesthesiologist.

1051 (b) Standards of practice.—Practice standards for Level III
1052 office surgery include all Level II office surgery standards and
1053 all of the following requirements:

1054 1. The physician performing the surgery must have staff
1055 privileges at a licensed hospital to perform the same procedure
1056 in that hospital as that being performed in the office surgery
1057 setting or must be able to document satisfactory completion of
1058 training, such as board certification or board qualification by
1059 a board approved by the American Board of Medical Specialties or
1060 any other board approved by the Board of Medicine or Board of
1061 Osteopathic Medicine, as applicable, or must be able to
1062 demonstrate to the accrediting organization or to the department
1063 comparable background, training, and experience. Such board
1064 certification or comparable background, training, and experience
1065 must also be directly related to and include the procedure being
1066 performed by the physician performing the surgery in the office
1067 surgery setting. In addition, the physician performing the
1068 surgery must have knowledge of the principles of general
1069 anesthesia.

1070 2. The physician performing the surgery must be currently
1071 certified in advanced cardiac life support.

1072 3. At least one operating assistant must be currently
1073 certified in basic life support.

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1074 4. An emergency policy and procedures manual related to
1075 serious anesthesia complications must be available in the office
1076 surgery and reviewed biannually by the designated physician,
1077 practiced with staff, updated, and posted in a conspicuous
1078 location in the office. Topics to be covered in the manual must
1079 include all of the following:

1080 a. Airway blockage and foreign body obstruction.

1081 b. Allergic reactions.

1082 c. Bradycardia.

1083 d. Bronchospasm.

1084 e. Cardiac arrest.

1085 f. Chest pain.

1086 g. Hypoglycemia.

1087 h. Hypotension.

1088 i. Hypoventilation.

1089 j. Laryngospasm.

1090 k. Local anesthetic toxicity reaction.

1091 l. Malignant hyperthermia.

1092 m. Any other topics the board determines by rule are
1093 warranted for patient safety and by the evolution of technology
1094 and medical practice.

1095 5. An office surgery performing Level III office surgeries
1096 must maintain all of the equipment and medications required for
1097 Level II office surgeries and comply with all of the following
1098 additional requirements:

1099 a. Maintain at least 720 mg of dantrolene on site if
1100 halogenated anesthetics or succinylcholine are used.

1101 b. Equipment and medication for monitored postanesthesia
1102 recovery must be available in the office.

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- 1103 6. Anesthetic safety regulations must be developed, posted
1104 in a conspicuous location in the office, and enforced by the
1105 designated physician. Such regulations must include all of the
1106 following requirements:
- 1107 a. All operating room electrical and anesthesia equipment
1108 must be inspected at least semiannually, and a written record of
1109 the results and corrective actions must be maintained.
- 1110 b. Flammable anesthetic agents may not be employed in
1111 office surgery facilities.
- 1112 c. Electrical equipment in anesthetizing areas must be on
1113 an audiovisual line isolation monitor, with the exception of
1114 radiologic equipment and fixed lighting more than 5 feet above
1115 the floor.
- 1116 d. Each anesthesia gas machine must have a pin index safety
1117 system or equivalent safety system and a minimum oxygen flow
1118 safety device.
- 1119 e. All reusable anesthesia equipment in direct contact with
1120 a patient must be cleaned or sterilized as appropriate after
1121 each use.
- 1122 f. The following monitors must be applied to all patients
1123 receiving conduction or general anesthesia:
- 1124 (I) Blood pressure cuff.
- 1125 (II) A continuous temperature device, readily available to
1126 measure the patient's temperature.
- 1127 (III) Pulse oximeter.
- 1128 (IV) Electrocardiogram.
- 1129 (V) An inspired oxygen concentration monitor and a
1130 capnograph, for patients receiving general anesthesia.
- 1131 g. Emergency intubation equipment must be available in all

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1132 office surgery suites.

1133 h. Surgical tables must be capable of Trendelenburg and
1134 other positions necessary to facilitate surgical procedures.

1135 i. An anesthesiologist, a certified registered nurse
1136 anesthetist, an anesthesiologist assistant, or a physician
1137 assistant qualified as set forth in board rule must administer
1138 the general or regional anesthesia.

1139 j. A physician, a registered nurse, a licensed practical
1140 nurse, a physician assistant, or an operating room technician
1141 must assist with the surgery. The anesthesia provider may not
1142 function in any other capacity during the procedure.

1143 k. The patient must be monitored in the recovery room until
1144 he or she has fully recovered from anesthesia. The monitoring
1145 must be provided by a physician, a physician assistant, a
1146 certified registered nurse anesthetist, an anesthesiologist
1147 assistant, or a registered nurse with postanesthesia care unit
1148 experience or the equivalent who is currently certified in
1149 advanced cardiac life support, or, in the case of pediatric
1150 patients, currently certified in pediatric advanced life
1151 support.

1152 (8) EXEMPTION.—This section does not apply to a physician
1153 who is dually licensed as a dentist under chapter 466 when he or
1154 she is performing dental procedures that fall within the scope
1155 of practice of dentistry and are regulated under chapter 466.

1156 (9) RULEMAKING.—The board may adopt by rule additional
1157 standards of practice for physicians who perform office
1158 surgeries or procedures under this section as warranted for
1159 patient safety and by the evolution of technology and medical
1160 practice.

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1161 Section 3. Section 459.0138, Florida Statutes, is amended
1162 to read:

1163 459.0138 Office surgeries.—

1164 (1) REGISTRATION.—

1165 (a)~~1~~. An office in which a physician performs or intends to
1166 perform a liposuction procedure in which more than 1,000 cubic
1167 centimeters of supernatant fat is temporarily or permanently
1168 removed, a liposuction procedure during which the patient is
1169 rotated between the supine, lateral, and prone positions, a
1170 Level II office surgery, or a Level III office surgery must
1171 register with the department. ~~unless the office is licensed as A~~
1172 facility licensed under chapter 390 or chapter 395 may not be
1173 registered under this section.

1174 (b)~~2~~. The department must complete an inspection of any
1175 office seeking registration under this section before the office
1176 may be registered.

1177 1. The inspection of the office seeking registration under
1178 this section must include inspection for compliance with the
1179 standards of practice set out in this section and s. 458.3281
1180 and any applicable board rules for the levels of office surgery
1181 and procedures listed on the application which any physician
1182 practicing at the office performs or intends to perform. The
1183 application must be updated within 10 calendar days before any
1184 additional surgical procedures or levels of office surgery are
1185 to be performed at the office. Failure to timely update the
1186 application for any such additional surgical procedures or
1187 levels of office surgery is a violation of this section and
1188 subject to discipline under ss. 456.072 and 459.015.

1189 2. The department must immediately suspend the registration

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1190 process of an office that refuses an inspection under
1191 subparagraph 1., and the applicant must be required to reapply
1192 for registration.

1193 3. If the department determines that an office seeking
1194 registration under this section is one in which a physician may
1195 perform, or intends to perform, liposuction procedures that
1196 include a patient being rotated between the supine, lateral, and
1197 prone positions during the procedure, or in which a physician
1198 may perform, or intends to perform, gluteal fat grafting
1199 procedures, the office must provide proof to the department that
1200 it has met the applicable requirements of s. 469 of the Florida
1201 Building Code, relating to office surgery suites, and s.
1202 458.3281 and the applicable rules adopted thereunder, and the
1203 department must inspect the office to ensure that all of the
1204 following are present or in place:

1205 a. Equipment and a procedure for measuring and documenting
1206 in a log the amount of supernatant fat removed, both temporarily
1207 and permanently, from a particular patient, including tissue
1208 disposal procedures.

1209 b. A procedure for measuring and documenting the amount of
1210 lidocaine injected for tumescent liposuction, if used.

