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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/25/2024	.	
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	.	

The Committee on Fiscal Policy (Garcia) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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

458.328 Office surgeries.—

(1) REGISTRATION.—

(a) ~~1~~. An office in which a physician performs or intends to



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10 perform a liposuction procedure in which more than 1,000 cubic
11 centimeters of supernatant fat is temporarily or permanently
12 removed, a liposuction procedure during which the patient is
13 rotated between the supine, lateral, and prone positions, a
14 Level II office surgery, or a Level III office surgery must
15 register with the department. ~~unless the office is licensed as A~~
16 facility licensed under chapter 390 or chapter 395 may not be
17 registered under this section.

18 (b)2. The department must complete an inspection of any
19 office seeking registration under this section before the office
20 may be registered.

21 1. The inspection of the office seeking registration under
22 this section must include inspection for compliance with the
23 standards of practice set out in this section and s. 458.3281
24 and any applicable board rules for the levels of office surgery
25 and procedures listed on the application which any physician
26 practicing at the office performs or intends to perform. The
27 application must be updated within 10 calendar days before any
28 additional surgical procedures or levels of office surgery are
29 to be performed at the office. Failure to timely update the
30 application for any such additional surgical procedures or
31 levels of office surgery is a violation of this section and
32 subject to discipline under ss. 456.072 and 458.331.

33 2. The department must immediately suspend the registration
34 process of an office that refuses an inspection under
35 subparagraph 1., and the applicant must be required to reapply
36 for registration.

37 3. If the department determines that an office seeking
38 registration under this section is one in which a physician may



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39 perform, or intends to perform, liposuction procedures that
40 include a patient being rotated between the supine, lateral, and
41 prone positions during the procedure, or in which a physician
42 may perform, or intends to perform, gluteal fat grafting
43 procedures, the office must provide proof to the department that
44 it has met the applicable requirements of s. 469 of the Florida
45 Building Code, relating to office surgery suites, and s.
46 458.3281 and the applicable rules adopted thereunder, and the
47 department must inspect the office to ensure that all of the
48 following are present or in place:

49 a. Equipment and a procedure for measuring and documenting
50 in a log the amount of supernatant fat removed, both temporarily
51 and permanently, from a particular patient, including tissue
52 disposal procedures.

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

55 c. Working ultrasound guidance equipment or other guidance
56 technology authorized under board rule which equals or exceeds
57 the quality of ultrasound guidance.

58 d. The office procedure for obtaining blood products.

59 e. Documentation on file at the office demonstrating that
60 any physician performing these procedures has privileges to
61 perform such procedures in a hospital no more than 20 minutes
62 away.

63 f. Procedures for emergency resuscitation and transport to
64 a hospital.

65 g. Procedures for anesthesia and surgical recordkeeping.

66 h. Any additional inspection requirements, as set by board
67 rule.



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68 4. If an applicant is unable to provide proof to the
69 department that the office seeking registration is in compliance
70 with the applicable requirements of s. 469 of the Florida
71 Building Code, relating to office surgery suites, or s. 458.3281
72 or the applicable rules adopted thereunder, in accordance with
73 subparagraph 3., the department must notify the Agency for
74 Health Care Administration and request the agency to inspect the
75 office and consult with the office about the process to apply
76 for ambulatory surgical center licensure under chapter 395 and
77 how the office may seek qualification for such licensure,
78 notwithstanding the office's failure to meet all requirements
79 associated with such licensure at the time of inspection and
80 notwithstanding any pertinent exceptions provided under s.
81 395.002(3).

82 ~~(c)(b)~~ To be ~~By January 1, 2020,~~ each office registered
83 under this section or s. 459.0138, an office must, at the time
84 of application, list a designated ~~designate a~~ physician who is
85 responsible for the office's compliance with the office health
86 and safety requirements of this section and rules adopted
87 hereunder. A designated physician must have a full, active, and
88 unencumbered license under this chapter or chapter 459 and shall
89 practice at the office for which he or she has assumed
90 responsibility. Within 10 calendar days after the termination of
91 a designated physician relationship, the office must notify the
92 department of the designation of another physician to serve as
93 the designated physician. The department may not register an
94 office if the office fails to comply with this requirement at
95 the time of application and must seek an emergency suspension of
96 suspend the registration of an office pursuant to s. 456.074(6)



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97 if the office fails to timely notify the department of its new
98 designated physician within 10 calendar days after the
99 termination of the previous designated physician relationship
100 comply with the requirements of this paragraph.

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

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

107 2. Anesthesia providers, including their license numbers.

108 3. Nursing personnel licensed under chapter 464, including
109 their license numbers unless already provided under subparagraph
110 2.

111 4. Physician assistants, including their respective license
112 numbers and supervising physicians.

113
114 The office must notify the department of the addition or
115 termination of any of the types of medical personnel specified
116 under this paragraph within 10 calendar days before such
117 addition or after such termination. Failure to timely notify the
118 department of such addition or termination is a violation of
119 this section and subject to discipline under ss. 456.072 and
120 458.331.

121 (e)-(e) As a condition of registration, each office must
122 establish financial responsibility by demonstrating that it has
123 met and continues to maintain, at a minimum, the same
124 requirements applicable to physicians in ss. 458.320 and
125 459.0085. Each physician practicing at an office registered



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126 under this section or s. 459.0138 must meet the financial
127 responsibility requirements under s. 458.320 or s. 459.0085, as
128 applicable.

129 (f)(d) Each physician practicing or intending to practice
130 at an office registered under this section or s. 459.0138 must
131 ~~shall~~ advise the board, in writing, within 10 calendar days
132 before after beginning or after ending his or her practice at a
133 registered office, as applicable.

134 (g)(e)1. The department shall inspect a registered office
135 at least annually, including a review of patient records,
136 anesthesia logs, surgery logs, and liposuction logs, to ensure
137 that the office is in compliance with this section and rules
138 adopted hereunder unless the office is accredited in office-
139 based surgery by the Joint Commission or other a nationally
140 recognized accrediting agency approved by the board. The
141 inspection may be unannounced, except for the inspection of an
142 office that meets the description of a clinic specified in s.
143 458.3265(1)(a)3.h., and those wholly owned and operated
144 physician offices described in s. 458.3265(1)(a)3.g. which
145 perform procedures referenced in s. 458.3265(1)(a)3.h., which
146 must be announced.

147 (h)2. The department must immediately suspend the
148 registration of a registered office that refuses an inspection
149 under paragraph (g) subparagraph 1. The office must close during
150 such suspension. The suspension must remain in effect for at
151 least 14 consecutive days and may not terminate until the
152 department issues a written declaration that the office may
153 reopen following the department's completion of an inspection of
154 the office.



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155 (i)~~(f)~~ The department may suspend or revoke the
156 registration of an office in which a procedure or surgery
157 identified in paragraph (a) is performed for failure of any of
158 its physicians, owners, or operators to comply with this section
159 and rules adopted hereunder or s. 459.0138 and rules adopted
160 thereunder. If an office's registration is revoked for any
161 reason, the department may deny any person named in the
162 registration documents of the office, including the persons who
163 own or operate the office, individually or as part of a group,
164 from registering an office to perform procedures or office
165 surgeries pursuant to this section or s. 459.0138 for 5 years
166 after the revocation date.

167 (j)~~(g)~~ The department may impose any penalty set forth in
168 s. 456.072(2) against the designated physician for failure of
169 the office to operate in compliance with the office health and
170 safety requirements of this section and rules adopted hereunder
171 or s. 459.0138 and rules adopted thereunder.

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

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

181 (2) REGISTRATION UPDATE.—

182 (a) An office that registered under this section before
183 July 1, 2024, in which a physician performs liposuction



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184 procedures that include a patient being rotated between the
185 supine, lateral, and prone positions during the procedure or in
186 which a physician performs gluteal fat grafting procedures must
187 provide a registration update to the department consistent with
188 the requirements of the initial registration under subsection
189 (1) no later than 30 days before the office surgery's next
190 annual inspection.

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

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

196 (d) In order to provide an office surgery time to update to
197 the requirements of subsection (1) and s. 458.3281, effective
198 July 1, 2024, and the applicable provisions of s. 469 of the
199 Florida Building Code, relating to office surgery suites, any
200 office surgery registered under this section before July 1,
201 2024, whose annual inspection is due in July or August 2024, may
202 request from the department, in writing, a 60-day postponement
203 of the required annual inspection, which postponement must be
204 granted.

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

210 (3) STANDARDS OF PRACTICE.—

211 (a) A physician performing a procedure or surgery in an
212 office registered under this section must comply with the



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213 applicable provisions of s. 469 of the Florida Building Code,
214 relating to office surgery suites, and the standards of practice
215 for office surgery set forth in this section and s. 458.3281 and
216 any applicable rules adopted thereunder.

217 (b) A physician may not perform any surgery or procedure
218 identified in paragraph (1) (a) in a setting other than an office
219 registered under this section or a facility licensed under
220 chapter 390 or chapter 395, as applicable. The board shall
221 impose a fine of \$5,000 per incident on a physician who violates
222 this paragraph performing a gluteal fat grafting procedure in an
223 office surgery setting shall adhere to standards of practice
224 pursuant to this subsection and rules adopted by the board.

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

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

229 2. Require major or prolonged intracranial, intrathoracic,
230 abdominal, or joint replacement procedures, except for
231 laparoscopic procedures;

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

235 4. Be emergent or life threatening.

236 (d) ~~(e)~~ A physician performing a gluteal fat grafting
237 procedure in an office surgery setting must comply with the
238 applicable provisions of s. 469 of the Florida Building Code,
239 relating to office surgery suites, and the standards of practice
240 under this subsection and s. 458.3281, and applicable rules
241 adopted thereunder, including, but not limited to, all of the



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242 following standards of practice:

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

247 2. Before a physician may delegate any duties during a
248 gluteal fat grafting procedure, the patient must provide
249 written, informed consent for such delegation. Any duty
250 delegated by a physician during a gluteal fat grafting procedure
251 must be performed under the direct supervision of the physician
252 performing such procedure. Fat extraction and gluteal fat
253 injections must be performed by the physician and may not be
254 delegated.

255 3. Fat may only be injected into the subcutaneous space of
256 the patient and may not cross the fascia overlying the gluteal
257 muscle. Intramuscular or submuscular fat injections are
258 prohibited.

259 4. When the physician performing a gluteal fat grafting
260 procedure injects fat into the subcutaneous space of the
261 patient, the physician must use ultrasound guidance, or guidance
262 with other technology authorized under board rule which equals
263 or exceeds the quality of ultrasound, during the placement and
264 navigation of the cannula to ensure that the fat is injected
265 into the subcutaneous space of the patient above the fascia
266 overlying the gluteal muscle. Such guidance with the use of
267 ultrasound or other technology is not required for other
268 portions of such procedure.

269 5. An office in which a physician performs gluteal fat
270 grafting procedures shall at all times maintain a ratio of one



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271 physician to one patient during all phases of the procedure,
272 beginning with the administration of anesthesia to the patient
273 and concluding with the extubation of the patient. After a
274 physician has commenced, and while he or she is engaged in, a
275 gluteal fat grafting procedure, the physician may not commence
276 or engage in another gluteal fat grafting procedure or any other
277 procedure with another patient at the same time.

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

281 ~~(e) An office in which a physician performs gluteal fat~~
282 ~~grafting procedures must at all times maintain a ratio of one~~
283 ~~physician to one patient during all phases of the procedure,~~
284 ~~beginning with the administration of anesthesia to the patient~~
285 ~~and concluding with the extubation of the patient. After a~~
286 ~~physician has commenced, and while he or she is engaged in, a~~
287 ~~gluteal fat grafting procedure, the physician may not commence~~
288 ~~or engage in another gluteal fat grafting procedure or any other~~
289 ~~procedure with another patient at the same time.~~

290 ~~(4)-(3)~~ RULEMAKING.—

291 (a) The board may shall adopt by rule additional standards
292 of practice for physicians who perform office procedures or
293 office surgeries under ~~pursuant to~~ this section, as warranted
294 for patient safety and by the evolution of technology and
295 medical practice.

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



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300 Section 2. Section 458.3281, Florida Statutes, is created
301 to read:

302 458.3281 Standard of practice for office surgery.—

303 (1) CONSTRUCTION.—This section does not relieve a physician
304 performing a procedure or surgery from the responsibility of
305 making the medical determination of whether an office is an
306 appropriate setting in which to perform that particular
307 procedure or surgery, taking into consideration the particular
308 patient on which the procedure or surgery is to be performed.

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

310 (a) "Certified in advanced cardiac life support" means a
311 person holds a current certification in an advanced cardiac life
312 support course with didactic and skills components, approved by
313 the American Heart Association, the American Safety and Health
314 Institute, the American Red Cross, Pacific Medical Training, or
315 the Advanced Cardiovascular Life Support (ACLS) Certification
316 Institute.

317 (b) "Certified in basic life support" means a person holds
318 a current certification in a basic life support course with
319 didactic and skills components, approved by the American Heart
320 Association, the American Safety and Health Institute, the
321 American Red Cross, Pacific Medical Training, or the ACLS
322 Certification Institute.

