



148378

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
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 perform a liposuction procedure in which more than 1,000 cubic



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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~~ 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  
39 perform, or intends to perform, liposuction procedures that



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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.

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)  
97 if the office fails to timely notify the department of its new



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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  
126 under this section or s. 459.0138 must meet the financial



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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)~~<sup>1</sup>. 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)<sup>2</sup>. 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.

155 (i)~~(f)~~ The department may suspend or revoke the



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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  
184 procedures that include a patient being rotated between the



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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  
213 applicable provisions of s. 469 of the Florida Building Code,





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214 relating to office surgery suites, and the standards of practice  
215 for office surgery set forth in this section and s. 458.3281, as  
216 applicable, and 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) ~~(c)~~ 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  
242 following standards of practice:



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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  
271 physician to one patient during all phases of the procedure,



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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.

300 Section 2. Section 458.3281, Florida Statutes, is created



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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  
329 repeated regularly and frequently in steady, rapid succession.



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330 (e) "Continuous monitoring" means monitoring that is  
331 prolonged without 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,  
358 abdominal, or major joint replacement procedures, except for



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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 requires only needle puncture of an artery or  
369 vein followed by insertion of catheters, wires, or similar  
370 devices that are then advanced through the blood vessels using  
371 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 30 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, relieving suffering, or any elective procedure for  
387 aesthetic, reconstructive, or cosmetic purposes. The term



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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  
416 all of the following have occurred before any surgery is



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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.

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





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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  
474 liposuction in the office surgery setting.



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

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

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

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

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

503 (i) The Standards of the American Society of



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504 Anesthesiologists for Basic Anesthetic Monitoring are hereby  
505 adopted and incorporated by reference as the standards for  
506 anesthetic monitoring by any qualified anesthesia provider under  
507 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  
532 an anesthesia machine.



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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.

561           (j)1. Because of the rapid changes in patient status during



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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.

590 c. During all anesthesia, every patient must have the



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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  
619 anesthesia with no sedation, the adequacy of ventilation must be



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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  
648 that the postoperative care arrangements made for the patient



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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.  
677 The manual must be updated and implemented annually. The policy





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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  
706 posting a sign in the office which states that the office is a



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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, and the name and  
724 location of the hospital with which the physician performing the  
725 surgery 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  
735 cubic centimeters of supernatant fat.



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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.

764 2. At least one operating assistant must be certified in



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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.

793 2. Hernia repair.



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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, a patient  
809 reflexively withdrawing from a painful stimulus is not  
810 considered a 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  
822 3 years before the date of the office's most recent annual



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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 must be  
832 able to establish comparable background, training, and  
833 experience. Such board certification or comparable background,  
834 training, and experience must also be directly related to and  
835 include the procedures being performed by the physician in the  
836 office surgery facility.

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

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

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



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



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881 equivalent drug that meets the prevailing practice standards.

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

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

887 a. A benzodiazepine.

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

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

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

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

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

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

905 h. Working sterilization equipment cultured weekly.

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

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





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

913 a. An anesthesiologist.

914 b. A certified registered nurse anesthetist.

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

919

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

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

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

936 (6) LEVEL II-A OFFICE SURGERY.—

937 (a) Scope.—Level II-A office surgeries are those Level II  
938 office surgeries that have a maximum planned duration of 5



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939 minutes or less and in which the chances of complications  
940 requiring hospitalization are remote.

941 (b) Standards of practice.—

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

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

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

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

959 (7) LEVEL III OFFICE SURGERY.—

960 (a) Scope.—

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

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

967 (I) Patients cannot be easily aroused but respond



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968 purposefully following repeated or painful stimulation;  
969 (II) The ability to independently maintain ventilatory  
970 function may be impaired;  
971 (III) Patients may require assistance in maintaining a  
972 patent airway and spontaneous ventilation may be inadequate; and  
973 (IV) Cardiovascular function is usually maintained.  
974  
975 For purposes of this sub-subparagraph, a reflexive withdrawal  
976 from a painful stimulus by a patient is not considered a  
977 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.  
996 a. All Level III office surgeries on patients classified as



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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 must be  
1019 able to demonstrate to the accrediting organization or to the  
1020 department comparable background, training, and experience. Such  
1021 board certification or comparable background, training, and  
1022 experience must also be directly related to and include the  
1023 procedure being performed by the physician performing the  
1024 surgery in the office surgery setting. In addition, the  
1025 physician performing the surgery must have knowledge of the



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1026 principles of general anesthesia.  
1027 2. The physician performing the surgery must be currently  
1028 certified in advanced cardiac life support.  
1029 3. At least one operating assistant must be currently  
1030 certified in basic life support.  
1031 4. An emergency policy and procedures manual related to  
1032 serious anesthesia complications must be available in the office  
1033 surgery and reviewed biannually by the designated physician,  
1034 practiced with staff, updated, and posted in a conspicuous  
1035 location in the office. Topics to be covered in the manual must  
1036 include all of the following:  
1037 a. Airway blockage and foreign body obstruction.  
1038 b. Allergic reactions.  
1039 c. Bradycardia.  
1040 d. Bronchospasm.  
1041 e. Cardiac arrest.  
1042 f. Chest pain.  
1043 g. Hypoglycemia.  
1044 h. Hypotension.  
1045 i. Hypoventilation.  
1046 j. Laryngospasm.  
1047 k. Local anesthetic toxicity reaction.  
1048 l. Malignant hyperthermia.  
1049 m. Any other topics the board determines by rule are  
1050 warranted for patient safety and by the evolution of technology  
1051 and medical practice.  
1052 5. An office surgery performing Level III office surgeries  
1053 must maintain all of the equipment and medications required for  
1054 Level II office surgeries and comply with all of the following



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1055 additional requirements:

1056 a. Maintain at least 720 mg of dantrolene on site if

1057 halogenated anesthetics or succinylcholine are used.

1058 b. Equipment and medication for monitored postanesthesia

1059 recovery must be available in the office.

1060 6. Anesthetic safety regulations must be developed, posted

1061 in a conspicuous location in the office, and enforced by the

1062 designated physician. Such regulations must include all of the

1063 following requirements:

1064 a. All operating room electrical and anesthesia equipment

1065 must be inspected at least semiannually, and a written record of

1066 the results and corrective actions must be maintained.

1067 b. Flammable anesthetic agents may not be employed in

1068 office surgery facilities.

1069 c. Electrical equipment in anesthetizing areas must be on

1070 an audiovisual line isolation monitor, with the exception of

1071 radiologic equipment and fixed lighting more than 5 feet above

1072 the floor.