1211 c. Working ultrasound guidance equipment or other guidance
1212 technology authorized under board rule which equals or exceeds
1213 the quality of ultrasound guidance.

1214 d. The office procedure for obtaining blood products.

1215 e. Documentation on file at the office demonstrating that
1216 any physician performing these procedures has privileges to
1217 perform such procedures in a hospital no more than 30 minutes
1218 away.

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1219 f. Procedures for emergency resuscitation and transport to
1220 a hospital.

1221 g. Procedures for anesthesia and surgical recordkeeping.

1222 h. Any additional inspection requirements, as set by board
1223 rule.

1224 4. If an applicant is required under subparagraph 3. to
1225 provide proof to the department that the office is in compliance
1226 with the applicable requirements of s. 469 of the Florida
1227 Building Code, relating to office surgery suites, or s. 458.3281
1228 and the applicable rules adopted thereunder, but is unable to
1229 provide such proof, the department must notify the Agency for
1230 Health Care Administration and request the agency to inspect the
1231 office and consult with the office about the process to apply
1232 for ambulatory surgical center licensure under chapter 395 and
1233 how the office may seek qualification for such licensure,
1234 notwithstanding the office's failure to meet all requirements
1235 associated with such licensure at the time of inspection and
1236 notwithstanding any pertinent exceptions provided under s.
1237 395.002 (3).

1238 (c)(b) To be ~~By January 1, 2020,~~ each office registered
1239 under this section or s. 458.328, an office must, at the time of
1240 application, list a designated ~~designate~~ a physician who is
1241 responsible for the office's compliance with the office health
1242 and safety requirements of this section and rules adopted
1243 hereunder. A designated physician must have a full, active, and
1244 unencumbered license under this chapter or chapter 458 and shall
1245 practice at the office for which he or she has assumed
1246 responsibility. Within 10 calendar days after the termination of
1247 a designated physician relationship, the office must notify the

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1248 department of the designation of another physician to serve as
1249 the designated physician. The department may not register an
1250 office if the office fails to comply with this requirement at
1251 the time of application and must seek an emergency suspension of
1252 the ~~suspend~~ a registration of ~~for~~ an office pursuant to s.
1253 456.074(6) if the office fails to timely notify the department
1254 of its new designated physician within 10 calendar days after
1255 the termination of the previous designated physician
1256 relationship ~~comply with the requirements of this paragraph.~~

1257 (d) As a condition of registration, each office must, at
1258 the time of application, list all medical personnel who will be
1259 practicing at the office, including all of the following:

1260 1. Physicians who intend to practice surgery or assist in
1261 surgery at the office seeking registration, including their
1262 respective license numbers and practice addresses.

1263 2. Anesthesia providers, including their license numbers.

1264 3. Nursing personnel licensed under chapter 464, including
1265 their license numbers unless already provided under subparagraph
1266 2.

1267 4. Physician assistants, including their respective license
1268 numbers and supervising physicians.

1269
1270 The office must notify the department of the addition or
1271 termination of any of the types of medical personnel specified
1272 under this paragraph within 10 calendar days before such
1273 addition or after such termination. Failure to timely notify the
1274 department of such addition or termination is a violation of
1275 this section and subject to discipline under ss. 456.072 and
1276 459.015.

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1277 (e)~~(e)~~ As a condition of registration, each office must
1278 establish financial responsibility by demonstrating that it has
1279 met and continues to maintain, at a minimum, the same
1280 requirements applicable to physicians in ss. 458.320 and
1281 459.0085. Each physician practicing at an office registered
1282 under this section or s. 458.328 must meet the financial
1283 responsibility requirements under s. 458.320 or s. 459.0085, as
1284 applicable.

1285 (f)~~(d)~~ Each physician practicing or intending to practice
1286 at an office registered under this section or s. 458.328 must
1287 ~~shall~~ advise the board, in writing, within 10 calendar days
1288 before ~~after~~ beginning or after ending his or her practice at a
1289 ~~the~~ registered office, as applicable.

1290 (g)~~(e)~~¹. The department shall inspect a registered office
1291 at least annually, including a review of patient records,
1292 anesthesia logs, surgery logs, and liposuction logs, to ensure
1293 that the office is in compliance with this section and rules
1294 adopted hereunder unless the office is accredited in office-
1295 based surgery by the Joint Commission or other ~~a~~ nationally
1296 recognized accrediting agency approved by the board. The
1297 inspection may be unannounced, except for the inspection of an
1298 office that meets the description of a clinic specified in s.
1299 459.0137(1)(a)3.h., and those wholly owned and operated
1300 physician offices described in s. 459.0137(1)(a)3.g. which
1301 perform procedures referenced in s. 459.0137(1)(a)3.h., which
1302 must be announced.

1303 (h)². The department must immediately suspend the
1304 registration of a registered office that refuses an inspection
1305 under paragraph (g) ~~subparagraph 1~~. The office must close during

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1306 such suspension. The suspension must remain in effect for at
1307 least 14 consecutive days and may not terminate until the
1308 department issues a written declaration that the office may
1309 reopen following the department's completion of an inspection of
1310 the office.

1311 (i)~~(f)~~ The department may suspend or revoke the
1312 registration of an office in which a procedure or surgery
1313 identified in paragraph (a) is performed for failure of any of
1314 its physicians, owners, or operators to comply with this section
1315 and rules adopted hereunder or s. 458.328 and rules adopted
1316 thereunder. If an office's registration is revoked for any
1317 reason, the department may deny any person named in the
1318 registration documents of the office, including the persons who
1319 own or operate the office, individually or as part of a group,
1320 from registering an office to perform procedures or office
1321 surgeries pursuant to this section or s. 458.328 for 5 years
1322 after the revocation date.

1323 (j)~~(g)~~ The department may impose any penalty set forth in
1324 s. 456.072(2) against the designated physician for failure of
1325 the office to operate in compliance with the office health and
1326 safety requirements of this section and rules adopted hereunder
1327 or s. 458.328 and rules adopted thereunder.

1328 ~~(h) A physician may only perform a procedure or surgery
1329 identified in paragraph (a) in an office that is registered with
1330 the department. The board shall impose a fine of \$5,000 per day
1331 on a physician who performs a procedure or surgery in an office
1332 that is not registered with the department.~~

1333 (k)~~(i)~~ The actual costs of registration and inspection or
1334 accreditation must ~~shall~~ be paid by the person seeking to

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1335 register and operate the office in which a procedure or surgery
1336 identified in paragraph (a) will be performed.

1337 (2) REGISTRATION UPDATE.—

1338 (a) An office that registered under this section before
1339 July 1, 2024, in which a physician performs liposuction
1340 procedures that include a patient being rotated between the
1341 supine, lateral, and prone positions during the procedure or in
1342 which a physician performs gluteal fat grafting procedures must
1343 provide a registration update to the department consistent with
1344 the requirements of the initial registration under subsection
1345 (1) no later than 30 days before the office surgery's next
1346 annual inspection.

1347 (b) Registration update inspections required under
1348 subsection (1) must be performed by the department on the date
1349 of the office surgery's next annual inspection.

1350 (c) During the registration update process, the office
1351 surgery may continue to operate under the original registration.

1352 (d) In order to provide an office surgery time to update to
1353 the requirements of subsection (1) and s. 459.0139, effective
1354 July 1, 2024, and the applicable provisions of s. 469 of the
1355 Florida Building Code, relating to office surgery suites, any
1356 office surgery registered under this section before July 1,
1357 2024, whose annual inspection is due in July or August 2024, may
1358 request from the department, in writing, a 60-day postponement
1359 of the required annual inspection, which postponement must be
1360 granted.

1361 (e) All other requests to the department for a postponement
1362 of the registration update inspection required under this
1363 registration update process must be in writing and be approved

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1364 by the chair of the Board of Medicine for good cause shown, and
1365 such postponement may not exceed 30 days.