323 (c) "Certified in pediatric advanced life support" means a
324 person holds a current certification in a pediatric advanced
325 life support course with didactic and skills components approved
326 by the American Heart Association, the American Safety and
327 Health Institute, or Pacific Medical Training.

328 (d) "Continual monitoring" means monitoring that is



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329 repeated regularly and frequently in steady, rapid succession.

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

332 (f) "Equipment" means a medical device, instrument, or tool
333 used to perform specific actions or take certain measurements
334 during, or while a patient is recovering from, a procedure or
335 surgery which must meet current performance standards according
336 to its manufacturer's guidelines for the specific device,
337 instrument, or tool, as applicable.

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

342 (h) "Office surgery" means a physician's office in which
343 surgical procedures are performed by a physician for the
344 practice of medicine as authorized by this section and board
345 rule. The office must be an office at which a physician
346 regularly performs consultations with surgical patients,
347 preoperative examinations, and postoperative care, as
348 necessitated by the standard of care related to the surgeries
349 performed at the physician's office, and at which patient
350 records are readily maintained and available. The types of
351 procedures or surgeries performed in an office surgery are those
352 which need not be performed in a facility licensed under chapter
353 390 or chapter 395, and are not of the type that:

354 1. Generally result in blood loss of more than 10 percent
355 of estimated blood volume in a patient with a normal hemoglobin
356 count;

357 2. Require major or prolonged intracranial, intrathoracic,



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358 abdominal, or major joint replacement procedures, except for
359 laparoscopic procedures;

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

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

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

366 (j) "Percutaneous endovascular intervention" means a
367 procedure performed without open direct visualization of the
368 target vessel and which requires only needle puncture of an
369 artery or vein followed by insertion of catheters, wires, or
370 similar devices that are then advanced through the blood vessels
371 using imaging guidance. Once the catheter reaches the intended
372 location, various maneuvers to address the diseased area may be
373 performed, including, but not limited to, injection of contrast
374 medium for imaging; treatment of vessels with angioplasty;
375 atherectomy; covered or uncovered stenting; embolization or
376 intentionally occluding vessels or organs; and delivering
377 medications or radiation or other energy, such as laser,
378 radiofrequency, or cryo.

379 (k) "Reasonable proximity" means a distance that does not
380 exceed 20 minutes of transport time to the hospital.

381 (l) "Surgery" means any manual or operative procedure
382 performed upon the body of a living human being, including, but
383 not limited to, those performed with the use of lasers, for the
384 purposes of preserving health, diagnosing or curing disease,
385 repairing injury, correcting a deformity or defect, prolonging
386 life, or relieving suffering, or any elective procedure for



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387 aesthetic, reconstructive, or cosmetic purposes. The term
388 includes, but is not limited to, incision or curettage of tissue
389 or an organ; suture or other repair of tissue or an organ,
390 including a closed as well as an open reduction of a fracture;
391 extraction of tissue, including premature extraction of the
392 products of conception from the uterus; insertion of natural or
393 artificial implants; or an endoscopic procedure with use of
394 local or general anesthetic.

395 (3) GENERAL REQUIREMENTS FOR OFFICE SURGERY.—

396 (a) The physician performing the surgery must examine the
397 patient immediately before the surgery to evaluate the risk of
398 anesthesia and of the surgical procedure to be performed. The
399 physician performing the surgery may delegate the preoperative
400 heart and lung evaluation to a qualified anesthesia provider
401 within the scope of the provider's practice and, if applicable,
402 protocol.

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

406 1. The patient's name, patient number, preoperative
407 diagnosis, postoperative diagnosis, surgical procedure,
408 anesthetic, anesthesia records, recovery records, and
409 complications, if any.

410 2. The name of each member of the surgical team, including
411 the surgeon, first assistant, anesthesiologist, nurse
412 anesthetist, anesthesiologist assistant, circulating nurse, and
413 operating room technician, as applicable.

414 (c) Each office surgery's designated physician shall ensure
415 that the office surgery has procedures in place to verify that



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416 all of the following have occurred before any surgery is
417 performed:

418 1. The patient has signed the informed consent form for the
419 procedure reflecting the patient's knowledge of identified risks
420 of the procedure, consent to the procedure, the type of
421 anesthesia and anesthesia provider to be used during the
422 procedure, and the fact that the patient may choose the type of
423 anesthesia provider for the procedure, such as an
424 anesthesiologist, a certified registered nurse anesthetist, a
425 physician assistant, an anesthesiologist assistant, or another
426 appropriately trained physician as provided by board rule.

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

428 3. The operative site has been verified.

429 4. The operative procedure to be performed has been
430 verified with the patient.

431 5. All of the information and actions required to be
432 verified under this paragraph are documented in the patient's
433 medical record.

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

437 (e) The physician performing the surgery shall maintain a
438 log of all liposuction procedures performed at the office
439 surgery where more than 1,000 cubic centimeters of supernatant
440 fat is temporarily or permanently removed and where Level II and
441 Level III surgical procedures are performed. The log must, at a
442 minimum, include all of the following:

443 1. A confidential patient identifier.

444 2. Time of arrival in the operating suite.



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

446 4. The patient's diagnosis, CPT codes used for the
447 procedure, the patient's classification for risk with anesthesia
448 according to the American Society of Anesthesiologists' physical
449 status classification system, and the type of procedure and
450 level of surgery performed.

451 5. Documentation of completion of the medical clearance
452 performed by the anesthesiologist or the physician performing
453 the surgery.

454 6. The name and provider type of the anesthesia provider
455 and the type of anesthesia used.

456 7. The duration of the procedure.

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

458 9. The type of postoperative care, duration of recovery,
459 disposition of the patient upon discharge, including the address
460 of where the patient is being discharged, discharge
461 instructions, and list of medications used during surgery and
462 recovery.

463
464 All surgical and anesthesia logs must be kept at the office
465 surgery and maintained for 6 years after the date of last
466 patient contact and must be provided to department investigators
467 upon request.

468 (f) For any liposuction procedure, the physician performing
469 the surgery is responsible for determining the appropriate
470 amount of supernatant fat to be removed from a particular
471 patient. A maximum of 4,000 cubic centimeters of supernatant fat
472 may be removed by liposuction in the office surgery setting. A
473 maximum of 50mg/kg of lidocaine may be injected for tumescent



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474 liposuction in the office surgery setting.

475 (g)1. Liposuction may be performed in combination with
476 another separate surgical procedure during a single Level II or
477 Level III surgical procedure only in the following
478 circumstances:

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

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

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

488 (h) For elective cosmetic and plastic surgery procedures
489 performed in a physician's office, the maximum planned duration
490 of all surgical procedures combined may not exceed 8 hours.
491 Except for elective cosmetic and plastic surgery, the physician
492 performing the surgery may not keep patients past midnight in a
493 physician's office. For elective cosmetic and plastic surgical
494 procedures, the patient must be discharged within 24 hours after
495 presenting to the office for surgery. However, an overnight stay
496 is allowed in the office if the total time the patient is at the
497 office does not exceed 23 hours and 59 minutes, including the
498 surgery time. An overnight stay in a physician's office for
499 elective cosmetic and plastic surgery must be strictly limited
500 to the physician's office. If the patient has not recovered
501 sufficiently to be safely discharged within the timeframes set
502 forth, the patient must be transferred to a hospital for



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503 continued postoperative care.

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

508 1. These standards apply to general anesthetics, regional
509 anesthetics, and monitored Level II and III anesthesia care.
510 However, in emergency circumstances, appropriate life support
511 measures take priority. These standards may be exceeded at any
512 time based on the judgment of the responsible supervising
513 physician or anesthesiologist. While these standards are
514 intended to encourage quality patient care, observing them does
515 not guarantee any specific patient outcome. This set of
516 standards addresses only the issue of basic anesthesia
517 monitoring, which is only one component of anesthesia care.

518 2. In certain rare or unusual circumstances, some of these
519 methods of monitoring may be clinically impractical, and
520 appropriate use of the described monitoring methods may fail to
521 detect adverse clinical developments. In such cases, a brief
522 interruption of continual monitoring may be unavoidable and does
523 not by itself constitute a violation of the standards of
524 practice of this section.

525 3. Under extenuating circumstances, the physician
526 performing the surgery or the anesthesiologist may waive the
527 following requirements:

528 a. The use of an oxygen analyzer with a low oxygen
529 concentration limit alarm, or other technology authorized under
530 board rule which equals or exceeds the quality of the oxygen
531 analyzer, during the administration of general anesthesia with



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532 an anesthesia machine.

533 b. The use of pulse oximetry with a variable pitch pulse
534 tone and an audible low threshold alarm, or other technology
535 authorized under board rule which equals or exceeds the quality
536 of a pulse oximeter, and the use of adequate illumination and
537 exposure of the patient to assess color.

538 c. The use of capnography, capnometry, or mass
539 spectroscopy, or other technology authorized under board rule
540 which equals or exceeds the quality of capnography, capnometry,
541 or mass spectroscopy, as a quantitative method of analyzing the
542 end-tidal carbon dioxide for continual monitoring for the
543 presence of expired carbon dioxide during ventilation, from the
544 time of the endotracheal tube or supraglottic airway placement
545 until extubation or removal or initiating transfer of the
546 patient to a postoperative care location.

547 d. The use of continuous electrocardiogram display, or
548 other technology authorized under board rule which equals or
549 exceeds the quality of electrocardiogram display, from the
550 beginning of anesthesia until preparing to leave the
551 anesthetizing location.

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

554
555 When any of the monitoring is waived for extenuating
556 circumstances under this subparagraph, it must be documented in
557 a note in the patient's medical record, including the reasons
558 for the need to waive the requirement. These standards are not
559 intended for the application to the care of an obstetrical
560 patient in labor or in the conduct of pain management.



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561 (j)1. Because of the rapid changes in patient status during
562 anesthesia, qualified anesthesia personnel must be continuously
563 present in the room to provide anesthesia care for the entire
564 duration of all general anesthetics, regional anesthetics, and
565 monitored anesthesia care conducted on the patient. In the event
566 that there is a direct known hazard, such as radiation, to the
567 anesthesia personnel which might require intermittent remote
568 observation of the patient, some provision for monitoring the
569 patient must be made. In the event that an emergency requires
570 the temporary absence of the person primarily responsible for
571 the anesthesia, the best judgment of the supervising physician
572 or anesthesiologist shall be exercised in comparing the
573 emergency with the anesthetized patient's condition and in the
574 selection of the person left responsible for the anesthesia
575 during the temporary absence.

576 2. During all anesthesia, the patient's oxygenation,
577 ventilation, circulation, and temperature must be continually
578 evaluated to ensure adequate oxygen concentration in the
579 inspired gas and the blood.

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

584 b. During all anesthesia, a quantitative method of
585 assessing oxygenation, such as pulse oximetry, must be employed.
586 When a pulse oximeter is used, the variable pitch pulse tone and
587 the low threshold alarm must be audible to the qualified
588 anesthesia provider. Adequate illumination and exposure of the
589 patient are necessary to assess color.



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590 c. During all anesthesia, every patient must have the
591 adequacy of his or her ventilation continually evaluated,
592 including, but not limited to, the evaluation of qualitative
593 clinical signs, such as chest excursion, observation of the
594 reservoir breathing bag, and auscultation of breath sounds.
595 Continual monitoring for the presence of expired carbon dioxide
596 must be performed unless invalidated by the nature of the
597 patient's condition, the procedure, or the equipment.
598 Quantitative monitoring of the volume of expired gas must also
599 be performed.

600 d. When an endotracheal tube or supraglottic airway is
601 inserted, its correct positioning must be verified by clinical
602 assessment and by identification of carbon dioxide in the
603 expired gas. Continual end-tidal carbon dioxide analysis, in use
604 from the time of endotracheal tube or supraglottic airway
605 placement until extubation or removal or initiating transfer of
606 the patient to a postoperative care location, must be performed
607 using a quantitative method, such as capnography, capnometry, or
608 mass spectroscopy, or other technology authorized under board
609 rule which equals or exceeds the quality of capnography,
610 capnometry, or mass spectroscopy. When capnography or capnometry
611 is used, the end-tidal carbon dioxide alarm must be audible to
612 the qualified anesthesia provider.

613 e. When ventilation is controlled by a mechanical
614 ventilator, there must be in continuous use a device capable of
615 detecting disconnection of components of the breathing system.
616 The device must give an audible signal when its alarm threshold
617 is exceeded.

618 f. During regional anesthesia without sedation or local



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619 anesthesia with no sedation, the adequacy of ventilation must be
620 evaluated by continual observation of qualitative clinical
621 signs. During moderate or deep sedation, the adequacy of
622 ventilation must be evaluated by continual observation of
623 qualitative clinical signs. Monitoring for the presence of
624 exhaled carbon dioxide is recommended.

625 g. Every patient receiving anesthesia must have the
626 electrocardiogram or other technology authorized under board
627 rule which equals or exceeds the quality of electrocardiogram
628 continuously displayed from the beginning of anesthesia until
629 preparing to leave the anesthetizing location.

630 h. Every patient receiving anesthesia must have arterial
631 blood pressure and heart rate determined and evaluated at least
632 every 5 minutes.