1073 d. Each anesthesia gas machine must have a pin-index system

1074 or equivalent safety system and a minimum oxygen flow safety

1075 device.

1076 e. All reusable anesthesia equipment in direct contact with

1077 a patient must be cleaned or sterilized as appropriate after

1078 each use.

1079 f. The following monitors must be applied to all patients

1080 receiving conduction or general anesthesia:

1081 (I) Blood pressure cuff.

1082 (II) A continuous temperature device, readily available to

1083 measure the patient's temperature.



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1084        (III) Pulse oximeter.  
1085        (IV) Electrocardiogram.  
1086        (V) An inspired oxygen concentration monitor and a  
1087 capnograph, for patients receiving general anesthesia.  
1088        g. Emergency intubation equipment must be available in all  
1089 office surgery suites.  
1090        h. Surgical tables must be capable of Trendelenburg and  
1091 other positions necessary to facilitate surgical procedures.  
1092        i. An anesthesiologist, a certified registered nurse  
1093 anesthetist, an anesthesiologist assistant, or a physician  
1094 assistant qualified as set forth in board rule must administer  
1095 the general or regional anesthesia.  
1096        j. A physician, a registered nurse, a licensed practical  
1097 nurse, a physician assistant, or an operating room technician  
1098 must assist with the surgery. The anesthesia provider may not  
1099 function in any other capacity during the procedure.  
1100        k. The patient must be monitored in the recovery room until  
1101 he or she has fully recovered from anesthesia. The monitoring  
1102 must be provided by a physician, a physician assistant, a  
1103 certified registered nurse anesthetist, an anesthesiologist  
1104 assistant, or a registered nurse with postanesthesia care unit  
1105 experience or the equivalent who is currently certified in  
1106 advanced cardiac life support, or, in the case of pediatric  
1107 patients, currently certified in pediatric advanced life  
1108 support.  
1109        (8) RULEMAKING.—The board may adopt by rule additional  
1110 standards of practice for physicians who perform office  
1111 surgeries or procedures under this section as warranted for  
1112 patient safety and by the evolution of technology and medical



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1113 practice.

1114 Section 3. Section 459.0138, Florida Statutes, is amended  
1115 to read:

1116 459.0138 Office surgeries.—

1117 (1) REGISTRATION.—

1118 (a)~~1~~. An office in which a physician performs or intends to  
1119 perform a liposuction procedure in which more than 1,000 cubic  
1120 centimeters of supernatant fat is temporarily or permanently  
1121 removed, a liposuction procedure during which the patient is  
1122 rotated between the supine, lateral, and prone positions, a  
1123 Level II office surgery, or a Level III office surgery must  
1124 register with the department. ~~unless the office is licensed as a~~ A  
1125 facility licensed under chapter 390 or chapter 395 may not be  
1126 registered under this section.

1127 (b)~~2~~. The department must complete an inspection of any  
1128 office seeking registration under this section before the office  
1129 may be registered.

1130 1. The inspection of the office seeking registration under  
1131 this section must include inspection for compliance with the  
1132 standards of practice set out in this section and s. 458.3281  
1133 and any applicable board rules for the levels of office surgery  
1134 and procedures listed on the application which any physician  
1135 practicing at the office performs or intends to perform. The  
1136 application must be updated within 10 calendar days before any  
1137 additional surgical procedures or levels of office surgery are  
1138 to be performed at the office. Failure to timely update the  
1139 application for any such additional surgical procedures or  
1140 levels of office surgery is a violation of this section and  
1141 subject to discipline under ss. 456.072 and 459.015.





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1142           2. The department must immediately suspend the registration  
1143 process of an office that refuses an inspection under  
1144 subparagraph 1., and the applicant must be required to reapply  
1145 for registration.

1146           3. If the department determines that an office seeking  
1147 registration under this section is one in which a physician may  
1148 perform, or intends to perform, liposuction procedures that  
1149 include a patient being rotated between the supine, lateral, and  
1150 prone positions during the procedure, or in which a physician  
1151 may perform, or intends to perform, gluteal fat grafting  
1152 procedures, the office must provide proof to the department that  
1153 it has met the applicable requirements of s. 469 of the Florida  
1154 Building Code, relating to office surgery suites, and s.  
1155 458.3281 and the applicable rules adopted thereunder, and the  
1156 department must inspect the office to ensure that all of the  
1157 following are present or in place:

1158           a. Equipment and a procedure for measuring and documenting  
1159 in a log the amount of supernatant fat removed, both temporarily  
1160 and permanently, from a particular patient, including tissue  
1161 disposal procedures.

1162           b. A procedure for measuring and documenting the amount of  
1163 lidocaine injected for tumescent liposuction, if used.

1164           c. Working ultrasound guidance equipment or other guidance  
1165 technology authorized under board rule which equals or exceeds  
1166 the quality of ultrasound guidance.

1167           d. The office procedure for obtaining blood products.

1168           e. Documentation on file at the office demonstrating that  
1169 any physician performing these procedures has privileges to  
1170 perform such procedures in a hospital no more than 20 minutes



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1171 away.  
1172 f. Procedures for emergency resuscitation and transport to  
1173 a hospital.  
1174 g. Procedures for anesthesia and surgical recordkeeping.  
1175 h. Any additional inspection requirements, as set by board  
1176 rule.  
1177 4. If an applicant is unable to provide proof to the  
1178 department that the office seeking registration is in compliance  
1179 with the applicable requirements of s. 469 of the Florida  
1180 Building Code, relating to office surgery suites, or s. 459.0139  
1181 or the applicable rules adopted thereunder, in accordance with  
1182 subparagraph 3., the department must notify the Agency for  
1183 Health Care Administration and request the agency to inspect the  
1184 office and consult with the office about the process to apply  
1185 for ambulatory surgical center licensure under chapter 395 and  
1186 how the office may seek qualification for such licensure,  
1187 notwithstanding the office's failure to meet all requirements  
1188 associated with such licensure at the time of inspection and  
1189 notwithstanding any pertinent exceptions provided under s.  
1190 395.002(3).  
1191 (c)(b) To be By January 1, 2020, each office registered  
1192 under this section or s. 458.328, an office must, at the time of  
1193 application, list a designated designate a physician who is  
1194 responsible for the office's compliance with the office health  
1195 and safety requirements of this section and rules adopted  
1196 hereunder. A designated physician must have a full, active, and  
1197 unencumbered license under this chapter or chapter 458 and shall  
1198 practice at the office for which he or she has assumed  
1199 responsibility. Within 10 calendar days after the termination of



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1200 a designated physician relationship, the office must notify the  
1201 department of the designation of another physician to serve as  
1202 the designated physician. The department may not register an  
1203 office if the office fails to comply with this requirement at  
1204 the time of application and must seek an emergency suspension of  
1205 the ~~suspend~~ a registration of ~~for~~ an office pursuant to s.  
1206 456.074(6) if the office fails to timely notify the department  
1207 of its new designated physician within 10 calendar days after  
1208 the termination of the previous designated physician  
1209 relationship ~~comply with the requirements of this paragraph.~~

1210 (d) As a condition of registration, each office must, at  
1211 the time of application, list all medical personnel who will be  
1212 practicing at the office, including all of the following:

1213 1. Physicians who intend to practice surgery or assist in  
1214 surgery at the office seeking registration, including their  
1215 respective license numbers and practice addresses.