1366 (3) STANDARDS OF PRACTICE.—

1367 (a) A physician performing a procedure or surgery in an
1368 office registered under this section must comply with the
1369 applicable provisions of s. 469 of the Florida Building Code,
1370 relating to office surgery suites, and the standards of practice
1371 for office surgery set forth in this section and s. 459.0139 and
1372 any applicable rules adopted thereunder.

1373 (b) A physician may not perform any surgery or procedure
1374 identified in paragraph (1)(a) in a setting other than an office
1375 registered under this section or a facility licensed under
1376 chapter 390 or chapter 395, as applicable. The board shall
1377 impose a fine of \$5,000 per incident on a physician who violates
1378 this paragraph performing a gluteal fat grafting procedure in an
1379 ~~office surgery setting shall adhere to standards of practice~~
1380 ~~pursuant to this subsection and rules adopted by the board.~~

1381 (c) ~~(b)~~ Office surgeries may not:

- 1382 1. Be a type of surgery that generally results in blood
- 1383 loss of more than 10 percent of estimated blood volume in a
- 1384 patient with a normal hemoglobin level;
- 1385 2. Require major or prolonged intracranial, intrathoracic,
- 1386 abdominal, or joint replacement procedures, except for
- 1387 laparoscopic procedures;
- 1388 3. Involve major blood vessels and be performed with direct
- 1389 visualization by open exposure of the major blood vessel, except
- 1390 for percutaneous endovascular intervention; or
- 1391 4. Be emergent or life threatening.

1392 (d) ~~(e)~~ A physician performing a gluteal fat grafting

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1393 procedure in an office surgery setting must comply with the
1394 applicable provisions of s. 469 of the Florida Building Code,
1395 relating to office surgery suites, and the standards of practice
1396 under this subsection and s. 459.0139 and applicable rules
1397 adopted thereunder, including, but not limited to, all of the
1398 following standards of practice:

1399 1. The A physician performing the a gluteal fat grafting
1400 procedure must conduct an in-person examination of the patient
1401 while physically present in the same room as the patient no
1402 later than the day before the procedure.

1403 2. Before a physician may delegate any duties during a
1404 gluteal fat grafting procedure, the patient must provide
1405 written, informed consent for such delegation. Any duty
1406 delegated by a physician during a gluteal fat grafting procedure
1407 must be performed under the direct supervision of the physician
1408 performing such procedure. Fat extraction and gluteal fat
1409 injections must be performed by the physician and may not be
1410 delegated.

1411 3. Fat may only be injected into the subcutaneous space of
1412 the patient and may not cross the fascia overlying the gluteal
1413 muscle. Intramuscular or submuscular fat injections are
1414 prohibited.

1415 4. When the physician performing a gluteal fat grafting
1416 procedure injects fat into the subcutaneous space of the
1417 patient, the physician must use ultrasound guidance, or guidance
1418 with other technology authorized under board rule which equals
1419 or exceeds the quality of ultrasound, during the placement and
1420 navigation of the cannula to ensure that the fat is injected
1421 into the subcutaneous space of the patient above the fascia

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1422 overlying the gluteal muscle. Such guidance with the use of
1423 ultrasound or other technology is not required for other
1424 portions of such procedure.

1425 5. An office in which a physician performs gluteal fat
1426 grafting procedures shall at all times maintain a ratio of one
1427 physician to one patient during all phases of the procedure,
1428 beginning with the administration of anesthesia to the patient
1429 and concluding with the extubation of the patient. After a
1430 physician has commenced, and while he or she is engaged in, a
1431 gluteal fat grafting procedure, the physician may not commence
1432 or engage in another gluteal fat grafting procedure or any other
1433 procedure with another patient at the same time.

1434 ~~(e)(d)~~ If a procedure in an office surgery setting results
1435 in hospitalization, the incident must be reported as an adverse
1436 incident pursuant to s. 458.351.

1437 ~~(c) An office in which a physician performs gluteal fat~~
1438 ~~grafting procedures must at all times maintain a ratio of one~~
1439 ~~physician to one patient during all phases of the procedure,~~
1440 ~~beginning with the administration of anesthesia to the patient~~
1441 ~~and concluding with the extubation of the patient. After a~~
1442 ~~physician has commenced, and while he or she is engaged in, a~~
1443 ~~gluteal fat grafting procedure, the physician may not commence~~
1444 ~~or engage in another gluteal fat grafting procedure or any other~~
1445 ~~procedure with another patient at the same time.~~

1446 (4)(3) RULEMAKING.-

1447 (a) The board may ~~shall~~ adopt by rule additional standards
1448 of practice for physicians who perform office procedures or
1449 ~~office~~ surgeries under ~~pursuant to~~ this section, as warranted
1450 for patient safety and by the evolution of technology and

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1451 medical practice.

1452 (b) The board may adopt rules to administer the
1453 registration, registration update, inspection, and safety of
1454 offices in which a physician performs office procedures or
1455 ~~office~~ surgeries under ~~pursuant to~~ this section.

1456 Section 4. Section 459.0139, Florida Statutes, is created
1457 to read:

1458 459.0139 Standard of practice for office surgery.-

1459 (1) CONSTRUCTION.-This section does not relieve a physician
1460 performing a procedure or surgery from the responsibility of
1461 making the medical determination of whether an office is an
1462 appropriate setting in which to perform that particular
1463 procedure or surgery, taking into consideration the particular
1464 patient on which the procedure or surgery is to be performed.

1465 (2) DEFINITIONS.-As used in this section, the term:

1466 (a) "Certified in advanced cardiac life support" means a
1467 person holds a current certification in an advanced cardiac life
1468 support course with didactic and skills components, approved by
1469 the American Heart Association, the American Safety and Health
1470 Institute, the American Red Cross, Pacific Medical Training, or
1471 the Advanced Cardiovascular Life Support (ACLS) Certification
1472 Institute.

1473 (b) "Certified in basic life support" means a person holds
1474 a current certification in a basic life support course with
1475 didactic and skills components, approved by the American Heart
1476 Association, the American Safety and Health Institute, the
1477 American Red Cross, Pacific Medical Training, or the ACLS
1478 Certification Institute.

1479 (c) "Certified in pediatric advanced life support" means a

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1480 person holds a current certification in a pediatric advanced
1481 life support course with didactic and skills components approved
1482 by the American Heart Association, the American Safety and
1483 Health Institute, or Pacific Medical Training.

1484 (d) "Continual monitoring" means monitoring that is
1485 repeated regularly and frequently in steady, rapid succession.

1486 (e) "Continuous" means monitoring that is prolonged without
1487 any interruption at any time.

1488 (f) "Equipment" means a medical device, instrument, or tool
1489 used to perform specific actions or take certain measurements
1490 during, or while a patient is recovering from, a procedure or
1491 surgery which must meet current performance standards according
1492 to its manufacturer's guidelines for the specific device,
1493 instrument, or tool, as applicable.

1494 (g) "Major blood vessels" means a group of critical
1495 arteries and veins, including the aorta, coronary arteries,
1496 pulmonary arteries, superior and inferior vena cava, pulmonary
1497 veins, and any intra-cerebral artery or vein.

1498 (h) "Office surgery" means a physician's office in which
1499 surgical procedures are performed by a physician for the
1500 practice of medicine as authorized by this section and board
1501 rule. The office must be an office at which a physician
1502 regularly performs consultations with surgical patients,
1503 preoperative examinations, and postoperative care, as
1504 necessitated by the standard of care related to the surgeries
1505 performed at the physician's office, and at which patient
1506 records are readily maintained and available. The types of
1507 procedures or surgeries performed in an office surgery are those
1508 which need not be performed in a facility licensed under chapter

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1509 390 or chapter 395, and are not of the type that:

1510 1. Generally result in blood loss of more than 10 percent
1511 of estimated blood volume in a patient with a normal hemoglobin
1512 count;

1513 2. Require major or prolonged intracranial, intrathoracic,
1514 abdominal, or major joint replacement procedures, except for
1515 laparoscopic procedures;

1516 3. Involve major blood vessels and are performed with
1517 direct visualization by open exposure of the major vessel,
1518 except for percutaneous endovascular intervention; or

1519 4. Are generally emergent or life threatening in nature.