633 i. Every patient receiving general anesthesia must have
634 circulatory function continually evaluated by at least one of
635 the following methods:

636 (I) Palpation of a pulse.

637 (II) Auscultation of heart sounds.

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

639 (IV) Ultrasound peripheral pulse monitoring.

640 (V) Pulse plethysmography or oximetry.

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

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

647 (k)1. The physician performing the surgery shall ensure



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648 that the postoperative care arrangements made for the patient
649 are adequate for the procedure being performed, as required by
650 board rule.

651 2. Management of postoperative care is the responsibility
652 of the physician performing the surgery and may be delegated as
653 determined by board rule. If the physician performing the
654 surgery is unavailable to provide postoperative care, the
655 physician performing the surgery must notify the patient of his
656 or her unavailability for postoperative care before the
657 procedure.

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

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

664 b. Once the physician performing the surgery has signed a
665 timed and dated discharge order, the office may provide only one
666 monitor to monitor the patient. The monitor must be qualified by
667 licensure and training to administer all of the medications
668 required on the crash cart and must be certified in advanced
669 cardiac life support.

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

672 4. The physician performing the surgery must be reachable
673 by telephone and readily available to return to the office if
674 needed.

675 5. A policy and procedures manual must be maintained in the
676 office at which Level II and Level III procedures are performed.



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677 The manual must be updated and implemented annually. The policy
678 and procedures manual must provide for all of the following:
679 a. Duties and responsibilities of all personnel.
680 b. A quality assessment and improvement system designed to
681 objectively and systematically monitor and evaluate the quality
682 and appropriateness of patient care and opportunities to improve
683 performance.
684 c. Cleaning procedures and protocols.
685 d. Sterilization procedures.
686 e. Infection control procedures and personnel
687 responsibilities.
688 f. Emergency procedures.
689 6. The designated physician shall establish a risk
690 management program that includes all of the following
691 components:
692 a. The identification, investigation, and analysis of the
693 frequency and causes of adverse incidents.
694 b. The identification of trends or patterns of adverse
695 incidents.
696 c. The development of appropriate measures to correct,
697 reduce, minimize, or eliminate the risk of adverse incidents.
698 d. The documentation of such functions and periodic review
699 of such information at least quarterly by the designated
700 physician.
701 7. The designated physician shall report to the department
702 any adverse incidents that occur within the scope of office
703 surgeries. This report must be made within 15 days after the
704 occurrence of an incident as required by s. 458.351.
705 8. The designated physician is responsible for prominently



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706 posting a sign in the office which states that the office is a
707 doctor's office regulated under this section and ss. 458.328,
708 458.3281, and 459.0138 and the applicable rules of the Board of
709 Medicine and the Board of Osteopathic Medicine as set forth in
710 rules 64B8 and 64B15, Florida Administrative Code. This notice
711 must also appear prominently within the required patient
712 informed consent form.

713 9. All physicians performing surgery at the office surgery
714 must be qualified by education, training, and experience to
715 perform any procedure the physician performs in the office
716 surgery.

717 10. When Level II, Level II-A, or Level III procedures are
718 performed in an office surgery setting, the physician performing
719 the surgery is responsible for providing the patient, in
720 writing, before the procedure, with the name and location of the
721 hospital where the physician performing the surgery has
722 privileges to perform the same procedure as the one being
723 performed in the office surgery setting or the name and location
724 of the hospital with which the physician performing the surgery
725 has a transfer agreement in the event of an emergency.

726 (4) LEVEL I OFFICE SURGERY.—

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

728 1. Minor procedures such as excision of skin lesions,
729 moles, warts, cysts, or lipomas and repair of lacerations or
730 surgery limited to the skin and subcutaneous tissue which are
731 performed under topical or local anesthesia not involving drug-
732 induced alteration of consciousness other than minimal pre-
733 operative tranquilization of the patient.

734 2. Liposuction involving the removal of less than 4,000



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735 cubic centimeters of supernatant fat.

736 3. Incision and drainage of superficial abscesses; limited
737 endoscopies, such as proctoscopies, skin biopsies,
738 arthrocentesis, thoracentesis, paracentesis, dilation of the
739 urethra, cystoscopic procedures, and closed reduction of simple
740 fractures; or small joint dislocations, such as in the finger or
741 toe joints.

742 4. Procedures in which anesthesia is limited to minimal
743 sedation. The patient's level of sedation must be that of
744 minimal sedation and anxiolysis, and the chances of
745 complications requiring hospitalization must be remote. As used
746 in this sub-subparagraph, the term "minimal sedation and
747 anxiolysis" means a drug-induced state during which patients
748 respond normally to verbal commands, and although cognitive
749 function and physical coordination may be impaired, airway
750 reflexes and ventilatory and cardiovascular functions remain
751 unaffected. Controlled substances, as defined in ss. 893.02 and
752 893.03, must be limited to oral administration in doses
753 appropriate for the unsupervised treatment of insomnia, anxiety,
754 or pain.

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

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

759 1. The medical education, training, and experience of the
760 physician performing the surgery must include training on proper
761 dosages and management of toxicity or hypersensitivity to
762 regional anesthetic drugs, and the physician must be certified
763 in advanced cardiac life support.



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764 2. At least one operating assistant must be certified in
765 basic life support.

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

770 a. Atropine, 3 mg.

771 b. Diphenhydramine, 50 mg.

772 c. Epinephrine, 1 mg in 10 ml.

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

774 e. Hydrocortisone, 100 mg.

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

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

779 4. When performing minor procedures, such as excision of
780 skin lesions, moles, warts, cysts, or lipomas and repair of
781 lacerations or surgery limited to the skin and subcutaneous
782 tissue performed under topical or local anesthesia in an office
783 surgery setting, physicians performing the procedure are exempt
784 from subparagraphs 1.-3. Current certification in basic life
785 support is recommended but not required.

786 5. A physician performing the surgery need not have an
787 assistant during the procedure unless the specific procedure
788 being performed requires an assistant.

789 (5) LEVEL II OFFICE SURGERY.—

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

792 1. Hemorrhoidectomy.



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793 2. Hernia repair.
794 3. Large joint dislocations.
795 4. Colonoscopy.
796 5. Liposuction involving the removal of up to 4,000 cubic
797 centimeters of supernatant fat.
798 6. Any other procedure the board designates by rule as a
799 Level II office surgery.
800 7. Surgeries in which the patient's level of sedation is
801 that of moderate sedation and analgesia or conscious sedation.
802 As used in this subparagraph, the term "moderate sedation and
803 analgesia or conscious sedation" is a drug-induced depression of
804 consciousness during which patients respond purposefully to
805 verbal commands, either alone or accompanied by light tactile
806 stimulation; interventions are not required to maintain a patent
807 airway; spontaneous ventilation is adequate; and cardiovascular
808 function is maintained. For purposes of this term, reflex
809 withdrawal from a painful stimulus is not considered a
810 purposeful response.
811 (b) Standards of practice.—Standards of practice for Level
812 II office surgery include, but are not limited to, the
813 following:
814 1. The physician performing the surgery, or the office
815 where the procedure is being performed, must have a transfer
816 agreement with a licensed hospital within reasonable proximity
817 if the physician performing the procedure does not have staff
818 privileges to perform the same procedure as that being performed
819 in the office surgery setting at a licensed hospital within
820 reasonable proximity. The transfer agreement required by this
821 section must be current and have been entered into no more than



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822 3 years before the date of the office's most recent annual
823 inspection under s. 458.328. A transfer agreement must
824 affirmatively disclose an effective date and a termination date.

825 2. The physician performing the surgery must have staff
826 privileges at a licensed hospital to perform the same procedure
827 in that hospital as that being performed in the office surgery
828 setting or must be able to document satisfactory completion of
829 training, such as board certification or board eligibility by a
830 board approved by the American Board of Medical Specialties or
831 any other board approved by the Board of Medicine or Board of
832 Osteopathic Medicine, as applicable, or must be able to
833 establish comparable background, training, and experience. Such
834 board certification or comparable background, training, and
835 experience must also be directly related to and include the
836 procedures being performed by the physician in the office
837 surgery facility.

838 3. One assistant must be currently certified in basic life
839 support.

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

842 5. A complete and current crash cart must be available at
843 all times at the location where the anesthesia is being
844 administered. The designated physician of an office surgery is
845 responsible for ensuring that the crash cart is replenished
846 after each use, the expiration dates for the crash cart's
847 medications are checked weekly, and crash cart events are
848 documented in the cart's logs. Medicines must be stored per the
849 manufacturer's recommendations, and multidose vials must be
850 dated once opened and checked daily for expiration. The crash



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851 cart must, at a minimum, include the following intravenous or
852 inhaled medications:
853 a. Adenosine, 18 mg.
854 b. Albuterol, 2.5 mg with a small volume nebulizer.
855 c. Amiodarone, 300 mg.
856 d. Atropine, 3 mg.
857 e. Calcium chloride, 1 gram.
858 f. Dextrose, 50 percent; 50 ml.
859 g. Diphenhydramine, 50 mg.
860 h. Dopamine, 200 mg, minimum.
861 i. Epinephrine, 1 mg, in 10 ml.
862 j. Epinephrine, 1 mg in 1 ml vial, 3 vials total.
863 k. Flumazenil, 1 mg.
864 l. Furosemide, 40 mg.
865 m. Hydrocortisone, 100 mg.
866 n. Lidocaine appropriate for cardiac administration, 100
867 mg.
868 o. Magnesium sulfate, 2 grams.
869 p. Naloxone, 1.2 mg.
870 q. A beta blocker class drug.
871 r. Sodium bicarbonate, 50 mEq/50 ml.
872 s. Paralytic agent that is appropriate for use in rapid
873 sequence intubation.
874 t. A calcium channel blocker class drug.
875 u. If nonneuraxial regional blocks are performed,
876 Intralipid, 20 percent, 500 ml solution.
877 v. Any additional medication the board determines by rule
878 is warranted for patient safety and by the evolution of
879 technology and medical practice.



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880 6. In the event of a drug shortage, the designated
881 physician is authorized to substitute a therapeutically
882 equivalent drug that meets the prevailing practice standards.

883 7. The designated physician is responsible for ensuring
884 that the office maintains documentation of its unsuccessful
885 efforts to obtain the required drug.

886 8. The designated physician is responsible for ensuring
887 that the following are present in the office surgery:

888 a. A benzodiazepine.

889 b. A positive pressure ventilation device, such as Ambu,
890 plus oxygen supply.

891 c. An end-tidal carbon dioxide detection device.

892 d. Monitors for blood pressure, electrocardiography, and
893 oxygen saturation.

894 e. Emergency intubation equipment that must, at a minimum,
895 include suction devices, endotracheal tubes, working
896 laryngoscopes, oropharyngeal airways, nasopharyngeal airways,
897 and bag valve mask apparatus that are sized appropriately for
898 the specific patient.

899 f. A working defibrillator with defibrillator pads or
900 defibrillator gel, or an automated external defibrillator unit.

901 g. Sufficient backup power to allow the physician
902 performing the surgery to safely terminate the procedure and to
903 allow the patient to emerge from the anesthetic, all without
904 compromising the sterility of the procedure or the environment
905 of care.

906 h. Working sterilization equipment cultured weekly.

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



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

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

914 a. An anesthesiologist.

915 b. A certified registered nurse anesthetist.

916 c. A registered nurse, if the physician performing the
917 surgery is certified in advanced cardiac life support and the
918 registered nurse assists only with local anesthesia or conscious
919 sedation.

920
921 An anesthesiologist assistant may assist the anesthesiologist as
922 provided by board rule. An assisting anesthesia provider may not
923 function in any other capacity during the procedure.

924 10. If additional anesthesia assistance is required by the
925 specific procedure or patient circumstances, such assistance
926 must be provided by a physician, osteopathic physician,
927 registered nurse, licensed practical nurse, or operating room
928 technician.

929 11. The designated physician is responsible for ensuring
930 that each patient is monitored in the recovery room until the
931 patient is fully recovered from anesthesia. Such monitoring must
932 be provided by a licensed physician, physician assistant,
933 registered nurse with postanesthesia care unit experience, or
934 the equivalent who is currently certified in advanced cardiac
935 life support, or, in the case of pediatric patients, currently
936 certified in pediatric advanced life support.

937 (6) LEVEL II-A OFFICE SURGERY.-



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

942 (b) Standards of practice.—

943 1. All practice standards for Level II office surgery set
944 forth in paragraph (5) (b) must be met for Level II-A office
945 surgery except for the requirements set forth in subparagraph
946 (5) (b) 9. regarding assistance by a qualified anesthesia
947 provider.

948 2. During the surgical procedure, the physician performing
949 the surgery must be assisted by a licensed physician, physician
950 assistant, registered nurse, or licensed practical nurse.

951 3. Additional assistance may be required by specific
952 procedure or patient circumstances.

953 4. Following the procedure, a licensed physician, physician
954 assistant, or registered nurse must be available to monitor the
955 patient in the recovery room until the patient is recovered from
956 anesthesia. The monitoring provider must be currently certified
957 in advanced cardiac life support, or, in the case of pediatric
958 patients, currently certified in pediatric advanced life
959 support.