1216 2. Anesthesia providers, including their license numbers.

1217 3. Nursing personnel licensed under chapter 464, including  
1218 their license numbers unless already provided under subparagraph  
1219 2.

1220 4. Physician assistants, including their respective license  
1221 numbers and supervising physicians.

1222  
1223 The office must notify the department of the addition or  
1224 termination of any of the types of medical personnel specified  
1225 under this paragraph within 10 calendar days before such  
1226 addition or after such termination. Failure to timely notify the  
1227 department of such addition or termination is a violation of  
1228 this section and subject to discipline under ss. 456.072 and



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1229 459.015.

1230 (e)~~(e)~~ As a condition of registration, each office must  
1231 establish financial responsibility by demonstrating that it has  
1232 met and continues to maintain, at a minimum, the same  
1233 requirements applicable to physicians in ss. 458.320 and  
1234 459.0085. Each physician practicing at an office registered  
1235 under this section or s. 458.328 must meet the financial  
1236 responsibility requirements under s. 458.320 or s. 459.0085, as  
1237 applicable.

1238 (f)~~(d)~~ Each physician practicing or intending to practice  
1239 at an office registered under this section or s. 458.328 must  
1240 ~~shall~~ advise the board, in writing, within 10 calendar days  
1241 before ~~after~~ beginning or after ending his or her practice at a  
1242 ~~the~~ registered office, as applicable.

1243 (g)~~(e)~~<sup>1</sup>. The department shall inspect a registered office  
1244 at least annually, including a review of patient records, to  
1245 ensure that the office is in compliance with this section and  
1246 rules adopted hereunder unless the office is accredited in  
1247 office-based surgery by the Joint Commission or other a  
1248 nationally recognized accrediting agency approved by the board.  
1249 The inspection may be unannounced, except for the inspection of  
1250 an office that meets the description of a clinic specified in s.  
1251 459.0137(1)(a)3.h., and those wholly owned and operated  
1252 physician offices described in s. 459.0137(1)(a)3.g. which  
1253 perform procedures referenced in s. 459.0137(1)(a)3.h., which  
1254 must be announced.

1255 (h)<sup>2</sup>~~2~~. The department must immediately suspend the  
1256 registration of a registered office that refuses an inspection  
1257 under paragraph (g) ~~subparagraph 1~~. The office must close during



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1258 such suspension. The suspension must remain in effect for at  
1259 least 14 consecutive days and may not terminate until the  
1260 department issues a written declaration that the office may  
1261 reopen following the department's completion of an inspection of  
1262 the office.

1263 (i)~~(f)~~ The department may suspend or revoke the  
1264 registration of an office in which a procedure or surgery  
1265 identified in paragraph (a) is performed for failure of any of  
1266 its physicians, owners, or operators to comply with this section  
1267 and rules adopted hereunder or s. 458.328 and rules adopted  
1268 thereunder. If an office's registration is revoked for any  
1269 reason, the department may deny any person named in the  
1270 registration documents of the office, including the persons who  
1271 own or operate the office, individually or as part of a group,  
1272 from registering an office to perform procedures or office  
1273 surgeries pursuant to this section or s. 458.328 for 5 years  
1274 after the revocation date.

1275 (j)~~(g)~~ The department may impose any penalty set forth in  
1276 s. 456.072(2) against the designated physician for failure of  
1277 the office to operate in compliance with the office health and  
1278 safety requirements of this section and rules adopted hereunder  
1279 or s. 458.328 and rules adopted thereunder.

1280 ~~(h) A physician may only perform a procedure or surgery  
1281 identified in paragraph (a) in an office that is registered with  
1282 the department. The board shall impose a fine of \$5,000 per day  
1283 on a physician who performs a procedure or surgery in an office  
1284 that is not registered with the department.~~

1285 (k)~~(i)~~ The actual costs of registration and inspection or  
1286 accreditation must ~~shall~~ be paid by the person seeking to



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1287 register and operate the office in which a procedure or surgery  
1288 identified in paragraph (a) will be performed.

1289 (2) REGISTRATION UPDATE.—

1290 (a) An office that registered under this section before  
1291 July 1, 2024, in which a physician performs liposuction  
1292 procedures that include a patient being rotated between the  
1293 supine, lateral, and prone positions during the procedure or in  
1294 which a physician performs gluteal fat grafting procedures must  
1295 provide a registration update to the department consistent with  
1296 the requirements of the initial registration under subsection  
1297 (1) no later than 30 days before the office surgery's next  
1298 annual inspection.

1299 (b) Registration update inspections required under  
1300 subsection (1) must be performed by the department on the date  
1301 of the office surgery's next annual inspection.

1302 (c) During the registration update process, the office  
1303 surgery may continue to operate under the original registration.

1304 (d) In order to provide an office surgery time to update to  
1305 the requirements of subsection (1) and s. 459.0139, effective  
1306 July 1, 2024, and the applicable provisions of s. 469 of the  
1307 Florida Building Code, relating to office surgery suites, any  
1308 office surgery registered under this section before July 1,  
1309 2024, whose annual inspection is due in July or August 2024, may  
1310 request from the department, in writing, a 60-day postponement  
1311 of the required annual inspection, which must be granted.

1312 (e) All other requests to the department for a postponement  
1313 of the required registration update inspection under this  
1314 registration update process must be in writing and be approved  
1315 by the chair of the Board of Medicine for good cause shown, and



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1316 such postponement may not exceed 30 days.

1317 (3) STANDARDS OF PRACTICE.—

1318 (a) A physician performing a procedure or surgery in an  
1319 office registered under this section must comply with the  
1320 applicable provisions of s. 469 of the Florida Building Code,  
1321 relating to office surgery suites, and the standards of practice  
1322 for office surgery set forth in this section and s. 459.0139.