1520 (i) "Pediatric patient" means a patient who is 13 years of
1521 age or younger.

1522 (j) "Percutaneous endovascular intervention" means a
1523 procedure performed without open direct visualization of the
1524 target vessel and which requires only needle puncture of an
1525 artery or vein followed by insertion of catheters, wires, or
1526 similar devices that are then advanced through the blood vessels
1527 using imaging guidance. Once the catheter reaches the intended
1528 location, various maneuvers to address the diseased area may be
1529 performed, including, but not limited to, injection of contrast
1530 medium for imaging; treatment of vessels with angioplasty;
1531 atherectomy; covered or uncovered stenting; embolization or
1532 intentionally occluding vessels or organs; and delivering
1533 medications or radiation or other energy, such as laser,
1534 radiofrequency, or cryo.

1535 (k) "Reasonable proximity" means a distance that does not
1536 exceed 30 minutes of transport time to the hospital.

1537 (l) "Surgery" means any manual or operative procedure

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1538 performed upon the body of a living human being, including, but
1539 not limited to, those performed with the use of lasers, for the
1540 purposes of preserving health, diagnosing or curing disease,
1541 repairing injury, correcting a deformity or defect, prolonging
1542 life, or relieving suffering, or any elective procedure for
1543 aesthetic, reconstructive, or cosmetic purposes. The term
1544 includes, but is not limited to, incision or curettage of tissue
1545 or an organ; suture or other repair of tissue or an organ,
1546 including a closed as well as an open reduction of a fracture;
1547 extraction of tissue, including premature extraction of the
1548 products of conception from the uterus; insertion of natural or
1549 artificial implants; or an endoscopic procedure with use of
1550 local or general anesthetic.

1551 (3) GENERAL REQUIREMENTS FOR OFFICE SURGERY.—

1552 (a) The physician performing the surgery must examine the
1553 patient immediately before the surgery to evaluate the risk of
1554 anesthesia and of the surgical procedure to be performed. The
1555 physician performing the surgery may delegate the preoperative
1556 heart and lung evaluation to a qualified anesthesia provider
1557 within the scope of the provider's practice and, if applicable,
1558 protocol.

1559 (b) The physician performing the surgery shall maintain
1560 complete patient records of each surgical procedure performed,
1561 which must include all of the following:

1562 1. The patient's name, patient number, preoperative
1563 diagnosis, postoperative diagnosis, surgical procedure,
1564 anesthetic, anesthesia records, recovery records, and
1565 complications, if any.

1566 2. The name of each member of the surgical team, including

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1567 the surgeon, first assistant, anesthesiologist, nurse
1568 anesthetist, anesthesiologist assistant, circulating nurse, and
1569 operating room technician, as applicable.

1570 (c) Each office surgery's designated physician shall ensure
1571 that the office surgery has procedures in place to verify that
1572 all of the following have occurred before any surgery is
1573 performed:

1574 1. The patient has signed the informed consent form for the
1575 procedure reflecting the patient's knowledge of identified risks
1576 of the procedure, consent to the procedure, the type of
1577 anesthesia and anesthesia provider to be used during the
1578 procedure, and the fact that the patient may choose the type of
1579 anesthesia provider for the procedure, such as an
1580 anesthesiologist, a certified registered nurse anesthetist, a
1581 physician assistant, an anesthesiologist assistant, or another
1582 appropriately trained physician as provided by board rule.

1583 2. The patient's identity has been verified.

1584 3. The operative site has been verified.

1585 4. The operative procedure to be performed has been
1586 verified with the patient.

1587 5. All of the information and actions required to be
1588 verified under this paragraph are documented in the patient's
1589 medical record.

1590 (d) With respect to the requirements set forth in paragraph
1591 (c), written informed consent is not necessary for minor Level I
1592 procedures limited to the skin and mucosa.

1593 (e) The physician performing the surgery shall maintain a
1594 log of all liposuction procedures performed at the office
1595 surgery where more than 1,000 cubic centimeters of supernatant

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1596 fat is temporarily or permanently removed and where Level II and
1597 Level III surgical procedures are performed. The log must, at a
1598 minimum, include all of the following:

1599 1. A confidential patient identifier.

1600 2. Time of arrival in the operating suite.

1601 3. The name of the physician performing the procedure.

1602 4. The patient's diagnosis, CPT codes used for the
1603 procedure, the patient's classification for risk with anesthesia
1604 according to the American Society of Anesthesiologists' physical
1605 status classification system, and the type of procedure and
1606 level of surgery performed.

1607 5. Documentation of completion of the medical clearance
1608 performed by the anesthesiologist or the physician performing
1609 the surgery.

1610 6. The name and provider type of the anesthesia provider
1611 and the type of anesthesia used.

1612 7. The duration of the procedure.

1613 8. Any adverse incidents as identified in s. 458.351.

1614 9. The type of postoperative care, duration of recovery,
1615 disposition of the patient upon discharge, including the address
1616 of where the patient is being discharged, discharge
1617 instructions, and list of medications used during surgery and
1618 recovery.

1619
1620 All surgical and anesthesia logs must be kept at the office
1621 surgery and maintained for 6 years after the date of last
1622 patient contact and must be provided to department investigators
1623 upon request.

1624 (f) For any liposuction procedure, the physician performing

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1625 the surgery is responsible for determining the appropriate
1626 amount of supernatant fat to be removed from a particular
1627 patient. A maximum of 4,000 cubic centimeters of supernatant fat
1628 may be removed by liposuction in the office surgery setting. A
1629 maximum of 50mg/kg of lidocaine may be injected for tumescent
1630 liposuction in the office surgery setting.

1631 (g)1. Liposuction may be performed in combination with
1632 another separate surgical procedure during a single Level II or
1633 Level III surgical procedure only in the following
1634 circumstances:

1635 a. When combined with an abdominoplasty, liposuction may
1636 not exceed 1,000 cubic centimeters of supernatant fat.

1637 b. When liposuction is associated and directly related to
1638 another procedure, the liposuction may not exceed 1,000 cubic
1639 centimeters of supernatant fat.

1640 2. Major liposuction in excess of 1,000 cubic centimeters
1641 of supernatant fat may not be performed on a patient's body in a
1642 location that is remote from the site of another procedure being
1643 performed on that patient.

1644 (h) For elective cosmetic and plastic surgery procedures
1645 performed in a physician's office, the maximum planned duration
1646 of all surgical procedures combined may not exceed 8 hours.
1647 Except for elective cosmetic and plastic surgery, the physician
1648 performing the surgery may not keep patients past midnight in a
1649 physician's office. For elective cosmetic and plastic surgical
1650 procedures, the patient must be discharged within 24 hours after
1651 presenting to the office for surgery. However, an overnight stay
1652 is allowed in the office if the total time the patient is at the
1653 office does not exceed 23 hours and 59 minutes, including the

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1654 surgery time. An overnight stay in a physician's office for
1655 elective cosmetic and plastic surgery must be strictly limited
1656 to the physician's office. If the patient has not recovered
1657 sufficiently to be safely discharged within the timeframes set
1658 forth, the patient must be transferred to a hospital for
1659 continued postoperative care.

1660 (i) The American Society of Anesthesiologists Standards for
1661 Basic Anesthetic Monitoring are hereby adopted and incorporated
1662 by reference as the standards for anesthetic monitoring by any
1663 qualified anesthesia provider under this section.