960 (7) LEVEL III OFFICE SURGERY.—

961 (a) Scope.—

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

966 a. "Deep sedation and analgesia" means a drug-induced



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967 depression of consciousness during which:
968 (I) Patients cannot be easily aroused but respond
969 purposefully following repeated or painful stimulation;
970 (II) The ability to independently maintain ventilatory
971 function may be impaired;
972 (III) Patients may require assistance in maintaining a
973 patent airway and spontaneous ventilation may be inadequate; and
974 (IV) Cardiovascular function is usually maintained.
975
976 For purposes of this sub-subparagraph, reflex withdrawal from a
977 painful stimulus is not considered a purposeful response.
978 b. "General anesthesia" means a drug-induced loss of
979 consciousness during which:
980 (I) Patients are not arousable, even by painful
981 stimulation;
982 (II) The ability to independently maintain ventilatory
983 function is often impaired;
984 (III) Patients often require assistance in maintaining a
985 patent airway and positive pressure ventilation may be required
986 because of depressed spontaneous ventilation or drug-induced
987 depression of neuromuscular function; and
988 (IV) Cardiovascular function may be impaired.
989 2. The use of spinal or epidural anesthesia for a procedure
990 requires that the procedure be considered a Level III office
991 surgery.
992 3. Only patients classified under the American Society of
993 Anesthesiologists' (ASA) risk classification criteria as Class I
994 or Class II are appropriate candidates for a Level III office
995 surgery.



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996 a. All Level III office surgeries on patients classified as
997 ASA III or higher must be performed only in a hospital or
998 ambulatory surgical center.

999 b. For all ASA II patients above the age of 50, the
1000 physician performing the surgery must obtain a complete workup
1001 performed before the performance of a Level III office surgery
1002 in the office surgery setting.

1003 c. If the patient has a cardiac history or is deemed to be
1004 a complicated medical patient, the patient must have a
1005 preoperative electrocardiogram and be referred to an appropriate
1006 consultant for medical optimization. The referral to a
1007 consultant may be waived after evaluation by the patient's
1008 anesthesiologist.

1009 (b) Standards of practice.—Practice standards for Level III
1010 office surgery include all Level II office surgery standards and
1011 all of the following requirements:

1012 1. The physician performing the surgery must have staff
1013 privileges at a licensed hospital to perform the same procedure
1014 in that hospital as that being performed in the office surgery
1015 setting or must be able to document satisfactory completion of
1016 training, such as board certification or board qualification by
1017 a board approved by the American Board of Medical Specialties or
1018 any other board approved by the Board of Medicine or Board of
1019 Osteopathic Medicine, as applicable, or must be able to
1020 demonstrate to the accrediting organization or to the department
1021 comparable background, training, and experience. Such board
1022 certification or comparable background, training, and experience
1023 must also be directly related to and include the procedure being
1024 performed by the physician performing the surgery in the office



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1025 surgery setting. In addition, the physician performing the
1026 surgery must have knowledge of the principles of general
1027 anesthesia.

1028 2. The physician performing the surgery must be currently
1029 certified in advanced cardiac life support.

1030 3. At least one operating assistant must be currently
1031 certified in basic life support.

1032 4. An emergency policy and procedures manual related to
1033 serious anesthesia complications must be available in the office
1034 surgery and reviewed biannually by the designated physician,
1035 practiced with staff, updated, and posted in a conspicuous
1036 location in the office. Topics to be covered in the manual must
1037 include all of the following:

1038 a. Airway blockage and foreign body obstruction.

1039 b. Allergic reactions.

1040 c. Bradycardia.

1041 d. Bronchospasm.

1042 e. Cardiac arrest.

1043 f. Chest pain.

1044 g. Hypoglycemia.

1045 h. Hypotension.

1046 i. Hypoventilation.

1047 j. Laryngospasm.

1048 k. Local anesthetic toxicity reaction.

1049 l. Malignant hyperthermia.

1050 m. Any other topics the board determines by rule are
1051 warranted for patient safety and by the evolution of technology
1052 and medical practice.

1053 5. An office surgery performing Level III office surgeries



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1054 must maintain all of the equipment and medications required for
1055 Level II office surgeries and comply with all of the following
1056 additional requirements:

1057 a. Maintain at least 720 mg of dantrolene on site if
1058 halogenated anesthetics or succinylcholine are used.

1059 b. Equipment and medication for monitored postanesthesia
1060 recovery must be available in the office.

1061 6. Anesthetic safety regulations must be developed, posted
1062 in a conspicuous location in the office, and enforced by the
1063 designated physician. Such regulations must include all of the
1064 following requirements:

1065 a. All operating room electrical and anesthesia equipment
1066 must be inspected at least semiannually, and a written record of
1067 the results and corrective actions must be maintained.

1068 b. Flammable anesthetic agents may not be employed in
1069 office surgery facilities.

1070 c. Electrical equipment in anesthetizing areas must be on
1071 an audiovisual line isolation monitor, with the exception of
1072 radiologic equipment and fixed lighting more than 5 feet above
1073 the floor.

1074 d. Each anesthesia gas machine must have a pin index safety
1075 system or equivalent safety system and a minimum oxygen flow
1076 safety device.

1077 e. All reusable anesthesia equipment in direct contact with
1078 a patient must be cleaned or sterilized as appropriate after
1079 each use.

1080 f. The following monitors must be applied to all patients
1081 receiving conduction or general anesthesia:

1082 (I) Blood pressure cuff.



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1083 (II) A continuous temperature device, readily available to
1084 measure the patient's temperature.

1085 (III) Pulse oximeter.

1086 (IV) Electrocardiogram.

1087 (V) An inspired oxygen concentration monitor and a
1088 capnograph, for patients receiving general anesthesia.

1089 g. Emergency intubation equipment must be available in all
1090 office surgery suites.

1091 h. Surgical tables must be capable of Trendelenburg and
1092 other positions necessary to facilitate surgical procedures.

1093 i. An anesthesiologist, a certified registered nurse
1094 anesthetist, an anesthesiologist assistant, or a physician
1095 assistant qualified as set forth in board rule must administer
1096 the general or regional anesthesia.

1097 j. A physician, a registered nurse, a licensed practical
1098 nurse, a physician assistant, or an operating room technician
1099 must assist with the surgery. The anesthesia provider may not
1100 function in any other capacity during the procedure.

1101 k. The patient must be monitored in the recovery room until
1102 he or she has fully recovered from anesthesia. The monitoring
1103 must be provided by a physician, a physician assistant, a
1104 certified registered nurse anesthetist, an anesthesiologist
1105 assistant, or a registered nurse with postanesthesia care unit
1106 experience or the equivalent who is currently certified in
1107 advanced cardiac life support, or, in the case of pediatric
1108 patients, currently certified in pediatric advanced life
1109 support.

1110 (8) EXEMPTION.—This section does not apply to a physician
1111 who is dually licensed as a dentist under chapter 466 when he or



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1112 she is performing dental procedures that fall within the scope
1113 of practice of dentistry and are regulated under chapter 466.

1114 (9) RULEMAKING.—The board may adopt by rule additional
1115 standards of practice for physicians who perform office
1116 surgeries or procedures under this section as warranted for
1117 patient safety and by the evolution of technology and medical
1118 practice.

1119 Section 3. Section 459.0138, Florida Statutes, is amended
1120 to read:

1121 459.0138 Office surgeries.—

1122 (1) REGISTRATION.—

1123 (a)~~1~~. An office in which a physician performs or intends to
1124 perform a liposuction procedure in which more than 1,000 cubic
1125 centimeters of supernatant fat is temporarily or permanently
1126 removed, a liposuction procedure during which the patient is
1127 rotated between the supine, lateral, and prone positions, a
1128 Level II office surgery, or a Level III office surgery must
1129 register with the department. ~~unless the office is licensed as A~~
1130 facility licensed under chapter 390 or chapter 395 may not be
1131 registered under this section.

1132 (b)~~2~~. The department must complete an inspection of any
1133 office seeking registration under this section before the office
1134 may be registered.

1135 1. The inspection of the office seeking registration under
1136 this section must include inspection for compliance with the
1137 standards of practice set out in this section and s. 458.3281
1138 and any applicable board rules for the levels of office surgery
1139 and procedures listed on the application which any physician
1140 practicing at the office performs or intends to perform. The



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1141 application must be updated within 10 calendar days before any
1142 additional surgical procedures or levels of office surgery are
1143 to be performed at the office. Failure to timely update the
1144 application for any such additional surgical procedures or
1145 levels of office surgery is a violation of this section and
1146 subject to discipline under ss. 456.072 and 459.015.

1147 2. The department must immediately suspend the registration
1148 process of an office that refuses an inspection under
1149 subparagraph 1., and the applicant must be required to reapply
1150 for registration.

1151 3. If the department determines that an office seeking
1152 registration under this section is one in which a physician may
1153 perform, or intends to perform, liposuction procedures that
1154 include a patient being rotated between the supine, lateral, and
1155 prone positions during the procedure, or in which a physician
1156 may perform, or intends to perform, gluteal fat grafting
1157 procedures, the office must provide proof to the department that
1158 it has met the applicable requirements of s. 469 of the Florida
1159 Building Code, relating to office surgery suites, and s.
1160 458.3281 and the applicable rules adopted thereunder, and the
1161 department must inspect the office to ensure that all of the
1162 following are present or in place:

1163 a. Equipment and a procedure for measuring and documenting
1164 in a log the amount of supernatant fat removed, both temporarily
1165 and permanently, from a particular patient, including tissue
1166 disposal procedures.

1167 b. A procedure for measuring and documenting the amount of
1168 lidocaine injected for tumescent liposuction, if used.

1169 c. Working ultrasound guidance equipment or other guidance



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1170 technology authorized under board rule which equals or exceeds
1171 the quality of ultrasound guidance.

1172 d. The office procedure for obtaining blood products.

1173 e. Documentation on file at the office demonstrating that
1174 any physician performing these procedures has privileges to
1175 perform such procedures in a hospital no more than 20 minutes
1176 away.

1177 f. Procedures for emergency resuscitation and transport to
1178 a hospital.

1179 g. Procedures for anesthesia and surgical recordkeeping.

1180 h. Any additional inspection requirements, as set by board
1181 rule.

1182 4. If an applicant is unable to provide proof to the
1183 department that the office seeking registration is in compliance
1184 with the applicable requirements of s. 469 of the Florida
1185 Building Code, relating to office surgery suites, or s. 459.0139
1186 or the applicable rules adopted thereunder, in accordance with
1187 subparagraph 3., the department must notify the Agency for
1188 Health Care Administration and request the agency to inspect the
1189 office and consult with the office about the process to apply
1190 for ambulatory surgical center licensure under chapter 395 and
1191 how the office may seek qualification for such licensure,
1192 notwithstanding the office's failure to meet all requirements
1193 associated with such licensure at the time of inspection and
1194 notwithstanding any pertinent exceptions provided under s.
1195 395.002(3).

1196 (c)(b) To be By January 1, 2020, each office registered
1197 under this section or s. 458.328, an office must, at the time of
1198 application, list a designated ~~designate~~ a physician who is



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1199 responsible for the office's compliance with the office health
1200 and safety requirements of this section and rules adopted
1201 hereunder. A designated physician must have a full, active, and
1202 unencumbered license under this chapter or chapter 458 and shall
1203 practice at the office for which he or she has assumed
1204 responsibility. Within 10 calendar days after the termination of
1205 a designated physician relationship, the office must notify the
1206 department of the designation of another physician to serve as
1207 the designated physician. The department may not register an
1208 office if the office fails to comply with this requirement at
1209 the time of application and must seek an emergency suspension of
1210 the ~~suspend~~ a registration of ~~for~~ an office pursuant to s.
1211 456.074(6) if the office fails to timely notify the department
1212 of its new designated physician within 10 calendar days after
1213 the termination of the previous designated physician
1214 relationship ~~comply with the requirements of this paragraph.~~

1215 (d) As a condition of registration, each office must, at
1216 the time of application, list all medical personnel who will be
1217 practicing at the office, including all of the following:

1218 1. Physicians who intend to practice surgery or assist in
1219 surgery at the office seeking registration, including their
1220 respective license numbers and practice addresses.

1221 2. Anesthesia providers, including their license numbers.

1222 3. Nursing personnel licensed under chapter 464, including
1223 their license numbers unless already provided under subparagraph
1224 2.

1225 4. Physician assistants, including their respective license
1226 numbers and supervising physicians.

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1228 The office must notify the department of the addition or
1229 termination of any of the types of medical personnel specified
1230 under this paragraph within 10 calendar days before such
1231 addition or after such termination. Failure to timely notify the
1232 department of such addition or termination is a violation of
1233 this section and subject to discipline under ss. 456.072 and
1234 459.015.

1235 (e)~~(e)~~ As a condition of registration, each office must
1236 establish financial responsibility by demonstrating that it has
1237 met and continues to maintain, at a minimum, the same
1238 requirements applicable to physicians in ss. 458.320 and
1239 459.0085. Each physician practicing at an office registered
1240 under this section or s. 458.328 must meet the financial
1241 responsibility requirements under s. 458.320 or s. 459.0085, as
1242 applicable.