1323 (b) A physician may not perform any surgery or procedure  
1324 identified in paragraph (1)(a) in a setting other than an office  
1325 registered under this section or a facility licensed under  
1326 chapter 390 or chapter 395, as applicable. The board shall  
1327 impose a fine of \$5,000 per incident on a physician who violates  
1328 this paragraph performing a gluteal fat grafting procedure in an  
1329 office surgery setting shall adhere to standards of practice  
1330 pursuant to this subsection and rules adopted by the board.

1331 (c) ~~(b)~~ Office surgeries may not:

1332 1. Be a type of surgery that generally results in blood  
1333 loss of more than 10 percent of estimated blood volume in a  
1334 patient with a normal hemoglobin level;

1335 2. Require major or prolonged intracranial, intrathoracic,  
1336 abdominal, or joint replacement procedures, except for  
1337 laparoscopic procedures;

1338 3. Involve major blood vessels and be performed with direct  
1339 visualization by open exposure of the major blood vessel, except  
1340 for percutaneous endovascular intervention; or

1341 4. Be emergent or life threatening.

1342 (d) ~~(c)~~ A physician performing a gluteal fat grafting  
1343 procedure in an office surgery setting must comply with the  
1344 applicable provisions of s. 469 of the Florida Building Code,



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1345 relating to office surgery suites, and the standards of practice  
1346 under this subsection and s. 459.0139 and applicable rules  
1347 adopted thereunder, including, but not limited to, all of the  
1348 following standards of practice:

1349       1. The A physician performing the a gluteal fat grafting  
1350 procedure must conduct an in-person examination of the patient  
1351 while physically present in the same room as the patient no  
1352 later than the day before the procedure.

1353       2. Before a physician may delegate any duties during a  
1354 gluteal fat grafting procedure, the patient must provide  
1355 written, informed consent for such delegation. Any duty  
1356 delegated by a physician during a gluteal fat grafting procedure  
1357 must be performed under the direct supervision of the physician  
1358 performing such procedure. Fat extraction and gluteal fat  
1359 injections must be performed by the physician and may not be  
1360 delegated.

1361       3. Fat may only be injected into the subcutaneous space of  
1362 the patient and may not cross the fascia overlying the gluteal  
1363 muscle. Intramuscular or submuscular fat injections are  
1364 prohibited.

1365       4. When the physician performing a gluteal fat grafting  
1366 procedure injects fat into the subcutaneous space of the  
1367 patient, the physician must use ultrasound guidance, or guidance  
1368 with other technology authorized under board rule which equals  
1369 or exceeds the quality of ultrasound, during the placement and  
1370 navigation of the cannula to ensure that the fat is injected  
1371 into the subcutaneous space of the patient above the fascia  
1372 overlying the gluteal muscle. Such guidance with the use of  
1373 ultrasound or other technology is not required for other





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1374 portions of such procedure.

1375 5. An office in which a physician performs gluteal fat  
1376 grafting procedures shall at all times maintain a ratio of one  
1377 physician to one patient during all phases of the procedure,  
1378 beginning with the administration of anesthesia to the patient  
1379 and concluding with the extubation of the patient. After a  
1380 physician has commenced, and while he or she is engaged in, a  
1381 gluteal fat grafting procedure, the physician may not commence  
1382 or engage in another gluteal fat grafting procedure or any other  
1383 procedure with another patient at the same time.

1384 (e)(d) If a procedure in an office surgery setting results  
1385 in hospitalization, the incident must be reported as an adverse  
1386 incident pursuant to s. 458.351.

1387 ~~(e) An office in which a physician performs gluteal fat~~  
1388 ~~grafting procedures must at all times maintain a ratio of one~~  
1389 ~~physician to one patient during all phases of the procedure,~~  
1390 ~~beginning with the administration of anesthesia to the patient~~  
1391 ~~and concluding with the extubation of the patient. After a~~  
1392 ~~physician has commenced, and while he or she is engaged in, a~~  
1393 ~~gluteal fat grafting procedure, the physician may not commence~~  
1394 ~~or engage in another gluteal fat grafting procedure or any other~~  
1395 ~~procedure with another patient at the same time.~~

1396 (4)(3) RULEMAKING.—

1397 (a) The board may ~~shall~~ adopt by rule additional standards  
1398 of practice for physicians who perform office procedures or  
1399 ~~office~~ surgeries under ~~pursuant to~~ this section, as warranted  
1400 for patient safety and by the evolution of technology and  
1401 medical practice.

1402 (b) The board may adopt rules to administer the



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1403 registration, registration update, inspection, and safety of  
1404 offices in which a physician performs office procedures or  
1405 ~~office~~ surgeries under ~~pursuant to~~ this section.

1406 Section 4. Section 459.0139, Florida Statutes, is created  
1407 to read:

1408 459.0139 Standard of practice for office surgery.-

1409 (1) CONSTRUCTION.-This section does not relieve a physician  
1410 performing a procedure or surgery from the responsibility of  
1411 making the medical determination of whether an office is an  
1412 appropriate setting in which to perform that particular  
1413 procedure or surgery, taking into consideration the particular  
1414 patient on which the procedure or surgery is to be performed.

1415 (2) DEFINITIONS.-As used in this section, the term:

1416 (a) "Certified in advanced cardiac life support" means a  
1417 person holds a current certification in an advanced cardiac life  
1418 support course with didactic and skills components, approved by  
1419 the American Heart Association, the American Safety and Health  
1420 Institute, the American Red Cross, Pacific Medical Training, or  
1421 the Advanced Cardiovascular Life Support (ACLS) Certification  
1422 Institute.

1423 (b) "Certified in basic life support" means a person holds  
1424 a current certification in a basic life support course with  
1425 didactic and skills components, approved by the American Heart  
1426 Association, the American Safety and Health Institute, the  
1427 American Red Cross, Pacific Medical Training, or the ACLS  
1428 Certification Institute.

1429 (c) "Certified in pediatric advanced life support" means a  
1430 person holds a current certification in a pediatric advanced  
1431 life support course with didactic and skills components approved



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1432 by the American Heart Association, the American Safety and  
1433 Health Institute, or Pacific Medical Training.

1434 (d) "Continual monitoring" means monitoring that is  
1435 repeated regularly and frequently in steady rapid succession.

1436 (e) "Continuous monitoring" means monitoring that is  
1437 prolonged without any interruption at any time.