1664 1. These standards apply to general anesthetics, regional
1665 anesthetics, and monitored Level II and III anesthesia care.
1666 However, in emergency circumstances, appropriate life support
1667 measures take priority. These standards may be exceeded at any
1668 time based on the judgment of the responsible supervising
1669 physician or anesthesiologist. While these standards are
1670 intended to encourage quality patient care, observing them does
1671 not guarantee any specific patient outcome. This set of
1672 standards addresses only the issue of basic anesthesia
1673 monitoring, which is only one component of anesthesia care.

1674 2. In certain rare or unusual circumstances, some of these
1675 methods of monitoring may be clinically impractical, and
1676 appropriate use of the described monitoring methods may fail to
1677 detect adverse clinical developments. In such cases, a brief
1678 interruption of continual monitoring may be unavoidable and does
1679 not by itself constitute a violation of the standards of
1680 practice of this section.

1681 3. Under extenuating circumstances, the physician
1682 performing the surgery or the anesthesiologist may waive the

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1683 following requirements:

1684 a. The use of an oxygen analyzer with a low oxygen
1685 concentration limit alarm, or other technology authorized under
1686 board rule which equals or exceeds the quality of the oxygen
1687 analyzer, during the administration of general anesthesia with
1688 an anesthesia machine.

1689 b. The use of pulse oximetry with a variable pitch pulse
1690 tone and an audible low threshold alarm, or other technology
1691 authorized under board rule which equals or exceeds the quality
1692 of a pulse oximeter, and the use of adequate illumination and
1693 exposure of the patient to assess color.

1694 c. The use of capnography, capnometry, or mass
1695 spectroscopy, or other technology authorized under board rule
1696 which equals or exceeds the quality of capnography, capnometry,
1697 or mass spectroscopy, as a quantitative method of analyzing the
1698 end-tidal carbon dioxide for continual monitoring for the
1699 presence of expired carbon dioxide during ventilation, from the
1700 time of the endotracheal tube or supraglottic airway placement
1701 until extubation or removal or initiating transfer of the
1702 patient to a postoperative care location.

1703 d. The use of continuous electrocardiogram display, or
1704 other technology authorized under board rule which equals or
1705 exceeds the quality of electrocardiogram display, from the
1706 beginning of anesthesia until preparing to leave the
1707 anesthetizing location.

1708 e. The measuring of arterial blood pressure and heart rate
1709 evaluated at least every 5 minutes during anesthesia.

1710
1711 When any of the monitoring is waived for extenuating

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1712 circumstances under this subparagraph, it must be documented in
1713 a note in the patient's medical record, including the reasons
1714 for the need to waive the requirement. These standards are not
1715 intended for the application to the care of an obstetrical
1716 patient in labor or in the conduct of pain management.

1717 (j)1. Because of the rapid changes in patient status during
1718 anesthesia, qualified anesthesia personnel must be continuously
1719 present in the room to provide anesthesia care for the entire
1720 duration of all general anesthetics, regional anesthetics, and
1721 monitored anesthesia care conducted on the patient. In the event
1722 that there is a direct known hazard, such as radiation, to the
1723 anesthesia personnel which might require intermittent remote
1724 observation of the patient, some provision for monitoring the
1725 patient must be made. In the event that an emergency requires
1726 the temporary absence of the person primarily responsible for
1727 the anesthesia, the best judgment of the supervising physician
1728 or anesthesiologist shall be exercised in comparing the
1729 emergency with the anesthetized patient's condition and in the
1730 selection of the person left responsible for the anesthesia
1731 during the temporary absence.

1732 2. During all anesthesia, the patient's oxygenation,
1733 ventilation, circulation, and temperature must be continually
1734 evaluated to ensure adequate oxygen concentration in the
1735 inspired gas and the blood.

1736 a. During all general anesthesia using an anesthesia
1737 machine, the concentration of oxygen in the patient's breathing
1738 system must be measured by an oxygen analyzer with a low oxygen
1739 concentration limit alarm used to measure blood oxygenation.

1740 b. During all anesthesia, a quantitative method of

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1741 assessing oxygenation, such as pulse oximetry, must be employed.
1742 When a pulse oximeter is used, the variable pitch pulse tone and
1743 the low threshold alarm must be audible to the qualified
1744 anesthesia provider. Adequate illumination and exposure of the
1745 patient are necessary to assess color.

1746 c. During all anesthesia, every patient must have the
1747 adequacy of his or her ventilation continually evaluated,
1748 including, but not limited to, the evaluation of qualitative
1749 clinical signs, such as chest excursion, observation of the
1750 reservoir breathing bag, and auscultation of breath sounds.
1751 Continual monitoring for the presence of expired carbon dioxide
1752 must be performed unless invalidated by the nature of the
1753 patient's condition, the procedure, or the equipment.
1754 Quantitative monitoring of the volume of expired gas must also
1755 be performed.

1756 d. When an endotracheal tube or supraglottic airway is
1757 inserted, its correct positioning must be verified by clinical
1758 assessment and by identification of carbon dioxide in the
1759 expired gas. Continual end-tidal carbon dioxide analysis, in use
1760 from the time of endotracheal tube or supraglottic airway
1761 placement until extubation or removal or initiating transfer of
1762 the patient to a postoperative care location, must be performed
1763 using a quantitative method, such as capnography, capnometry, or
1764 mass spectroscopy, or other technology authorized under board
1765 rule which equals or exceeds the quality of capnography,
1766 capnometry, or mass spectroscopy. When capnography or capnometry
1767 is used, the end-tidal carbon dioxide alarm must be audible to
1768 the qualified anesthesia provider.

1769 e. When ventilation is controlled by a mechanical

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1770 ventilator, there must be in continuous use a device capable of
1771 detecting disconnection of components of the breathing system.
1772 The device must give an audible signal when its alarm threshold
1773 is exceeded.

1774 f. During regional anesthesia without sedation or local
1775 anesthesia with no sedation, the adequacy of ventilation must be
1776 evaluated by continual observation of qualitative clinical
1777 signs. During moderate or deep sedation, the adequacy of
1778 ventilation must be evaluated by continual observation of
1779 qualitative clinical signs. Monitoring for the presence of
1780 exhaled carbon dioxide is recommended.

1781 g. Every patient receiving anesthesia must have the
1782 electrocardiogram or other technology authorized under board
1783 rule which equals or exceeds the quality of electrocardiogram
1784 continuously displayed from the beginning of anesthesia until
1785 preparing to leave the anesthetizing location.

1786 h. Every patient receiving anesthesia must have arterial
1787 blood pressure and heart rate determined and evaluated at least
1788 every 5 minutes.

1789 i. Every patient receiving general anesthesia must have
1790 circulatory function continually evaluated by at least one of
1791 the following methods:

1792 (I) Palpation of a pulse.

1793 (II) Auscultation of heart sounds.

1794 (III) Monitoring of a tracing of intra-arterial pressure.

1795 (IV) Ultrasound peripheral pulse monitoring.

1796 (V) Pulse plethysmography or oximetry.

1797 (VI) Other technology authorized under board rule which
1798 equals or exceeds the quality of any of the methods listed in

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1799 sub-sub-subparagraphs (I)-(V).

1800 j. Every patient receiving anesthesia must have his or her
1801 temperature monitored when clinically significant changes in
1802 body temperature are intended, anticipated, or suspected.

1803 (k)1. The physician performing the surgery shall ensure
1804 that the postoperative care arrangements made for the patient
1805 are adequate for the procedure being performed, as required by
1806 board rule.

1807 2. Management of postoperative care is the responsibility
1808 of the physician performing the surgery and may be delegated as
1809 determined by board rule. If the physician performing the
1810 surgery is unavailable to provide postoperative care, the
1811 physician performing the surgery must notify the patient of his
1812 or her unavailability for postoperative care before the
1813 procedure.