1243 (f)~~(d)~~ Each physician practicing or intending to practice
1244 at an office registered under this section or s. 458.328 must
1245 ~~shall~~ advise the board, in writing, within 10 calendar days
1246 before ~~after~~ beginning or after ending his or her practice at a
1247 ~~the~~ registered office, as applicable.

1248 (g)~~(e)~~¹. The department shall inspect a registered office
1249 at least annually, including a review of patient records,
1250 anesthesia logs, surgery logs, and liposuction logs, to ensure
1251 that the office is in compliance with this section and rules
1252 adopted hereunder unless the office is accredited in office-
1253 based surgery by the Joint Commission or other ~~a~~ nationally
1254 recognized accrediting agency approved by the board. The
1255 inspection may be unannounced, except for the inspection of an
1256 office that meets the description of a clinic specified in s.



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1257 459.0137(1)(a)3.h., and those wholly owned and operated
1258 physician offices described in s. 459.0137(1)(a)3.g. which
1259 perform procedures referenced in s. 459.0137(1)(a)3.h., which
1260 must be announced.

1261 (h)~~2-~~ The department must immediately suspend the
1262 registration of a registered office that refuses an inspection
1263 under paragraph (g) ~~subparagraph 1~~. The office must close during
1264 such suspension. The suspension must remain in effect for at
1265 least 14 consecutive days and may not terminate until the
1266 department issues a written declaration that the office may
1267 reopen following the department's completion of an inspection of
1268 the office.

1269 (i)~~(f)~~ The department may suspend or revoke the
1270 registration of an office in which a procedure or surgery
1271 identified in paragraph (a) is performed for failure of any of
1272 its physicians, owners, or operators to comply with this section
1273 and rules adopted hereunder or s. 458.328 and rules adopted
1274 thereunder. If an office's registration is revoked for any
1275 reason, the department may deny any person named in the
1276 registration documents of the office, including the persons who
1277 own or operate the office, individually or as part of a group,
1278 from registering an office to perform procedures or office
1279 surgeries pursuant to this section or s. 458.328 for 5 years
1280 after the revocation date.

1281 (j)~~(g)~~ The department may impose any penalty set forth in
1282 s. 456.072(2) against the designated physician for failure of
1283 the office to operate in compliance with the office health and
1284 safety requirements of this section and rules adopted hereunder
1285 or s. 458.328 and rules adopted thereunder.



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1286 ~~(h) A physician may only perform a procedure or surgery~~
1287 ~~identified in paragraph (a) in an office that is registered with~~
1288 ~~the department. The board shall impose a fine of \$5,000 per day~~
1289 ~~on a physician who performs a procedure or surgery in an office~~
1290 ~~that is not registered with the department.~~

1291 ~~(k)~~~~(i)~~ The actual costs of registration and inspection or
1292 accreditation must ~~shall~~ be paid by the person seeking to
1293 register and operate the office in which a procedure or surgery
1294 identified in paragraph (a) will be performed.

1295 (2) REGISTRATION UPDATE.—

1296 (a) An office that registered under this section before
1297 July 1, 2024, in which a physician performs liposuction
1298 procedures that include a patient being rotated between the
1299 supine, lateral, and prone positions during the procedure or in
1300 which a physician performs gluteal fat grafting procedures must
1301 provide a registration update to the department consistent with
1302 the requirements of the initial registration under subsection
1303 (1) no later than 30 days before the office surgery's next
1304 annual inspection.

1305 (b) Registration update inspections required under
1306 subsection (1) must be performed by the department on the date
1307 of the office surgery's next annual inspection.

1308 (c) During the registration update process, the office
1309 surgery may continue to operate under the original registration.

1310 (d) In order to provide an office surgery time to update to
1311 the requirements of subsection (1) and s. 459.0139, effective
1312 July 1, 2024, and the applicable provisions of s. 469 of the
1313 Florida Building Code, relating to office surgery suites, any
1314 office surgery registered under this section before July 1,



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1315 2024, whose annual inspection is due in July or August 2024, may
1316 request from the department, in writing, a 60-day postponement
1317 of the required annual inspection, which postponement must be
1318 granted.

1319 (e) All other requests to the department for a postponement
1320 of the registration update inspection required under this
1321 registration update process must be in writing and be approved
1322 by the chair of the Board of Medicine for good cause shown, and
1323 such postponement may not exceed 30 days.

1324 (3) STANDARDS OF PRACTICE.—

1325 (a) A physician performing a procedure or surgery in an
1326 office registered under this section must comply with the
1327 applicable provisions of s. 469 of the Florida Building Code,
1328 relating to office surgery suites, and the standards of practice
1329 for office surgery set forth in this section and s. 459.0139 and
1330 any applicable rules adopted thereunder.

1331 (b) A physician may not perform any surgery or procedure
1332 identified in paragraph (1) (a) in a setting other than an office
1333 registered under this section or a facility licensed under
1334 chapter 390 or chapter 395, as applicable. The board shall
1335 impose a fine of \$5,000 per incident on a physician who violates
1336 this paragraph performing a gluteal fat grafting procedure in an
1337 office surgery setting shall adhere to standards of practice
1338 pursuant to this subsection and rules adopted by the board.

1339 (c) ~~(b)~~ Office surgeries may not:

1340 1. Be a type of surgery that generally results in blood
1341 loss of more than 10 percent of estimated blood volume in a
1342 patient with a normal hemoglobin level;

1343 2. Require major or prolonged intracranial, intrathoracic,



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1344 abdominal, or joint replacement procedures, except for
1345 laparoscopic procedures;

1346 3. Involve major blood vessels and be performed with direct
1347 visualization by open exposure of the major blood vessel, except
1348 for percutaneous endovascular intervention; or

1349 4. Be emergent or life threatening.

1350 (d) ~~(e)~~ A physician performing a gluteal fat grafting
1351 procedure in an office surgery setting must comply with the
1352 applicable provisions of s. 469 of the Florida Building Code,
1353 relating to office surgery suites, and the standards of practice
1354 under this subsection and s. 459.0139 and applicable rules
1355 adopted thereunder, including, but not limited to, all of the
1356 following standards of practice:

1357 1. The A physician performing the a gluteal fat grafting
1358 procedure must conduct an in-person examination of the patient
1359 while physically present in the same room as the patient no
1360 later than the day before the procedure.

1361 2. Before a physician may delegate any duties during a
1362 gluteal fat grafting procedure, the patient must provide
1363 written, informed consent for such delegation. Any duty
1364 delegated by a physician during a gluteal fat grafting procedure
1365 must be performed under the direct supervision of the physician
1366 performing such procedure. Fat extraction and gluteal fat
1367 injections must be performed by the physician and may not be
1368 delegated.

1369 3. Fat may only be injected into the subcutaneous space of
1370 the patient and may not cross the fascia overlying the gluteal
1371 muscle. Intramuscular or submuscular fat injections are
1372 prohibited.



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1373 4. When the physician performing a gluteal fat grafting
1374 procedure injects fat into the subcutaneous space of the
1375 patient, the physician must use ultrasound guidance, or guidance
1376 with other technology authorized under board rule which equals
1377 or exceeds the quality of ultrasound, during the placement and
1378 navigation of the cannula to ensure that the fat is injected
1379 into the subcutaneous space of the patient above the fascia
1380 overlying the gluteal muscle. Such guidance with the use of
1381 ultrasound or other technology is not required for other
1382 portions of such procedure.

1383 5. An office in which a physician performs gluteal fat
1384 grafting procedures shall at all times maintain a ratio of one
1385 physician to one patient during all phases of the procedure,
1386 beginning with the administration of anesthesia to the patient
1387 and concluding with the extubation of the patient. After a
1388 physician has commenced, and while he or she is engaged in, a
1389 gluteal fat grafting procedure, the physician may not commence
1390 or engage in another gluteal fat grafting procedure or any other
1391 procedure with another patient at the same time.

1392 ~~(e)-(d)~~ If a procedure in an office surgery setting results
1393 in hospitalization, the incident must be reported as an adverse
1394 incident pursuant to s. 458.351.

1395 ~~(e) An office in which a physician performs gluteal fat~~
1396 ~~grafting procedures must at all times maintain a ratio of one~~
1397 ~~physician to one patient during all phases of the procedure,~~
1398 ~~beginning with the administration of anesthesia to the patient~~
1399 ~~and concluding with the extubation of the patient. After a~~
1400 ~~physician has commenced, and while he or she is engaged in, a~~
1401 ~~gluteal fat grafting procedure, the physician may not commence~~



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1402 ~~or engage in another gluteal fat grafting procedure or any other~~
1403 ~~procedure with another patient at the same time.~~

1404 (4) (3) RULEMAKING.—

1405 (a) The board may ~~shall~~ adopt by rule additional standards
1406 of practice for physicians who perform office procedures or
1407 ~~office~~ surgeries under ~~pursuant to~~ this section, as warranted
1408 for patient safety and by the evolution of technology and
1409 medical practice.

1410 (b) The board may adopt rules to administer the
1411 registration, registration update, inspection, and safety of
1412 offices in which a physician performs office procedures or
1413 ~~office~~ surgeries under ~~pursuant to~~ this section.

1414 Section 4. Section 459.0139, Florida Statutes, is created
1415 to read:

1416 459.0139 Standard of practice for office surgery.—

1417 (1) CONSTRUCTION.—This section does not relieve a physician
1418 performing a procedure or surgery from the responsibility of
1419 making the medical determination of whether an office is an
1420 appropriate setting in which to perform that particular
1421 procedure or surgery, taking into consideration the particular
1422 patient on which the procedure or surgery is to be performed.

1423 (2) DEFINITIONS.—As used in this section, the term:

1424 (a) "Certified in advanced cardiac life support" means a
1425 person holds a current certification in an advanced cardiac life
1426 support course with didactic and skills components, approved by
1427 the American Heart Association, the American Safety and Health
1428 Institute, the American Red Cross, Pacific Medical Training, or
1429 the Advanced Cardiovascular Life Support (ACLS) Certification
1430 Institute.



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1431 (b) "Certified in basic life support" means a person holds
1432 a current certification in a basic life support course with
1433 didactic and skills components, approved by the American Heart
1434 Association, the American Safety and Health Institute, the
1435 American Red Cross, Pacific Medical Training, or the ACLS
1436 Certification Institute.

1437 (c) "Certified in pediatric advanced life support" means a
1438 person holds a current certification in a pediatric advanced
1439 life support course with didactic and skills components approved
1440 by the American Heart Association, the American Safety and
1441 Health Institute, or Pacific Medical Training.

1442 (d) "Continual monitoring" means monitoring that is
1443 repeated regularly and frequently in steady, rapid succession.

1444 (e) "Continuous" means monitoring that is prolonged without
1445 any interruption at any time.

1446 (f) "Equipment" means a medical device, instrument, or tool
1447 used to perform specific actions or take certain measurements
1448 during, or while a patient is recovering from, a procedure or
1449 surgery which must meet current performance standards according
1450 to its manufacturer's guidelines for the specific device,
1451 instrument, or tool, as applicable.

1452 (g) "Major blood vessels" means a group of critical
1453 arteries and veins, including the aorta, coronary arteries,
1454 pulmonary arteries, superior and inferior vena cava, pulmonary
1455 veins, and any intra-cerebral artery or vein.

1456 (h) "Office surgery" means a physician's office in which
1457 surgical procedures are performed by a physician for the
1458 practice of medicine as authorized by this section and board
1459 rule. The office must be an office at which a physician



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1460 regularly performs consultations with surgical patients,
1461 preoperative examinations, and postoperative care, as
1462 necessitated by the standard of care related to the surgeries
1463 performed at the physician's office, and at which patient
1464 records are readily maintained and available. The types of
1465 procedures or surgeries performed in an office surgery are those
1466 which need not be performed in a facility licensed under chapter
1467 390 or chapter 395, and are not of the type that:

1468 1. Generally result in blood loss of more than 10 percent
1469 of estimated blood volume in a patient with a normal hemoglobin
1470 count;

1471 2. Require major or prolonged intracranial, intrathoracic,
1472 abdominal, or major joint replacement procedures, except for
1473 laparoscopic procedures;

1474 3. Involve major blood vessels and are performed with
1475 direct visualization by open exposure of the major vessel,
1476 except for percutaneous endovascular intervention; or

1477 4. Are generally emergent or life threatening in nature.

1478 (i) "Pediatric patient" means a patient who is 13 years of
1479 age or younger.

1480 (j) "Percutaneous endovascular intervention" means a
1481 procedure performed without open direct visualization of the
1482 target vessel and which requires only needle puncture of an
1483 artery or vein followed by insertion of catheters, wires, or
1484 similar devices that are then advanced through the blood vessels
1485 using imaging guidance. Once the catheter reaches the intended
1486 location, various maneuvers to address the diseased area may be
1487 performed, including, but not limited to, injection of contrast
1488 medium for imaging; treatment of vessels with angioplasty;



1489 atherectomy; covered or uncovered stenting; embolization or
1490 intentionally occluding vessels or organs; and delivering
1491 medications or radiation or other energy, such as laser,
1492 radiofrequency, or cryo.