1438 (f) "Equipment" means a medical device, instrument, or tool  
1439 used to perform specific actions, carry out desired effects, or  
1440 take certain measurements during, or while recovering from, a  
1441 procedure or surgery which must meet current performance  
1442 standards according to its manufacturer's guidelines for the  
1443 specific device, instrument, or tool, as applicable.

1444 (g) "Major blood vessels" means a group of critical  
1445 arteries and veins, including the aorta, coronary arteries,  
1446 pulmonary arteries, superior and inferior vena cava, pulmonary  
1447 veins, and any intra-cerebral artery or vein.

1448 (h) "Office surgery" means a physician's office in which  
1449 surgical procedures are performed by a physician for the  
1450 practice of medicine as authorized by this section and board  
1451 rule. The office must be an office at which a physician  
1452 regularly performs consultations with surgical patients,  
1453 preoperative examinations, and postoperative care, as  
1454 necessitated by the standard of care, related to the procedures  
1455 performed at the physician's office, and at which patient  
1456 records are readily maintained and available. The types of  
1457 procedures or surgeries performed in an office surgery are those  
1458 which need not be performed in a facility licensed under chapter  
1459 390 or chapter 395, and are not of the type that:

1460 1. Generally result in blood loss of more than 10 percent



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1461 of estimated blood volume in a patient with a normal hemoglobin  
1462 count;

1463 2. Require major or prolonged intracranial, intrathoracic,  
1464 abdominal, or major joint replacement procedures, except for  
1465 laparoscopic procedures;

1466 3. Involve major blood vessels and are performed with  
1467 direct visualization by open exposure of the major vessel,  
1468 except for percutaneous endovascular intervention; or

1469 4. Are generally emergent or life threatening in nature.

1470 (i) "Pediatric patient" means a patient who is 13 years of  
1471 age or younger.

1472 (j) "Percutaneous endovascular intervention" means a  
1473 procedure performed without open direct visualization of the  
1474 target vessel and requiring only needle puncture of an artery or  
1475 vein followed by insertion of catheters, wires, or similar  
1476 devices which are then advanced through the blood vessels using  
1477 imaging guidance. Once the catheter reaches the intended  
1478 location, various maneuvers to address the diseased area may be  
1479 performed, which include, but are not limited to, injection of  
1480 contrast medium for imaging; treatment of vessels with  
1481 angioplasty; atherectomy; covered or uncovered stenting;  
1482 embolization or intentionally occluding vessels or organs; and  
1483 delivering medications, radiation, or other energy, such as  
1484 laser, radiofrequency, or cryo.

1485 (k) "Reasonable proximity" means a distance that does not  
1486 exceed thirty 30 minutes of transport time to the hospital.

1487 (l) "Surgery" means any manual or operative procedure  
1488 performed upon the body of a living human being, including, but  
1489 not limited to, those performed with the use of lasers, for the



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1490 purposes of preserving health, diagnosing or curing disease,  
1491 repairing injury, correcting a deformity or defect, prolonging  
1492 life, relieving suffering, or any elective procedure for  
1493 aesthetic, reconstructive, or cosmetic purposes. The term  
1494 includes, but is not limited to, incision or curettage of tissue  
1495 or an organ; suture or other repair of tissue or an organ,  
1496 including a closed as well as an open reduction of a fracture;  
1497 extraction of tissue, including premature extraction of the  
1498 products of conception from the uterus; insertion of natural or  
1499 artificial implants; or an endoscopic procedure with use of  
1500 local or general anesthetic.

1501 (3) GENERAL REQUIREMENTS FOR OFFICE SURGERY.—

1502 (a) The physician performing the operation must examine the  
1503 patient immediately before the surgery to evaluate the risk of  
1504 anesthesia and of the surgical procedure to be performed. The  
1505 physician performing the surgery may delegate the preoperative  
1506 heart-lung evaluation to a qualified anesthesia provider within  
1507 the scope of the provider's practice and, if applicable,  
1508 protocol.

1509 (b) The physician performing the surgery shall maintain  
1510 complete patient records of each surgical procedure performed,  
1511 which must include all of the following:

1512 1. The patient's name, patient number, preoperative  
1513 diagnosis, postoperative diagnosis, surgical procedure,  
1514 anesthetic, anesthesia records, recovery records, and  
1515 complications, if any.

1516 2. The name of each member of the surgical team, including  
1517 the surgeon, first assistant, anesthesiologist, nurse  
1518 anesthetist, anesthesiologist assistant, circulating nurse, and



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1519 operating room technician.

1520 (c) Each office surgery's designated physician shall ensure  
1521 that the office surgery has procedures in place to verify that  
1522 all of the following have occurred before any surgery is  
1523 performed:

1524 1. The patient has signed the informed consent form for the  
1525 procedure reflecting the patient's knowledge of identified risks  
1526 of the procedure, consent to the procedure, the type of  
1527 anesthesia and anesthesia provider to be used during the  
1528 procedure, and the fact that the patient may choose the type of  
1529 anesthesia provider for the procedure, such as an  
1530 anesthesiologist, a certified registered nurse anesthetist, a  
1531 physician assistant, an anesthesiologist assistant, or another  
1532 appropriately trained physician as provided by board rule.

1533 2. The patient's identity has been verified.

1534 3. The operative site has been verified.

1535 4. The operative procedure to be performed has been  
1536 verified with the patient.

1537 5. All of the information and actions required to be  
1538 verified under this paragraph are documented in the patient's  
1539 medical record.

1540 (d) With respect to the requirement set forth in paragraph  
1541 (c), written informed consent is not necessary for minor Level I  
1542 procedures limited to the skin and mucosa.