1814 3. If there is an overnight stay at the office in relation
1815 to any surgical procedure:

1816 a. The office must provide at least two persons to act as
1817 monitors, one of whom must be certified in advanced cardiac life
1818 support, and maintain a monitor-to-patient ratio of at least one
1819 monitor to two patients.

1820 b. Once the physician performing the surgery has signed a
1821 timed and dated discharge order, the office may provide only one
1822 monitor to monitor the patient. The monitor must be qualified by
1823 licensure and training to administer all of the medications
1824 required on the crash cart and must be certified in advanced
1825 cardiac life support.

1826 c. A complete and current crash cart must be present in the
1827 office surgery and immediately accessible for the monitors.

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1828 4. The physician performing the surgery must be reachable
1829 by telephone and readily available to return to the office if
1830 needed.

1831 5. A policy and procedures manual must be maintained in the
1832 office at which Level II and Level III procedures are performed.
1833 The manual must be updated and implemented annually. The policy
1834 and procedures manual must provide for all of the following:

1835 a. Duties and responsibilities of all personnel.

1836 b. A quality assessment and improvement system designed to
1837 objectively and systematically monitor and evaluate the quality
1838 and appropriateness of patient care and opportunities to improve
1839 performance.

1840 c. Cleaning procedures and protocols.

1841 d. Sterilization procedures.

1842 e. Infection control procedures and personnel
1843 responsibilities.

1844 f. Emergency procedures.

1845 6. The designated physician shall establish a risk
1846 management program that includes all of the following
1847 components:

1848 a. The identification, investigation, and analysis of the
1849 frequency and causes of adverse incidents.

1850 b. The identification of trends or patterns of adverse
1851 incidents.

1852 c. The development of appropriate measures to correct,
1853 reduce, minimize, or eliminate the risk of adverse incidents.

1854 d. The documentation of such functions and periodic review
1855 of such information at least quarterly by the designated
1856 physician.

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1857 7. The designated physician shall report to the department
1858 any adverse incidents that occur within the scope of office
1859 surgeries. This report must be made within 15 days after the
1860 occurrence of an incident as required by s. 458.351.

1861 8. The designated physician is responsible for prominently
1862 posting a sign in the office which states that the office is a
1863 doctor's office regulated under this section and ss. 458.328,
1864 458.3281, and 459.0138 and the applicable rules of the Board of
1865 Medicine and the Board of Osteopathic Medicine as set forth in
1866 rules 64B8 and 64B15, Florida Administrative Code. This notice
1867 must also appear prominently within the required patient
1868 informed consent form.

1869 9. All physicians performing surgery at the office surgery
1870 must be qualified by education, training, and experience to
1871 perform any procedure the physician performs in the office
1872 surgery.

1873 10. When Level II, Level II-A, or Level III procedures are
1874 performed in an office surgery setting, the physician performing
1875 the surgery is responsible for providing the patient, in
1876 writing, before the procedure, with the name and location of the
1877 hospital where the physician performing the surgery has
1878 privileges to perform the same procedure as the one being
1879 performed in the office surgery setting or the name and location
1880 of the hospital with which the physician performing the surgery
1881 has a transfer agreement in the event of an emergency.

1882 (4) LEVEL I OFFICE SURGERY.—

1883 (a) Scope.—Level I office surgery includes the following:

1884 1. Minor procedures such as excision of skin lesions,
1885 moles, warts, cysts, or lipomas and repair of lacerations or

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1886 surgery limited to the skin and subcutaneous tissue which are
1887 performed under topical or local anesthesia not involving drug-
1888 induced alteration of consciousness other than minimal pre-
1889 operative tranquilization of the patient.

1890 2. Liposuction involving the removal of less than 4,000
1891 cubic centimeters of supernatant fat.

1892 3. Incision and drainage of superficial abscesses; limited
1893 endoscopies, such as proctoscopies, skin biopsies,
1894 arthrocentesis, thoracentesis, paracentesis, dilation of the
1895 urethra, cystoscopic procedures, and closed reduction of simple
1896 fractures; or small joint dislocations, such as in the finger or
1897 toe joints.

1898 4. Procedures in which anesthesia is limited to minimal
1899 sedation. The patient's level of sedation must be that of
1900 minimal sedation and anxiolysis, and the chances of
1901 complications requiring hospitalization must be remote. As used
1902 in this sub-subparagraph, the term "minimal sedation and
1903 anxiolysis" means a drug-induced state during which patients
1904 respond normally to verbal commands, and although cognitive
1905 function and physical coordination may be impaired, airway
1906 reflexes and ventilatory and cardiovascular functions remain
1907 unaffected. Controlled substances, as defined in ss. 893.02 and
1908 893.03, must be limited to oral administration in doses
1909 appropriate for the unsupervised treatment of insomnia, anxiety,
1910 or pain.

1911 5. Procedures for which chances of complications requiring
1912 hospitalization are remote as specified in board rule.

1913 (b) Standards of practice.—Standards of practice for Level
1914 I office surgery include all of the following:

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1915 1. The medical education, training, and experience of the
1916 physician performing the surgery must include training on proper
1917 dosages and management of toxicity or hypersensitivity to
1918 regional anesthetic drugs, and the physician must be certified
1919 in advanced cardiac life support.

1920 2. At least one operating assistant must be certified in
1921 basic life support.

1922 3. Intravenous access supplies, oxygen, oral airways, and a
1923 positive pressure ventilation device must be available in the
1924 office surgery, along with the following medications, stored per
1925 the manufacturer's recommendation:

1926 a. Atropine, 3 mg.

1927 b. Diphenhydramine, 50 mg.

1928 c. Epinephrine, 1 mg in 10 ml.

1929 d. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

1930 e. Hydrocortisone, 100 mg.

1931 f. If a benzodiazepine is administered, flumazenil, 0.5 mg
1932 in 5 ml vial, 2 vials total.

1933 g. If an opiate is administered, naloxone, 0.4 mg in 1 ml
1934 vial, 2 vials total.

1935 4. When performing minor procedures, such as excision of
1936 skin lesions, moles, warts, cysts, or lipomas and repair of
1937 lacerations or surgery limited to the skin and subcutaneous
1938 tissue performed under topical or local anesthesia in an office
1939 surgery setting, physicians performing the procedure are exempt
1940 from subparagraphs 1.-3. Current certification in basic life
1941 support is recommended but not required.

1942 5. A physician performing the surgery need not have an
1943 assistant during the procedure unless the specific procedure

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1944 being performed requires an assistant.

1945 (5) LEVEL II OFFICE SURGERY.—

1946 (a) Scope.—Level II office surgery includes, but is not
1947 limited to, all of the following procedures:

1948 1. Hemorrhoidectomy.

1949 2. Hernia repair.

1950 3. Large joint dislocations.

1951 4. Colonoscopy.

1952 5. Liposuction involving the removal of up to 4,000 cubic
1953 centimeters of supernatant fat.

1954 6. Any other procedure the board designates by rule as a
1955 Level II office surgery.

1956 7. Surgeries in which the patient's level of sedation is
1957 that of moderate sedation and analgesia or conscious sedation.

1958 As used in this subparagraph, the term "moderate sedation and
1959 analgesia or conscious sedation" is a drug-induced depression of
1960 consciousness during which patients respond purposefully to
1961 verbal commands, either alone or accompanied by light tactile
1962 stimulation; interventions are not required to maintain a patent
1963 airway; spontaneous ventilation is adequate; and cardiovascular
1964 function is maintained. For purposes of this term, reflex
1965 withdrawal from a painful stimulus is not considered a
1966 purposeful response.