1493 (k) "Reasonable proximity" means a distance that does not
1494 exceed 20 minutes of transport time to the hospital.

1495 (l) "Surgery" means any manual or operative procedure
1496 performed upon the body of a living human being, including, but
1497 not limited to, those performed with the use of lasers, for the
1498 purposes of preserving health, diagnosing or curing disease,
1499 repairing injury, correcting a deformity or defect, prolonging
1500 life, or relieving suffering, or any elective procedure for
1501 aesthetic, reconstructive, or cosmetic purposes. The term
1502 includes, but is not limited to, incision or curettage of tissue
1503 or an organ; suture or other repair of tissue or an organ,
1504 including a closed as well as an open reduction of a fracture;
1505 extraction of tissue, including premature extraction of the
1506 products of conception from the uterus; insertion of natural or
1507 artificial implants; or an endoscopic procedure with use of
1508 local or general anesthetic.

1509 (3) GENERAL REQUIREMENTS FOR OFFICE SURGERY.—

1510 (a) The physician performing the surgery must examine the
1511 patient immediately before the surgery to evaluate the risk of
1512 anesthesia and of the surgical procedure to be performed. The
1513 physician performing the surgery may delegate the preoperative
1514 heart and lung evaluation to a qualified anesthesia provider
1515 within the scope of the provider's practice and, if applicable,
1516 protocol.

1517 (b) The physician performing the surgery shall maintain



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1518 complete patient records of each surgical procedure performed,
1519 which must include all of the following:

1520 1. The patient's name, patient number, preoperative
1521 diagnosis, postoperative diagnosis, surgical procedure,
1522 anesthetic, anesthesia records, recovery records, and
1523 complications, if any.

1524 2. The name of each member of the surgical team, including
1525 the surgeon, first assistant, anesthesiologist, nurse
1526 anesthetist, anesthesiologist assistant, circulating nurse, and
1527 operating room technician, as applicable.

1528 (c) Each office surgery's designated physician shall ensure
1529 that the office surgery has procedures in place to verify that
1530 all of the following have occurred before any surgery is
1531 performed:

1532 1. The patient has signed the informed consent form for the
1533 procedure reflecting the patient's knowledge of identified risks
1534 of the procedure, consent to the procedure, the type of
1535 anesthesia and anesthesia provider to be used during the
1536 procedure, and the fact that the patient may choose the type of
1537 anesthesia provider for the procedure, such as an
1538 anesthesiologist, a certified registered nurse anesthetist, a
1539 physician assistant, an anesthesiologist assistant, or another
1540 appropriately trained physician as provided by board rule.

1541 2. The patient's identity has been verified.

1542 3. The operative site has been verified.

1543 4. The operative procedure to be performed has been
1544 verified with the patient.

1545 5. All of the information and actions required to be
1546 verified under this paragraph are documented in the patient's



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1547 medical record.

1548 (d) With respect to the requirements set forth in paragraph

1549 (c), written informed consent is not necessary for minor Level I

1550 procedures limited to the skin and mucosa.

1551 (e) The physician performing the surgery shall maintain a

1552 log of all liposuction procedures performed at the office

1553 surgery where more than 1,000 cubic centimeters of supernatant

1554 fat is temporarily or permanently removed and where Level II and

1555 Level III surgical procedures are performed. The log must, at a

1556 minimum, include all of the following:

1557 1. A confidential patient identifier.

1558 2. Time of arrival in the operating suite.

1559 3. The name of the physician performing the procedure.

1560 4. The patient's diagnosis, CPT codes used for the

1561 procedure, the patient's classification for risk with anesthesia

1562 according to the American Society of Anesthesiologists' physical

1563 status classification system, and the type of procedure and

1564 level of surgery performed.

1565 5. Documentation of completion of the medical clearance

1566 performed by the anesthesiologist or the physician performing

1567 the surgery.

1568 6. The name and provider type of the anesthesia provider

1569 and the type of anesthesia used.

1570 7. The duration of the procedure.

1571 8. Any adverse incidents as identified in s. 458.351.

1572 9. The type of postoperative care, duration of recovery,

1573 disposition of the patient upon discharge, including the address

1574 of where the patient is being discharged, discharge

1575 instructions, and list of medications used during surgery and



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1576 recovery.

1577

1578 All surgical and anesthesia logs must be kept at the office
1579 surgery and maintained for 6 years after the date of last
1580 patient contact and must be provided to department investigators
1581 upon request.

1582 (f) For any liposuction procedure, the physician performing
1583 the surgery is responsible for determining the appropriate
1584 amount of supernatant fat to be removed from a particular
1585 patient. A maximum of 4,000 cubic centimeters of supernatant fat
1586 may be removed by liposuction in the office surgery setting. A
1587 maximum of 50mg/kg of lidocaine may be injected for tumescent
1588 liposuction in the office surgery setting.

1589 (g)1. Liposuction may be performed in combination with
1590 another separate surgical procedure during a single Level II or
1591 Level III surgical procedure only in the following
1592 circumstances:

1593 a. When combined with an abdominoplasty, liposuction may
1594 not exceed 1,000 cubic centimeters of supernatant fat.

1595 b. When liposuction is associated and directly related to
1596 another procedure, the liposuction may not exceed 1,000 cubic
1597 centimeters of supernatant fat.

1598 2. Major liposuction in excess of 1,000 cubic centimeters
1599 of supernatant fat may not be performed on a patient's body in a
1600 location that is remote from the site of another procedure being
1601 performed on that patient.

1602 (h) For elective cosmetic and plastic surgery procedures
1603 performed in a physician's office, the maximum planned duration
1604 of all surgical procedures combined may not exceed 8 hours.



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1605 Except for elective cosmetic and plastic surgery, the physician
1606 performing the surgery may not keep patients past midnight in a
1607 physician's office. For elective cosmetic and plastic surgical
1608 procedures, the patient must be discharged within 24 hours after
1609 presenting to the office for surgery. However, an overnight stay
1610 is allowed in the office if the total time the patient is at the
1611 office does not exceed 23 hours and 59 minutes, including the
1612 surgery time. An overnight stay in a physician's office for
1613 elective cosmetic and plastic surgery must be strictly limited
1614 to the physician's office. If the patient has not recovered
1615 sufficiently to be safely discharged within the timeframes set
1616 forth, the patient must be transferred to a hospital for
1617 continued postoperative care.

1618 (i) The American Society of Anesthesiologists Standards for
1619 Basic Anesthetic Monitoring are hereby adopted and incorporated
1620 by reference as the standards for anesthetic monitoring by any
1621 qualified anesthesia provider under this section.

1622 1. These standards apply to general anesthetics, regional
1623 anesthetics, and monitored Level II and III anesthesia care.
1624 However, in emergency circumstances, appropriate life support
1625 measures take priority. These standards may be exceeded at any
1626 time based on the judgment of the responsible supervising
1627 physician or anesthesiologist. While these standards are
1628 intended to encourage quality patient care, observing them does
1629 not guarantee any specific patient outcome. This set of
1630 standards addresses only the issue of basic anesthesia
1631 monitoring, which is only one component of anesthesia care.

1632 2. In certain rare or unusual circumstances, some of these
1633 methods of monitoring may be clinically impractical, and



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1634 appropriate use of the described monitoring methods may fail to
1635 detect adverse clinical developments. In such cases, a brief
1636 interruption of continual monitoring may be unavoidable and does
1637 not by itself constitute a violation of the standards of
1638 practice of this section.

1639 3. Under extenuating circumstances, the physician
1640 performing the surgery or the anesthesiologist may waive the
1641 following requirements:

1642 a. The use of an oxygen analyzer with a low oxygen
1643 concentration limit alarm, or other technology authorized under
1644 board rule which equals or exceeds the quality of the oxygen
1645 analyzer, during the administration of general anesthesia with
1646 an anesthesia machine.

1647 b. The use of pulse oximetry with a variable pitch pulse
1648 tone and an audible low threshold alarm, or other technology
1649 authorized under board rule which equals or exceeds the quality
1650 of a pulse oximeter, and the use of adequate illumination and
1651 exposure of the patient to assess color.

1652 c. The use of capnography, capnometry, or mass
1653 spectroscopy, or other technology authorized under board rule
1654 which equals or exceeds the quality of capnography, capnometry,
1655 or mass spectroscopy, as a quantitative method of analyzing the
1656 end-tidal carbon dioxide for continual monitoring for the
1657 presence of expired carbon dioxide during ventilation, from the
1658 time of the endotracheal tube or supraglottic airway placement
1659 until extubation or removal or initiating transfer of the
1660 patient to a postoperative care location.

1661 d. The use of continuous electrocardiogram display, or
1662 other technology authorized under board rule which equals or



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1663 exceeds the quality of electrocardiogram display, from the
1664 beginning of anesthesia until preparing to leave the
1665 anesthetizing location.

1666 e. The measuring of arterial blood pressure and heart rate
1667 evaluated at least every 5 minutes during anesthesia.

1668
1669 When any of the monitoring is waived for extenuating
1670 circumstances under this subparagraph, it must be documented in
1671 a note in the patient's medical record, including the reasons
1672 for the need to waive the requirement. These standards are not
1673 intended for the application to the care of an obstetrical
1674 patient in labor or in the conduct of pain management.

1675 (j)1. Because of the rapid changes in patient status during
1676 anesthesia, qualified anesthesia personnel must be continuously
1677 present in the room to provide anesthesia care for the entire
1678 duration of all general anesthetics, regional anesthetics, and
1679 monitored anesthesia care conducted on the patient. In the event
1680 that there is a direct known hazard, such as radiation, to the
1681 anesthesia personnel which might require intermittent remote
1682 observation of the patient, some provision for monitoring the
1683 patient must be made. In the event that an emergency requires
1684 the temporary absence of the person primarily responsible for
1685 the anesthesia, the best judgment of the supervising physician
1686 or anesthesiologist shall be exercised in comparing the
1687 emergency with the anesthetized patient's condition and in the
1688 selection of the person left responsible for the anesthesia
1689 during the temporary absence.

1690 2. During all anesthesia, the patient's oxygenation,
1691 ventilation, circulation, and temperature must be continually



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1692 evaluated to ensure adequate oxygen concentration in the
1693 inspired gas and the blood.

1694 a. During all general anesthesia using an anesthesia
1695 machine, the concentration of oxygen in the patient's breathing
1696 system must be measured by an oxygen analyzer with a low oxygen
1697 concentration limit alarm used to measure blood oxygenation.

1698 b. During all anesthesia, a quantitative method of
1699 assessing oxygenation, such as pulse oximetry, must be employed.
1700 When a pulse oximeter is used, the variable pitch pulse tone and
1701 the low threshold alarm must be audible to the qualified
1702 anesthesia provider. Adequate illumination and exposure of the
1703 patient are necessary to assess color.

1704 c. During all anesthesia, every patient must have the
1705 adequacy of his or her ventilation continually evaluated,
1706 including, but not limited to, the evaluation of qualitative
1707 clinical signs, such as chest excursion, observation of the
1708 reservoir breathing bag, and auscultation of breath sounds.
1709 Continual monitoring for the presence of expired carbon dioxide
1710 must be performed unless invalidated by the nature of the
1711 patient's condition, the procedure, or the equipment.
1712 Quantitative monitoring of the volume of expired gas must also
1713 be performed.

1714 d. When an endotracheal tube or supraglottic airway is
1715 inserted, its correct positioning must be verified by clinical
1716 assessment and by identification of carbon dioxide in the
1717 expired gas. Continual end-tidal carbon dioxide analysis, in use
1718 from the time of endotracheal tube or supraglottic airway
1719 placement until extubation or removal or initiating transfer of
1720 the patient to a postoperative care location, must be performed



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1721 using a quantitative method, such as capnography, capnometry, or
1722 mass spectroscopy, or other technology authorized under board
1723 rule which equals or exceeds the quality of capnography,
1724 capnometry, or mass spectroscopy. When capnography or capnometry
1725 is used, the end-tidal carbon dioxide alarm must be audible to
1726 the qualified anesthesia provider.

1727 e. When ventilation is controlled by a mechanical
1728 ventilator, there must be in continuous use a device capable of
1729 detecting disconnection of components of the breathing system.
1730 The device must give an audible signal when its alarm threshold
1731 is exceeded.

1732 f. During regional anesthesia without sedation or local
1733 anesthesia with no sedation, the adequacy of ventilation must be
1734 evaluated by continual observation of qualitative clinical
1735 signs. During moderate or deep sedation, the adequacy of
1736 ventilation must be evaluated by continual observation of
1737 qualitative clinical signs. Monitoring for the presence of
1738 exhaled carbon dioxide is recommended.

1739 g. Every patient receiving anesthesia must have the
1740 electrocardiogram or other technology authorized under board
1741 rule which equals or exceeds the quality of electrocardiogram
1742 continuously displayed from the beginning of anesthesia until
1743 preparing to leave the anesthetizing location.

1744 h. Every patient receiving anesthesia must have arterial
1745 blood pressure and heart rate determined and evaluated at least
1746 every 5 minutes.