1543 (e) The physician performing the surgery shall maintain a  
1544 log of all liposuction procedures performed at the office  
1545 surgery where more than 1,000 cubic centimeters of supernatant  
1546 fat is temporarily or permanently removed and where Level II and  
1547 Level III surgical procedures are performed. The log must, at a



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1548 minimum, include all of the following:  
1549 1. A confidential patient identifier.  
1550 2. Time of arrival in the operating suite.  
1551 3. The name of the physician performing the procedure.  
1552 4. The patient's diagnosis, CPT codes used for the  
1553 procedure, the patient's classification for risk with anesthesia  
1554 according to the American Society of Anesthesiologists' physical  
1555 status classification system, and the type of procedure and  
1556 level of surgery performed.  
1557 5. Documentation of completion of the medical clearance  
1558 performed by the anesthesiologist or the physician performing  
1559 the surgery.  
1560 6. The name and provider type of the anesthesia provider  
1561 and the type of anesthesia used.  
1562 7. The duration of the procedure.  
1563 8. Any adverse incidents as identified in s. 458.351.  
1564 9. The type of postoperative care, duration of recovery,  
1565 disposition of the patient upon discharge, including the address  
1566 of where the patient is being discharged, discharge  
1567 instructions, and list of medications used during surgery and  
1568 recovery.  
1569  
1570 All surgical and anesthesia logs must be kept at the office  
1571 surgery and maintained for 6 years after the date of last  
1572 patient contact and must be provided to department investigators  
1573 upon request.  
1574 (f) For any liposuction procedure, the physician performing  
1575 the surgery is responsible for determining the appropriate  
1576 amount of supernatant fat to be removed from a particular



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1577 patient. A maximum of 4,000 cubic centimeters of supernatant fat  
1578 may be removed by liposuction in the office surgery setting. A  
1579 maximum of 50mg/kg of lidocaine can be injected for tumescent  
1580 liposuction in the office surgery setting.

1581 (g)1. Liposuction may be performed in combination with  
1582 another separate surgical procedure during a single Level II or  
1583 Level III operation only in the following circumstances:

1584 a. When combined with an abdominoplasty, liposuction may  
1585 not exceed 1,000 cubic centimeters of supernatant fat.

1586 b. When liposuction is associated and directly related to  
1587 another procedure, the liposuction may not exceed 1,000 cubic  
1588 centimeters of supernatant fat.

1589 2. Major liposuction in excess of 1,000 cubic centimeters  
1590 of supernatant fat may not be performed on a patient's body in a  
1591 location that is remote from the site of another procedure being  
1592 performed on that patient.

1593 (h) For elective cosmetic and plastic surgery procedures  
1594 performed in a physician's office, the maximum planned duration  
1595 of all surgical procedures combined may not exceed 8 hours.  
1596 Except for elective cosmetic and plastic surgery, the physician  
1597 performing the surgery may not keep patients past midnight in a  
1598 physician's office. For elective cosmetic and plastic surgical  
1599 procedures, the patient must be discharged within 24 hours after  
1600 presenting to the office for surgery. However, an overnight stay  
1601 is allowed in the office if the total time the patient is at the  
1602 office does not exceed 23 hours and 59 minutes, including the  
1603 surgery time. An overnight stay in a physician's office for  
1604 elective cosmetic and plastic surgery must be strictly limited  
1605 to the physician's office. If the patient has not recovered





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1606 sufficiently to be safely discharged within the timeframes set  
1607 forth, the patient must be transferred to a hospital for  
1608 continued postoperative care.

1609 (i) The Standards of the American Society of  
1610 Anesthesiologists for Basic Anesthetic Monitoring are hereby  
1611 adopted and incorporated by reference as the standards for  
1612 anesthetic monitoring by any qualified anesthesia provider under  
1613 this section.

1614 1. These standards apply to general anesthetics, regional  
1615 anesthetics, and monitored Level II and III anesthesia care.  
1616 However, in emergency circumstances, appropriate life support  
1617 measures take priority. These standards may be exceeded at any  
1618 time based on the judgment of the responsible supervising  
1619 physician or anesthesiologist. While these standards are  
1620 intended to encourage quality patient care, observing them does  
1621 not guarantee any specific patient outcome. This set of  
1622 standards addresses only the issue of basic anesthesia  
1623 monitoring, which is only one component of anesthesia care.

1624 2. In certain rare or unusual circumstances, some of these  
1625 methods of monitoring may be clinically impractical, and  
1626 appropriate use of the described monitoring methods may fail to  
1627 detect adverse clinical developments. In such cases, a brief  
1628 interruption of continual monitoring may be unavoidable and does  
1629 not by itself constitute a violation of the standards of  
1630 practice of this section.

1631 3. Under extenuating circumstances, the responsible  
1632 supervising physician or anesthesiologist may waive the  
1633 following requirements:

1634 a. The use of an oxygen analyzer with a low oxygen



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1635 concentration limit alarm, or other technology authorized under  
1636 board rule which equals or exceeds the quality of the oxygen  
1637 analyzer, during the administration of general anesthesia with  
1638 an anesthesia machine.

1639 b. The use of pulse oximetry with a variable pitch pulse  
1640 tone and an audible low threshold alarm, or other technology  
1641 authorized under board rule which equals or exceeds the quality  
1642 of a pulse oximeter, and the use of adequate illumination and  
1643 exposure of the patient to assess color.

1644 c. The use of capnography, capnometry, or mass  
1645 spectroscopy, or other technology authorized under board rule  
1646 which equals or exceeds the quality of capnography, capnometry,  
1647 or mass spectroscopy, as a quantitative method of analyzing the  
1648 end-tidal carbon dioxide for continual monitoring for the  
1649 presence of expired carbon dioxide during ventilation from the  
1650 time of the endotracheal tube or supraglottic airway placement,  
1651 until extubation or removal or initiating transfer of the  
1652 patient to a postoperative care location.

1653 d. The use of continuous electrocardiogram display, or  
1654 other technology authorized under board rule which equals or  
1655 exceeds the quality of electrocardiogram display, from the  
1656 beginning of anesthesia until preparing to leave the  
1657 anesthetizing location.

1658 e. The measuring of arterial blood pressure and heart rate  
1659 evaluated at least every 5 minutes during anesthesia.

1660  
1661 When any of the monitoring is waived for extenuating  
1662 circumstances under this subparagraph, it must be documented in  
1663 a note in the patient's medical record, including the reasons



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1664 for the need to waive the requirement. These standards are not  
1665 intended for the application to the care of an obstetrical  
1666 patient in labor or in the conduct of pain management.

1667 (j)1. Because of the rapid changes in patient status during  
1668 anesthesia, qualified anesthesia personnel must be continuously  
1669 present in the room to monitor the patient and provide  
1670 anesthesia care for the entire duration of all general  
1671 anesthetics, regional anesthetics, and monitored anesthesia care  
1672 conducted on the patient. In the event that there is a direct  
1673 known hazard, such as radiation, to the anesthesia personnel  
1674 which might require intermittent remote observation of the  
1675 patient, some provision for monitoring the patient must be made.  
1676 In the event that an emergency requires the temporary absence of  
1677 the person primarily responsible for the anesthetic, the best  
1678 judgment of the supervising physician or anesthesiologist shall  
1679 be exercised in comparing the emergency with the anesthetized  
1680 patient's condition and in the selection of the person left  
1681 responsible for the anesthetic during the temporary absence.