1967 (b) Standards of practice.—Standards of practice for Level
1968 II office surgery include, but are not limited to, the
1969 following:

1970 1. The physician performing the surgery, or the office
1971 where the procedure is being performed, must have a transfer
1972 agreement with a licensed hospital within reasonable proximity

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1973 if the physician performing the procedure does not have staff
1974 privileges to perform the same procedure as that being performed
1975 in the office surgery setting at a licensed hospital within
1976 reasonable proximity. The transfer agreement required by this
1977 section must be current and have been entered into no more than
1978 5 years before the date of the office's most recent annual
1979 inspection under s. 459.0138. A transfer agreement must
1980 affirmatively disclose an effective date and a termination date.

1981 2. The physician performing the surgery must have staff
1982 privileges at a licensed hospital to perform the same procedure
1983 in that hospital as that being performed in the office surgery
1984 setting or must be able to document satisfactory completion of
1985 training, such as board certification or board eligibility by a
1986 board approved by the American Board of Medical Specialties or
1987 any other board approved by the Board of Medicine or Board of
1988 Osteopathic Medicine, as applicable, or must be able to
1989 establish comparable background, training, and experience. Such
1990 board certification or comparable background, training, and
1991 experience must also be directly related to and include the
1992 procedures being performed by the physician in the office
1993 surgery facility.

1994 3. One assistant must be currently certified in basic life
1995 support.

1996 4. The physician performing the surgery must be currently
1997 certified in advanced cardiac life support.

1998 5. A complete and current crash cart must be available at
1999 all times at the location where the anesthesia is being
2000 administered. The designated physician of an office surgery is
2001 responsible for ensuring that the crash cart is replenished

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2002 after each use, the expiration dates for the crash cart's
2003 medications are checked weekly, and crash cart events are
2004 documented in the cart's logs. Medicines must be stored per the
2005 manufacturer's recommendations, and multidose vials must be
2006 dated once opened and checked daily for expiration. The crash
2007 cart must, at a minimum, include the following intravenous or
2008 inhaled medications:

2009 a. Adenosine, 18 mg.

2010 b. Albuterol, 2.5 mg with a small volume nebulizer.

2011 c. Amiodarone, 300 mg.

2012 d. Atropine, 3 mg.

2013 e. Calcium chloride, 1 gram.

2014 f. Dextrose, 50 percent; 50 ml.

2015 g. Diphenhydramine, 50 mg.

2016 h. Dopamine, 200 mg, minimum.

2017 i. Epinephrine, 1 mg, in 10 ml.

2018 j. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

2019 k. Flumazenil, 1 mg.

2020 l. Furosemide, 40 mg.

2021 m. Hydrocortisone, 100 mg.

2022 n. Lidocaine appropriate for cardiac administration, 100
2023 mg.

2024 o. Magnesium sulfate, 2 grams.

2025 p. Naloxone, 1.2 mg.

2026 q. A beta blocker class drug.

2027 r. Sodium bicarbonate, 50 mEq/50 ml.

2028 s. Paralytic agent that is appropriate for use in rapid
2029 sequence intubation.

2030 t. A calcium channel blocker class drug.

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- 2031 u. If nonneuraxial regional blocks are performed,
2032 Intralipid, 20 percent, 500 ml solution.
- 2033 v. Any additional medication the board determines by rule
2034 is warranted for patient safety and by the evolution of
2035 technology and medical practice.
- 2036 6. In the event of a drug shortage, the designated
2037 physician is authorized to substitute a therapeutically
2038 equivalent drug that meets the prevailing practice standards.
- 2039 7. The designated physician is responsible for ensuring
2040 that the office maintains documentation of its unsuccessful
2041 efforts to obtain the required drug.
- 2042 8. The designated physician is responsible for ensuring
2043 that the following are present in the office surgery:
- 2044 a. A benzodiazepine.
- 2045 b. A positive pressure ventilation device, such as Ambu,
2046 plus oxygen supply.
- 2047 c. An end-tidal carbon dioxide detection device.
- 2048 d. Monitors for blood pressure, electrocardiography, and
2049 oxygen saturation.
- 2050 e. Emergency intubation equipment that must, at a minimum,
2051 include suction devices, endotracheal tubes, working
2052 laryngoscopes, oropharyngeal airways, nasopharyngeal airways,
2053 and bag valve mask apparatus that are sized appropriately for
2054 the specific patient.
- 2055 f. A working defibrillator with defibrillator pads or
2056 defibrillator gel, or an automated external defibrillator unit.
- 2057 g. Sufficient backup power to allow the physician
2058 performing the surgery to safely terminate the procedure and to
2059 allow the patient to emerge from the anesthetic, all without

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2060 compromising the sterility of the procedure or the environment
2061 of care.

2062 h. Working sterilization equipment cultured weekly.

2063 i. Sufficient intravenous solutions and equipment for a
2064 minimum of a week's worth of surgical cases.

2065 j. Any other equipment required by board rule, as warranted
2066 by the evolution of technology and medical practice.

2067 9. The physician performing the surgery must be assisted by
2068 a qualified anesthesia provider, which may include any of the
2069 following types of providers:

2070 a. An anesthesiologist.

2071 b. A certified registered nurse anesthetist.

2072 c. A registered nurse, if the physician performing the
2073 surgery is certified in advanced cardiac life support and the
2074 registered nurse assists only with local anesthesia or conscious
2075 sedation.

2076
2077 An anesthesiologist assistant may assist the anesthesiologist as
2078 provided by board rule. An assisting anesthesia provider may not
2079 function in any other capacity during the procedure.

2080 10. If additional anesthesia assistance is required by the
2081 specific procedure or patient circumstances, such assistance
2082 must be provided by a physician, osteopathic physician,
2083 registered nurse, licensed practical nurse, or operating room
2084 technician.

2085 11. The designated physician is responsible for ensuring
2086 that each patient is monitored in the recovery room until the
2087 patient is fully recovered from anesthesia. Such monitoring must
2088 be provided by a licensed physician, physician assistant,

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2089 registered nurse with postanesthesia care unit experience, or
2090 the equivalent who is currently certified in advanced cardiac
2091 life support, or, in the case of pediatric patients, currently
2092 certified in pediatric advanced life support.

2093 (6) LEVEL II-A OFFICE SURGERY.—

2094 (a) Scope.—Level II-A office surgeries are those Level II
2095 office surgeries that have a maximum planned duration of 5
2096 minutes or less and in which the chances of complications
2097 requiring hospitalization are remote.

2098 (b) Standards of practice.—

2099 1. All practice standards for Level II office surgery set
2100 forth in paragraph (5) (b) must be met for Level II-A office
2101 surgery except for the requirements set forth in subparagraph
2102 (5) (b) 9. regarding assistance by a qualified anesthesia
2103 provider.

2104 2. During the surgical procedure, the physician performing
2105 the surgery must be assisted by a licensed physician, physician
2106 assistant, registered nurse, or licensed practical nurse.

2107 3. Additional assistance may be required by specific
2108 procedure or patient circumstances.

2109 4. Following the procedure, a licensed physician, physician
2110 assistant, or registered nurse must be available to monitor the
2111 patient in the recovery room until the patient is recovered from
2112 anesthesia. The monitoring provider must be currently certified
2113 in advanced cardiac life support, or, in the case of pediatric
2114 patients, currently certified in pediatric advanced life
2115 support.

2116 (7) LEVEL III OFFICE SURGERY.—

2117 (a) Scope.—

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2118 1. Level III office surgery includes those types of surgery
2119 during which the patient's level of sedation is that of deep
2120 sedation and analgesia or general anesthesia. As used in this
2121 subparagraph, the term:

2122 a. "Deep sedation and analgesia" means a drug-induced
2123 depression of consciousness during which:

2124 (I) Patients cannot be easily aroused but respond
2125 purposefully following repeated or painful stimulation;

2126 (II) The ability to independently maintain ventilatory
2127 function may be impaired;

2128 (III) Patients may require assistance in maintaining a
2129 patent airway and spontaneous ventilation may be inadequate; and

2130 (IV) Cardiovascular function is usually maintained.