1747 i. Every patient receiving general anesthesia must have
1748 circulatory function continually evaluated by at least one of
1749 the following methods:



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1750 (I) Palpation of a pulse.
1751 (II) Auscultation of heart sounds.
1752 (III) Monitoring of a tracing of intra-arterial pressure.
1753 (IV) Ultrasound peripheral pulse monitoring.
1754 (V) Pulse plethysmography or oximetry.
1755 (VI) Other technology authorized under board rule which
1756 equals or exceeds the quality of any of the methods listed in
1757 sub-sub-subparagraphs (I)-(V).

1758 j. Every patient receiving anesthesia must have his or her
1759 temperature monitored when clinically significant changes in
1760 body temperature are intended, anticipated, or suspected.

1761 (k)1. The physician performing the surgery shall ensure
1762 that the postoperative care arrangements made for the patient
1763 are adequate for the procedure being performed, as required by
1764 board rule.

1765 2. Management of postoperative care is the responsibility
1766 of the physician performing the surgery and may be delegated as
1767 determined by board rule. If the physician performing the
1768 surgery is unavailable to provide postoperative care, the
1769 physician performing the surgery must notify the patient of his
1770 or her unavailability for postoperative care before the
1771 procedure.

1772 3. If there is an overnight stay at the office in relation
1773 to any surgical procedure:

1774 a. The office must provide at least two persons to act as
1775 monitors, one of whom must be certified in advanced cardiac life
1776 support, and maintain a monitor-to-patient ratio of at least one
1777 monitor to two patients.

1778 b. Once the physician performing the surgery has signed a



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1779 timed and dated discharge order, the office may provide only one
1780 monitor to monitor the patient. The monitor must be qualified by
1781 licensure and training to administer all of the medications
1782 required on the crash cart and must be certified in advanced
1783 cardiac life support.

1784 c. A complete and current crash cart must be present in the
1785 office surgery and immediately accessible for the monitors.

1786 4. The physician performing the surgery must be reachable
1787 by telephone and readily available to return to the office if
1788 needed.

1789 5. A policy and procedures manual must be maintained in the
1790 office at which Level II and Level III procedures are performed.
1791 The manual must be updated and implemented annually. The policy
1792 and procedures manual must provide for all of the following:

1793 a. Duties and responsibilities of all personnel.

1794 b. A quality assessment and improvement system designed to
1795 objectively and systematically monitor and evaluate the quality
1796 and appropriateness of patient care and opportunities to improve
1797 performance.

1798 c. Cleaning procedures and protocols.

1799 d. Sterilization procedures.

1800 e. Infection control procedures and personnel
1801 responsibilities.

1802 f. Emergency procedures.

1803 6. The designated physician shall establish a risk
1804 management program that includes all of the following
1805 components:

1806 a. The identification, investigation, and analysis of the
1807 frequency and causes of adverse incidents.



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1808 b. The identification of trends or patterns of adverse
1809 incidents.

1810 c. The development of appropriate measures to correct,
1811 reduce, minimize, or eliminate the risk of adverse incidents.

1812 d. The documentation of such functions and periodic review
1813 of such information at least quarterly by the designated
1814 physician.

1815 7. The designated physician shall report to the department
1816 any adverse incidents that occur within the scope of office
1817 surgeries. This report must be made within 15 days after the
1818 occurrence of an incident as required by s. 458.351.

1819 8. The designated physician is responsible for prominently
1820 posting a sign in the office which states that the office is a
1821 doctor's office regulated under this section and ss. 458.328,
1822 458.3281, and 459.0138 and the applicable rules of the Board of
1823 Medicine and the Board of Osteopathic Medicine as set forth in
1824 rules 64B8 and 64B15, Florida Administrative Code. This notice
1825 must also appear prominently within the required patient
1826 informed consent form.

1827 9. All physicians performing surgery at the office surgery
1828 must be qualified by education, training, and experience to
1829 perform any procedure the physician performs in the office
1830 surgery.

1831 10. When Level II, Level II-A, or Level III procedures are
1832 performed in an office surgery setting, the physician performing
1833 the surgery is responsible for providing the patient, in
1834 writing, before the procedure, with the name and location of the
1835 hospital where the physician performing the surgery has
1836 privileges to perform the same procedure as the one being



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1837 performed in the office surgery setting or the name and location
1838 of the hospital with which the physician performing the surgery
1839 has a transfer agreement in the event of an emergency.

1840 (4) LEVEL I OFFICE SURGERY.-

1841 (a) Scope.-Level I office surgery includes the following:

1842 1. Minor procedures such as excision of skin lesions,
1843 moles, warts, cysts, or lipomas and repair of lacerations or
1844 surgery limited to the skin and subcutaneous tissue which are
1845 performed under topical or local anesthesia not involving drug-
1846 induced alteration of consciousness other than minimal pre-
1847 operative tranquilization of the patient.

1848 2. Liposuction involving the removal of less than 4,000
1849 cubic centimeters of supernatant fat.

1850 3. Incision and drainage of superficial abscesses; limited
1851 endoscopies, such as proctoscopies, skin biopsies,
1852 arthrocentesis, thoracentesis, paracentesis, dilation of the
1853 urethra, cystoscopic procedures, and closed reduction of simple
1854 fractures; or small joint dislocations, such as in the finger or
1855 toe joints.

1856 4. Procedures in which anesthesia is limited to minimal
1857 sedation. The patient's level of sedation must be that of
1858 minimal sedation and anxiolysis, and the chances of
1859 complications requiring hospitalization must be remote. As used
1860 in this sub-subparagraph, the term "minimal sedation and
1861 anxiolysis" means a drug-induced state during which patients
1862 respond normally to verbal commands, and although cognitive
1863 function and physical coordination may be impaired, airway
1864 reflexes and ventilatory and cardiovascular functions remain
1865 unaffected. Controlled substances, as defined in ss. 893.02 and



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1866 893.03, must be limited to oral administration in doses
1867 appropriate for the unsupervised treatment of insomnia, anxiety,
1868 or pain.

1869 5. Procedures for which chances of complications requiring
1870 hospitalization are remote as specified in board rule.

1871 (b) Standards of practice.—Standards of practice for Level
1872 I office surgery include all of the following:

1873 1. The medical education, training, and experience of the
1874 physician performing the surgery must include training on proper
1875 dosages and management of toxicity or hypersensitivity to
1876 regional anesthetic drugs, and the physician must be certified
1877 in advanced cardiac life support.

1878 2. At least one operating assistant must be certified in
1879 basic life support.

1880 3. Intravenous access supplies, oxygen, oral airways, and a
1881 positive pressure ventilation device must be available in the
1882 office surgery, along with the following medications, stored per
1883 the manufacturer's recommendation:

1884 a. Atropine, 3 mg.

1885 b. Diphenhydramine, 50 mg.

1886 c. Epinephrine, 1 mg in 10 ml.

1887 d. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

1888 e. Hydrocortisone, 100 mg.

1889 f. If a benzodiazepine is administered, flumazenil, 0.5 mg
1890 in 5 ml vial, 2 vials total.

1891 g. If an opiate is administered, naloxone, 0.4 mg in 1 ml
1892 vial, 2 vials total.

1893 4. When performing minor procedures, such as excision of
1894 skin lesions, moles, warts, cysts, or lipomas and repair of



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1895 lacerations or surgery limited to the skin and subcutaneous
1896 tissue performed under topical or local anesthesia in an office
1897 surgery setting, physicians performing the procedure are exempt
1898 from subparagraphs 1.-3. Current certification in basic life
1899 support is recommended but not required.

1900 5. A physician performing the surgery need not have an
1901 assistant during the procedure unless the specific procedure
1902 being performed requires an assistant.

1903 (5) LEVEL II OFFICE SURGERY.—

1904 (a) Scope.—Level II office surgery includes, but is not
1905 limited to, all of the following procedures:

1906 1. Hemorrhoidectomy.

1907 2. Hernia repair.

1908 3. Large joint dislocations.

1909 4. Colonoscopy.

1910 5. Liposuction involving the removal of up to 4,000 cubic
1911 centimeters of supernatant fat.

1912 6. Any other procedure the board designates by rule as a
1913 Level II office surgery.

1914 7. Surgeries in which the patient's level of sedation is
1915 that of moderate sedation and analgesia or conscious sedation.

1916 As used in this subparagraph, the term "moderate sedation and
1917 analgesia or conscious sedation" is a drug-induced depression of
1918 consciousness during which patients respond purposefully to
1919 verbal commands, either alone or accompanied by light tactile
1920 stimulation; interventions are not required to maintain a patent
1921 airway; spontaneous ventilation is adequate; and cardiovascular
1922 function is maintained. For purposes of this term, reflex
1923 withdrawal from a painful stimulus is not considered a



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1924 purposeful response.

1925 (b) Standards of practice.—Standards of practice for Level
1926 II office surgery include, but are not limited to, the
1927 following:

1928 1. The physician performing the surgery, or the office
1929 where the procedure is being performed, must have a transfer
1930 agreement with a licensed hospital within reasonable proximity
1931 if the physician performing the procedure does not have staff
1932 privileges to perform the same procedure as that being performed
1933 in the office surgery setting at a licensed hospital within
1934 reasonable proximity. The transfer agreement required by this
1935 section must be current and have been entered into no more than
1936 3 years before the date of the office's most recent annual
1937 inspection under s. 459.0138. A transfer agreement must
1938 affirmatively disclose an effective date and a termination date.

1939 2. The physician performing the surgery must have staff
1940 privileges at a licensed hospital to perform the same procedure
1941 in that hospital as that being performed in the office surgery
1942 setting or must be able to document satisfactory completion of
1943 training, such as board certification or board eligibility by a
1944 board approved by the American Board of Medical Specialties or
1945 any other board approved by the Board of Medicine or Board of
1946 Osteopathic Medicine, as applicable, or must be able to
1947 establish comparable background, training, and experience. Such
1948 board certification or comparable background, training, and
1949 experience must also be directly related to and include the
1950 procedures being performed by the physician in the office
1951 surgery facility.

1952 3. One assistant must be currently certified in basic life



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1953 support.
1954 4. The physician performing the surgery must be currently
1955 certified in advanced cardiac life support.
1956 5. A complete and current crash cart must be available at
1957 all times at the location where the anesthesia is being
1958 administered. The designated physician of an office surgery is
1959 responsible for ensuring that the crash cart is replenished
1960 after each use, the expiration dates for the crash cart's
1961 medications are checked weekly, and crash cart events are
1962 documented in the cart's logs. Medicines must be stored per the
1963 manufacturer's recommendations, and multidose vials must be
1964 dated once opened and checked daily for expiration. The crash
1965 cart must, at a minimum, include the following intravenous or
1966 inhaled medications:
1967 a. Adenosine, 18 mg.
1968 b. Albuterol, 2.5 mg with a small volume nebulizer.
1969 c. Amiodarone, 300 mg.
1970 d. Atropine, 3 mg.
1971 e. Calcium chloride, 1 gram.
1972 f. Dextrose, 50 percent; 50 ml.
1973 g. Diphenhydramine, 50 mg.
1974 h. Dopamine, 200 mg, minimum.
1975 i. Epinephrine, 1 mg, in 10 ml.
1976 j. Epinephrine, 1 mg in 1 ml vial, 3 vials total.
1977 k. Flumazenil, 1 mg.
1978 l. Furosemide, 40 mg.
1979 m. Hydrocortisone, 100 mg.
1980 n. Lidocaine appropriate for cardiac administration, 100
1981 mg.



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- 1982 o. Magnesium sulfate, 2 grams.
- 1983 p. Naloxone, 1.2 mg.
- 1984 q. A beta blocker class drug.
- 1985 r. Sodium bicarbonate, 50 mEq/50 ml.
- 1986 s. Paralytic agent that is appropriate for use in rapid
1987 sequence intubation.
- 1988 t. A calcium channel blocker class drug.
- 1989 u. If nonneuraxial regional blocks are performed,
1990 Intralipid, 20 percent, 500 ml solution.
- 1991 v. Any additional medication the board determines by rule
1992 is warranted for patient safety and by the evolution of
1993 technology and medical practice.
- 1994 6. In the event of a drug shortage, the designated
1995 physician is authorized to substitute a therapeutically
1996 equivalent drug that meets the prevailing practice standards.
- 1997 7. The designated physician is responsible for ensuring
1998 that the office maintains documentation of its unsuccessful
1999 efforts to obtain the required drug.
- 2000 8. The designated physician is responsible for ensuring
2001 that the following are present in the office surgery:
- 2002 a. A benzodiazepine.
- 2003 b. A positive pressure ventilation device, such as Ambu,
2004 plus oxygen supply.
- 2005 c. An end-tidal carbon dioxide detection device.
- 2006 d. Monitors for blood pressure, electrocardiography, and
2007 oxygen saturation.
- 2008 e. Emergency intubation equipment that must, at a minimum,
2009 include suction devices, endotracheal tubes, working
2010 laryngoscopes, oropharyngeal airways, nasopharyngeal airways,



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2011 and bag valve mask apparatus that are sized appropriately for
2012 the specific patient.

2013 f. A working defibrillator with defibrillator pads or
2014 defibrillator gel, or an automated external defibrillator unit.