1682 2. During all anesthetics, the patient's oxygenation,  
1683 ventilation, circulation, and temperature must be continually  
1684 evaluated to ensure adequate oxygen concentration in the  
1685 inspired gas and the blood during all anesthetics.

1686 a. During all general anesthesia using an anesthesia  
1687 machine, the concentration of oxygen in the patient breathing  
1688 system must be measured by an oxygen analyzer with a low oxygen  
1689 concentration limit alarm used to measure blood oxygenation.

1690 b. During all anesthetics, a quantitative method of  
1691 assessing oxygenation, such as pulse oximetry, must be employed.  
1692 When a pulse oximeter is used, the variable pitch pulse tone and



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1693 the low threshold alarm must be audible to the qualified  
1694 anesthesia provider. Adequate illumination and exposure of the  
1695 patient are necessary to assess color.

1696 c. During all anesthetics, every patient must have the  
1697 adequacy of his or her ventilation continually evaluated,  
1698 including, but not limited to, the evaluation of qualitative  
1699 clinical signs, such as chest excursion, observation of the  
1700 reservoir breathing bag, and auscultation of breath sounds.  
1701 Continual monitoring for the presence of expired carbon dioxide  
1702 must be performed unless invalidated by the nature of the  
1703 patient's condition, the procedure, or the equipment.

1704 Quantitative monitoring of the volume of expired gas is strongly  
1705 encouraged.

1706 d. When an endotracheal tube or supraglottic airway is  
1707 inserted, its correct positioning must be verified by clinical  
1708 assessment and by identification of carbon dioxide in the  
1709 expired gas. Continual end-tidal carbon dioxide analysis, in use  
1710 from the time of endotracheal tube or supraglottic airway  
1711 placement until extubation or removal or initiating transfer of  
1712 the patient to a postoperative care location, must be performed  
1713 using a quantitative method, such as capnography, capnometry, or  
1714 mass spectroscopy or other technology authorized under board  
1715 rule which equals or exceeds the quality of capnography,  
1716 capnometry, or mass spectroscopy. When capnography or capnometry  
1717 is used, the end-tidal carbon dioxide alarm must be audible to  
1718 the qualified anesthesia provider.

1719 e. When ventilation is controlled by a mechanical  
1720 ventilator, there must be in continuous use a device that is  
1721 capable of detecting disconnection of components of the



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1722 breathing system. The device must give an audible signal when  
1723 its alarm threshold is exceeded.

1724 f. During regional anesthesia without sedation or local  
1725 anesthesia with no sedation, the adequacy of ventilation must be  
1726 evaluated by continual observation of qualitative clinical  
1727 signs. During moderate or deep sedation, the adequacy of  
1728 ventilation must be evaluated by continual observation of  
1729 qualitative clinical signs. Monitoring for the presence of  
1730 exhaled carbon dioxide is recommended.

1731 g. Every patient receiving anesthesia must have the  
1732 electrocardiogram or other technology authorized under board  
1733 rule which equals or exceeds the quality of electrocardiogram  
1734 continuously displayed from the beginning of anesthesia until  
1735 preparing to leave the anesthetizing location.

1736 h. Every patient receiving anesthesia must have arterial  
1737 blood pressure and heart rate determined and evaluated at least  
1738 every 5 minutes.

1739 i. Every patient receiving general anesthesia must have  
1740 circulatory function continually evaluated by at least one of  
1741 the following methods:

1742 (I) Palpation of a pulse.

1743 (II) Auscultation of heart sounds.

1744 (III) Monitoring of a tracing of intra-arterial pressure.

1745 (IV) Ultrasound peripheral pulse monitoring.

1746 (V) Pulse plethysmography or oximetry.

1747 (VI) Other technology authorized under board rule which  
1748 equals or exceeds the quality of any of the methods listed in  
1749 sub-sub-subparagraphs (I)-(V).

1750 j. Every patient receiving anesthesia must have his or her



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1751 temperature monitored when clinically significant changes in  
1752 body temperature are intended, anticipated, or suspected.

1753 (k)1. The physician performing the surgery shall ensure  
1754 that the postoperative care arrangements made for the patient  
1755 are adequate for the procedure being performed, as required by  
1756 board rule.

1757 2. Management of postoperative care is the responsibility  
1758 of the physician performing the surgery and may be delegated as  
1759 determined by board rule. If the physician performing the  
1760 surgery is unavailable to provide postoperative care, the  
1761 physician performing the surgery must notify the patient of his  
1762 or her unavailability for postoperative care before the  
1763 procedure.

1764 3. If there is an overnight stay at the office in relation  
1765 to any surgical procedure:

1766 a. The office must provide at least two persons to act as  
1767 monitors, one of whom must be certified in advanced cardiac life  
1768 support, and maintain a monitor-to-patient ratio of at least one  
1769 monitor to two patients.

1770 b. Once the physician performing the surgery has signed a  
1771 timed and dated discharge order, the office may provide only one  
1772 monitor to monitor the patient. The monitor must be qualified by  
1773 licensure and training to administer all of the medications  
1774 required on the crash cart and must be certified in advanced  
1775 cardiac life support.

1776 c. A complete and current crash cart must be present in the  
1777 office surgery and immediately accessible for the monitors.

1778 4. The physician performing the surgery must be reachable  
1779 by telephone and readily available to return to the office if



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1780 needed.

1781 5. A policy and procedures manual must be maintained in the

1782 office at which Level II and Level III procedures are performed.

1783 The manual must be updated and implemented annually. The policy

1784 and procedures manual must provide for all of the following:

1785 a. Duties and responsibilities of all personnel.

1786 b. A quality assessment and improvement system designed to

1787 objectively and systematically monitor and evaluate the quality

1788 and appropriateness of patient care and opportunities to improve

1789 performance.

1790 c. Cleaning procedures and protocols.

1791 d. Sterilization procedures.

1792 e. Infection control procedures and personnel

1793 responsibilities.

1794 f. Emergency procedures.

1795 6. The designated physician shall establish a risk

1796 management program that includes all of the following

1797 components:

1798 a. The identification, investigation, and analysis of the

1799 frequency and causes of adverse incidents.

1800 b. The identification of trends or patterns of adverse

1801 incidents.

1802 c. The development of appropriate measures to correct,

1803 reduce, minimize, or eliminate the risk of adverse incidents.

1804 d. The documentation of such functions and periodic review

1805 of such information at least quarterly by the designated

1806 physician.