2131
2132 For purposes of this sub-subparagraph, reflex withdrawal from a
2133 painful stimulus is not considered a purposeful response.

2134 b. "General anesthesia" means a drug-induced loss of
2135 consciousness during which:

2136 (I) Patients are not arousable, even by painful
2137 stimulation;

2138 (II) The ability to independently maintain ventilatory
2139 function is often impaired;

2140 (III) Patients often require assistance in maintaining a
2141 patent airway and positive pressure ventilation may be required
2142 because of depressed spontaneous ventilation or drug-induced
2143 depression of neuromuscular function; and

2144 (IV) Cardiovascular function may be impaired.

2145 2. The use of spinal or epidural anesthesia for a procedure
2146 requires that the procedure be considered a Level III office

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2147 surgery.

2148 3. Only patients classified under the American Society of
2149 Anesthesiologists' (ASA) risk classification criteria as Class I
2150 or Class II are appropriate candidates for a Level III office
2151 surgery.

2152 a. All Level III office surgeries on patients classified as
2153 ASA III or higher must be performed only in a hospital or
2154 ambulatory surgical center.

2155 b. For all ASA II patients above the age of 50, the
2156 physician performing the surgery must obtain a complete workup
2157 performed before the performance of a Level III office surgery
2158 in the office surgery setting.

2159 c. If the patient has a cardiac history or is deemed to be
2160 a complicated medical patient, the patient must have a
2161 preoperative electrocardiogram and be referred to an appropriate
2162 consultant for medical optimization. The referral to a
2163 consultant may be waived after evaluation by the patient's
2164 anesthesiologist.

2165 (b) Standards of practice.—Practice standards for Level III
2166 office surgery include all Level II office surgery standards and
2167 all of the following requirements:

2168 1. The physician performing the surgery must have staff
2169 privileges at a licensed hospital to perform the same procedure
2170 in that hospital as that being performed in the office surgery
2171 setting or must be able to document satisfactory completion of
2172 training, such as board certification or board qualification by
2173 a board approved by the American Board of Medical Specialties or
2174 any other board approved by the Board of Medicine or Board of
2175 Osteopathic Medicine, as applicable, or must be able to

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2176 demonstrate to the accrediting organization or to the department
2177 comparable background, training, and experience. Such board
2178 certification or comparable background, training, and experience
2179 must also be directly related to and include the procedure being
2180 performed by the physician performing the surgery in the office
2181 surgery setting. In addition, the physician performing the
2182 surgery must have knowledge of the principles of general
2183 anesthesia.

2184 2. The physician performing the surgery must be currently
2185 certified in advanced cardiac life support.

2186 3. At least one operating assistant must be currently
2187 certified in basic life support.

2188 4. An emergency policy and procedures manual related to
2189 serious anesthesia complications must be available in the office
2190 surgery and reviewed biannually by the designated physician,
2191 practiced with staff, updated, and posted in a conspicuous
2192 location in the office. Topics to be covered in the manual must
2193 include all of the following:

2194 a. Airway blockage and foreign body obstruction.

2195 b. Allergic reactions.

2196 c. Bradycardia.

2197 d. Bronchospasm.

2198 e. Cardiac arrest.

2199 f. Chest pain.

2200 g. Hypoglycemia.

2201 h. Hypotension.

2202 i. Hypoventilation.

2203 j. Laryngospasm.

2204 k. Local anesthetic toxicity reaction.

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- 2205 1. Malignant hyperthermia.
- 2206 m. Any other topics the board determines by rule are
2207 warranted for patient safety and by the evolution of technology
2208 and medical practice.
- 2209 5. An office surgery performing Level III office surgeries
2210 must maintain all of the equipment and medications required for
2211 Level II office surgeries and comply with all of the following
2212 additional requirements:
- 2213 a. Maintain at least 720 mg of dantrolene on site if
2214 halogenated anesthetics or succinylcholine are used.
- 2215 b. Equipment and medication for monitored postanesthesia
2216 recovery must be available in the office.
- 2217 6. Anesthetic safety regulations must be developed, posted
2218 in a conspicuous location in the office, and enforced by the
2219 designated physician. Such regulations must include all of the
2220 following requirements:
- 2221 a. All operating room electrical and anesthesia equipment
2222 must be inspected at least semiannually, and a written record of
2223 the results and corrective actions must be maintained.
- 2224 b. Flammable anesthetic agents may not be employed in
2225 office surgery facilities.
- 2226 c. Electrical equipment in anesthetizing areas must be on
2227 an audiovisual line isolation monitor, with the exception of
2228 radiologic equipment and fixed lighting more than 5 feet above
2229 the floor.
- 2230 d. Each anesthesia gas machine must have a pin index safety
2231 system or equivalent safety system and a minimum oxygen flow
2232 safety device.
- 2233 e. All reusable anesthesia equipment in direct contact with

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2234 a patient must be cleaned or sterilized as appropriate after
2235 each use.

2236 f. The following monitors must be applied to all patients
2237 receiving conduction or general anesthesia:

2238 (I) Blood pressure cuff.

2239 (II) A continuous temperature device, readily available to
2240 measure the patient's temperature.

2241 (III) Pulse oximeter.

2242 (IV) Electrocardiogram.

2243 (V) An inspired oxygen concentration monitor and a
2244 capnograph, for patients receiving general anesthesia.

2245 g. Emergency intubation equipment must be available in all
2246 office surgery suites.

2247 h. Surgical tables must be capable of Trendelenburg and
2248 other positions necessary to facilitate surgical procedures.

2249 i. An anesthesiologist, a certified registered nurse
2250 anesthetist, an anesthesiologist assistant, or a physician
2251 assistant qualified as set forth in board rule must administer
2252 the general or regional anesthesia.

2253 j. A physician, a registered nurse, a licensed practical
2254 nurse, a physician assistant, or an operating room technician
2255 must assist with the surgery. The anesthesia provider may not
2256 function in any other capacity during the procedure.

2257 k. The patient must be monitored in the recovery room until
2258 he or she has fully recovered from anesthesia. The monitoring
2259 must be provided by a physician, a physician assistant, a
2260 certified registered nurse anesthetist, an anesthesiologist
2261 assistant, or a registered nurse with postanesthesia care unit
2262 experience or the equivalent who is currently certified in

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2263 advanced cardiac life support, or, in the case of pediatric
2264 patients, currently certified in pediatric advanced life
2265 support.

2266 (8) EXEMPTION.—This section does not apply to a physician
2267 who is dually licensed as a dentist under chapter 466 when he or
2268 she is performing dental procedures that fall within the scope
2269 of practice of dentistry and are regulated under chapter 466.

2270 (9) RULEMAKING.—The board may adopt by rule additional
2271 standards of practice for physicians who perform office
2272 surgeries or procedures under this section as warranted for
2273 patient safety and by the evolution of technology and medical
2274 practice.

2275 Section 5. Subsection (6) of section 456.074, Florida
2276 Statutes, is amended to read

2277 456.074 Certain health care practitioners; immediate
2278 suspension of license.—

2279 (6) The department must issue an emergency order suspending
2280 or restricting the registration of an office registered under s.
2281 458.328 or s. 459.0138 ~~s. 459.0139~~ upon a finding of probable
2282 cause that the office or a physician practicing in the office is
2283 not in compliance with the standards of practice for office
2284 surgery adopted by the boards pursuant to s. 458.328 or s.
2285 459.0138, as applicable, or is in violation of s. 458.331(1)(v)
2286 or s. 459.015(1)(z), and that such noncompliance or violation
2287 constitutes an immediate danger to the public.

2288 Section 6. This act shall take effect upon becoming a law.