2015 g. Sufficient backup power to allow the physician
2016 performing the surgery to safely terminate the procedure and to
2017 allow the patient to emerge from the anesthetic, all without
2018 compromising the sterility of the procedure or the environment
2019 of care.

2020 h. Working sterilization equipment cultured weekly.

2021 i. Sufficient intravenous solutions and equipment for a
2022 minimum of a week's worth of surgical cases.

2023 j. Any other equipment required by board rule, as warranted
2024 by the evolution of technology and medical practice.

2025 9. The physician performing the surgery must be assisted by
2026 a qualified anesthesia provider, which may include any of the
2027 following types of providers:

2028 a. An anesthesiologist.

2029 b. A certified registered nurse anesthetist.

2030 c. A registered nurse, if the physician performing the
2031 surgery is certified in advanced cardiac life support and the
2032 registered nurse assists only with local anesthesia or conscious
2033 sedation.

2034
2035 An anesthesiologist assistant may assist the anesthesiologist as
2036 provided by board rule. An assisting anesthesia provider may not
2037 function in any other capacity during the procedure.

2038 10. If additional anesthesia assistance is required by the
2039 specific procedure or patient circumstances, such assistance



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2040 must be provided by a physician, osteopathic physician,
2041 registered nurse, licensed practical nurse, or operating room
2042 technician.

2043 11. The designated physician is responsible for ensuring
2044 that each patient is monitored in the recovery room until the
2045 patient is fully recovered from anesthesia. Such monitoring must
2046 be provided by a licensed physician, physician assistant,
2047 registered nurse with postanesthesia care unit experience, or
2048 the equivalent who is currently certified in advanced cardiac
2049 life support, or, in the case of pediatric patients, currently
2050 certified in pediatric advanced life support.

2051 (6) LEVEL II-A OFFICE SURGERY.—

2052 (a) Scope.—Level II-A office surgeries are those Level II
2053 office surgeries that have a maximum planned duration of 5
2054 minutes or less and in which the chances of complications
2055 requiring hospitalization are remote.

2056 (b) Standards of practice.—

2057 1. All practice standards for Level II office surgery set
2058 forth in paragraph (5) (b) must be met for Level II-A office
2059 surgery except for the requirements set forth in subparagraph
2060 (5) (b) 9. regarding assistance by a qualified anesthesia
2061 provider.

2062 2. During the surgical procedure, the physician performing
2063 the surgery must be assisted by a licensed physician, physician
2064 assistant, registered nurse, or licensed practical nurse.

2065 3. Additional assistance may be required by specific
2066 procedure or patient circumstances.

2067 4. Following the procedure, a licensed physician, physician
2068 assistant, or registered nurse must be available to monitor the



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2069 patient in the recovery room until the patient is recovered from
2070 anesthesia. The monitoring provider must be currently certified
2071 in advanced cardiac life support, or, in the case of pediatric
2072 patients, currently certified in pediatric advanced life
2073 support.

2074 (7) LEVEL III OFFICE SURGERY.—

2075 (a) Scope.—

2076 1. Level III office surgery includes those types of surgery
2077 during which the patient's level of sedation is that of deep
2078 sedation and analgesia or general anesthesia. As used in this
2079 subparagraph, the term:

2080 a. "Deep sedation and analgesia" means a drug-induced
2081 depression of consciousness during which:

2082 (I) Patients cannot be easily aroused but respond
2083 purposefully following repeated or painful stimulation;

2084 (II) The ability to independently maintain ventilatory
2085 function may be impaired;

2086 (III) Patients may require assistance in maintaining a
2087 patent airway and spontaneous ventilation may be inadequate; and

2088 (IV) Cardiovascular function is usually maintained.

2089
2090 For purposes of this sub-subparagraph, reflex withdrawal from a
2091 painful stimulus is not considered a purposeful response.

2092 b. "General anesthesia" means a drug-induced loss of
2093 consciousness during which:

2094 (I) Patients are not arousable, even by painful
2095 stimulation;

2096 (II) The ability to independently maintain ventilatory
2097 function is often impaired;



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2098 (III) Patients often require assistance in maintaining a
2099 patent airway and positive pressure ventilation may be required
2100 because of depressed spontaneous ventilation or drug-induced
2101 depression of neuromuscular function; and

2102 (IV) Cardiovascular function may be impaired.

2103 2. The use of spinal or epidural anesthesia for a procedure
2104 requires that the procedure be considered a Level III office
2105 surgery.

2106 3. Only patients classified under the American Society of
2107 Anesthesiologists' (ASA) risk classification criteria as Class I
2108 or Class II are appropriate candidates for a Level III office
2109 surgery.

2110 a. All Level III office surgeries on patients classified as
2111 ASA III or higher must be performed only in a hospital or
2112 ambulatory surgical center.

2113 b. For all ASA II patients above the age of 50, the
2114 physician performing the surgery must obtain a complete workup
2115 performed before the performance of a Level III office surgery
2116 in the office surgery setting.

2117 c. If the patient has a cardiac history or is deemed to be
2118 a complicated medical patient, the patient must have a
2119 preoperative electrocardiogram and be referred to an appropriate
2120 consultant for medical optimization. The referral to a
2121 consultant may be waived after evaluation by the patient's
2122 anesthesiologist.

2123 (b) Standards of practice.—Practice standards for Level III
2124 office surgery include all Level II office surgery standards and
2125 all of the following requirements:

2126 1. The physician performing the surgery must have staff



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2127 privileges at a licensed hospital to perform the same procedure
2128 in that hospital as that being performed in the office surgery
2129 setting or must be able to document satisfactory completion of
2130 training, such as board certification or board qualification by
2131 a board approved by the American Board of Medical Specialties or
2132 any other board approved by the Board of Medicine or Board of
2133 Osteopathic Medicine, as applicable, or must be able to
2134 demonstrate to the accrediting organization or to the department
2135 comparable background, training, and experience. Such board
2136 certification or comparable background, training, and experience
2137 must also be directly related to and include the procedure being
2138 performed by the physician performing the surgery in the office
2139 surgery setting. In addition, the physician performing the
2140 surgery must have knowledge of the principles of general
2141 anesthesia.

2142 2. The physician performing the surgery must be currently
2143 certified in advanced cardiac life support.

2144 3. At least one operating assistant must be currently
2145 certified in basic life support.

2146 4. An emergency policy and procedures manual related to
2147 serious anesthesia complications must be available in the office
2148 surgery and reviewed biannually by the designated physician,
2149 practiced with staff, updated, and posted in a conspicuous
2150 location in the office. Topics to be covered in the manual must
2151 include all of the following:

2152 a. Airway blockage and foreign body obstruction.

2153 b. Allergic reactions.

2154 c. Bradycardia.

2155 d. Bronchospasm.



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- 2156 e. Cardiac arrest.
- 2157 f. Chest pain.
- 2158 g. Hypoglycemia.
- 2159 h. Hypotension.
- 2160 i. Hypoventilation.
- 2161 j. Laryngospasm.
- 2162 k. Local anesthetic toxicity reaction.
- 2163 l. Malignant hyperthermia.
- 2164 m. Any other topics the board determines by rule are
2165 warranted for patient safety and by the evolution of technology
2166 and medical practice.
- 2167 5. An office surgery performing Level III office surgeries
2168 must maintain all of the equipment and medications required for
2169 Level II office surgeries and comply with all of the following
2170 additional requirements:
- 2171 a. Maintain at least 720 mg of dantrolene on site if
2172 halogenated anesthetics or succinylcholine are used.
- 2173 b. Equipment and medication for monitored postanesthesia
2174 recovery must be available in the office.
- 2175 6. Anesthetic safety regulations must be developed, posted
2176 in a conspicuous location in the office, and enforced by the
2177 designated physician. Such regulations must include all of the
2178 following requirements:
- 2179 a. All operating room electrical and anesthesia equipment
2180 must be inspected at least semiannually, and a written record of
2181 the results and corrective actions must be maintained.
- 2182 b. Flammable anesthetic agents may not be employed in
2183 office surgery facilities.
- 2184 c. Electrical equipment in anesthetizing areas must be on



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2185 an audiovisual line isolation monitor, with the exception of
2186 radiologic equipment and fixed lighting more than 5 feet above
2187 the floor.

2188 d. Each anesthesia gas machine must have a pin index safety
2189 system or equivalent safety system and a minimum oxygen flow
2190 safety device.

2191 e. All reusable anesthesia equipment in direct contact with
2192 a patient must be cleaned or sterilized as appropriate after
2193 each use.

2194 f. The following monitors must be applied to all patients
2195 receiving conduction or general anesthesia:

2196 (I) Blood pressure cuff.

2197 (II) A continuous temperature device, readily available to
2198 measure the patient's temperature.

2199 (III) Pulse oximeter.

2200 (IV) Electrocardiogram.

2201 (V) An inspired oxygen concentration monitor and a
2202 capnograph, for patients receiving general anesthesia.

2203 g. Emergency intubation equipment must be available in all
2204 office surgery suites.

2205 h. Surgical tables must be capable of Trendelenburg and
2206 other positions necessary to facilitate surgical procedures.

2207 i. An anesthesiologist, a certified registered nurse
2208 anesthetist, an anesthesiologist assistant, or a physician
2209 assistant qualified as set forth in board rule must administer
2210 the general or regional anesthesia.

2211 j. A physician, a registered nurse, a licensed practical
2212 nurse, a physician assistant, or an operating room technician
2213 must assist with the surgery. The anesthesia provider may not



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2214 function in any other capacity during the procedure.

2215 k. The patient must be monitored in the recovery room until
2216 he or she has fully recovered from anesthesia. The monitoring
2217 must be provided by a physician, a physician assistant, a
2218 certified registered nurse anesthetist, an anesthesiologist
2219 assistant, or a registered nurse with postanesthesia care unit
2220 experience or the equivalent who is currently certified in
2221 advanced cardiac life support, or, in the case of pediatric
2222 patients, currently certified in pediatric advanced life
2223 support.

2224 (8) EXEMPTION.—This section does not apply to a physician
2225 who is dually licensed as a dentist under chapter 466 when he or
2226 she is performing dental procedures that fall within the scope
2227 of practice of dentistry and are regulated under chapter 466.

2228 (9) RULEMAKING.—The board may adopt by rule additional
2229 standards of practice for physicians who perform office
2230 surgeries or procedures under this section as warranted for
2231 patient safety and by the evolution of technology and medical
2232 practice.

2233 Section 5. Subsection (6) of section 456.074, Florida
2234 Statutes, is amended to read

2235 456.074 Certain health care practitioners; immediate
2236 suspension of license.—

2237 (6) The department must issue an emergency order suspending
2238 or restricting the registration of an office registered under s.
2239 458.328 or s. 459.0138 ~~s. 459.0139~~ upon a finding of probable
2240 cause that the office or a physician practicing in the office is
2241 not in compliance with the standards of practice for office
2242 surgery adopted by the boards pursuant to s. 458.328 or s.



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2243 459.0138, as applicable, or is in violation of s. 458.331(1)(v)
2244 or s. 459.015(1)(z), and that such noncompliance or violation
2245 constitutes an immediate danger to the public.

2246 Section 6. This act shall take effect upon becoming a law.
2247

2248 ===== T I T L E A M E N D M E N T =====

2249 And the title is amended as follows:

2250 Delete everything before the enacting clause
2251 and insert:

2252 A bill to be entitled
2253 An act relating to office surgeries; amending ss.
2254 458.328 and 459.0138, F.S.; revising the types of
2255 procedures for which a medical office must register
2256 with the Department of Health to perform office
2257 surgeries; specifying inspection procedures for such
2258 offices seeking registration with the department;
2259 requiring that certain offices seeking registration
2260 provide proof to the department that they have met
2261 specified requirements and rules; requiring the
2262 department to inspect such offices to ensure that
2263 certain equipment and procedures are present or in
2264 place; requiring the department to notify the Agency
2265 for Health Care Administration if an applicant is
2266 unable to provide certain proof to the department and
2267 to request that the agency inspect and consult with
2268 the office; deleting obsolete language; providing that
2269 the department may not register and must seek an
2270 emergency suspension of an office under specified
2271 circumstances; requiring that each office, as a



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2272 condition of registration, list certain medical
2273 personnel and thereafter notify the department of the
2274 addition or termination of such personnel within a
2275 specified timeframe; providing for disciplinary action
2276 for failure to comply; revising the materials that the
2277 department must review when inspecting a registered
2278 office; requiring offices already registered with the
2279 department as of a specified date to provide a
2280 registration update within a specified timeframe;
2281 specifying requirements for such registration update
2282 process; revising requirements for the standards of
2283 practice for office surgeries; providing an
2284 administrative penalty; revising rulemaking
2285 requirements; creating ss. 458.3281 and 459.0139,
2286 F.S.; providing construction; defining terms;
2287 specifying general requirements for office surgeries;
2288 specifying standards of practice for office surgeries,
2289 delineated by the level of surgery being performed;
2290 providing an exemption; authorizing the Board of
2291 Medicine and the Board of Osteopathic Medicine, as
2292 applicable, to adopt additional standards of practice
2293 by rule; amending s. 456.074, F.S.; correcting a
2294 cross-reference; providing an effective date.