1807 7. The designated physician shall report to the department

1808 any adverse incidents that occur within the scope of office



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1809 surgeries. This report must be made within 15 days after the  
1810 occurrence of an incident as required by s. 458.351.

1811 8. The designated physician is responsible for prominently  
1812 posting a sign in the office which states that the office is a  
1813 doctor's office regulated under this section and ss. 458.328,  
1814 458.3281, 459.0138 and the applicable rules of the Board of  
1815 Medicine and Osteopathic Medicine as set forth in rules 64B8 and  
1816 64B15, Florida Administrative Code. This notice must also appear  
1817 prominently within the required patient informed consent.

1818 9. All physicians performing surgery at the office surgery  
1819 must be qualified by education, training, and experience to  
1820 perform any procedure the physician performs in the office  
1821 surgery.

1822 10. When Level II, Level II-A, or Level III procedures are  
1823 performed in an office surgery, the physician performing the  
1824 surgery is responsible for providing the patient, in writing,  
1825 before the procedure, the name and location of the hospital  
1826 where the physician performing the surgery has privileges to  
1827 perform the same procedure as the one being performed in the  
1828 outpatient setting, or the name and location of the hospital  
1829 where the physician performing the surgery or the facility has a  
1830 transfer agreement.

1831 (4) LEVEL I OFFICE SURGERY.—

1832 (a) Scope.—Level I office surgery includes all of the  
1833 following:

1834 1. Minor procedures such as excision of skin lesions,  
1835 moles, warts, cysts, or lipomas, and repair of lacerations or  
1836 surgery limited to the skin and subcutaneous tissue which are  
1837 performed under topical or local anesthesia not involving drug-





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1838 induced alteration of consciousness other than minimal pre-  
1839 operative tranquilization of the patient.

1840 2. Liposuction involving the removal of less than 4,000  
1841 cubic centimeters of supernatant fat.

1842 3. Incision and drainage of superficial abscesses; limited  
1843 endoscopies, such as proctoscopies, skin biopsies,  
1844 arthrocentesis, thoracentesis, paracentesis, dilation of  
1845 urethra, cystoscopic procedures, and closed reduction of simple  
1846 fractures; or small joint dislocations, such as in the finger or  
1847 toe joints.

1848 4. Procedures in which anesthesia is limited to minimal  
1849 sedation. The patient's level of sedation must be that of  
1850 minimal sedation and anxiolysis and the chances of complications  
1851 requiring hospitalization must be remote. As used in this sub-  
1852 subparagraph, the term "minimal sedation and anxiolysis" means a  
1853 drug-induced state during which patients respond normally to  
1854 verbal commands, and although cognitive function and physical  
1855 coordination may be impaired, airway reflexes and ventilatory  
1856 and cardiovascular functions remain unaffected. Controlled  
1857 substances, as defined in ss. 893.02 and 893.03, must be limited  
1858 to oral administration in doses appropriate for the unsupervised  
1859 treatment of insomnia, anxiety, or pain.

1860 5. Procedures for which chances of complications requiring  
1861 hospitalization are remote as specified in board rule.

1862 (b) Standards of practice.—Standards of practice for Level  
1863 I office surgery include all of the following:

1864 1. The medical education, training, and experience of the  
1865 physician performing the surgery must include training on proper  
1866 dosages and management of toxicity or hypersensitivity to



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1867 regional anesthetic drugs, and the physician must be certified  
1868 in advanced cardiac life support.

1869 2. At least one operating assistant must be certified in  
1870 basic life support.

1871 3. Intravenous access supplies, oxygen, oral airways, and a  
1872 positive pressure ventilation device must be available in the  
1873 office surgery, along with the following medications, stored per  
1874 the manufacturer's recommendation:

1875 a. Atropine, 3 mg.

1876 b. Diphenhydramine, 50 mg.

1877 c. Epinephrine, 1 mg in 10 ml.

1878 d. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

1879 e. Hydrocortisone, 100 mg.

1880 f. If a benzodiazepine is administered, flumazenil, 0.5 mg  
1881 in 5 ml vial, 2 vials total.

1882 g. If an opiate is administered, naloxone, 0.4 mg in 1 ml  
1883 vial, 2 vials total.

1884 4. When performing minor procedures, such as excision of  
1885 skin lesions, moles, warts, cysts, or lipomas, and repair of  
1886 lacerations or surgery limited to the skin and subcutaneous  
1887 tissue performed under topical or local anesthesia, physicians  
1888 are exempt from subparagraphs 1.-3. Current certification in  
1889 basic life support is recommended but not required.

1890 5. A physician performing the surgery need not have an  
1891 assistant during the procedure unless the specific procedure  
1892 being performed requires an assistant.

1893 (5) LEVEL II OFFICE SURGERY.—

1894 (a) Scope.—Level II office surgery includes, but is not  
1895 limited to, all of the following procedures:



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- 1896        1. Hemorrhoidectomy.
- 1897        2. Hernia repair.
- 1898        3. Large joint dislocations.
- 1899        4. Colonoscopy.
- 1900        5. Liposuction involving the removal of up to 4,000 cubic  
1901 centimeters of supernatant fat.
- 1902        6. Any other procedure the board designates by rule as a  
1903 Level II office surgery.
- 1904        7. Surgeries in which the patient's level of sedation is  
1905 that of moderate sedation and analgesia or conscious sedation.  
1906 As used in this subparagraph, the term "moderate sedation and  
1907 analgesia or conscious sedation" is a drug-induced depression of  
1908 consciousness during which patients respond purposefully to  
1909 verbal commands, either alone or accompanied by light tactile  
1910 stimulation; interventions are not required to maintain a patent  
1911 airway; spontaneous ventilation is adequate; and cardiovascular  
1912 function is maintained. For purposes of the term, a patient  
1913 reflexively withdrawing from a painful stimulus is not  
1914 considered a purposeful response.
- 1915        (b) Standards of practice.—Standards of practice for Level  
1916 II office surgery include, but are not limited to, the  
1917 following:
- 1918        1. The physician performing the surgery, or the office  
1919 where the procedure is being performed, must have a transfer  
1920 agreement with a licensed hospital within reasonable proximity  
1921 if the physician performing the procedure does not have staff  
1922 privileges to perform the same procedure as that being performed  
1923 in the office surgery setting at a licensed hospital within  
1924 reasonable proximity. The transfer agreement required by this



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1925 section must be current and have been entered into no more than  
1926 3 years before the date of the office's most recent annual  
1927 inspection under s. 459.0138. A transfer agreement must  
1928 affirmatively disclose an effective date and a termination date.

1929 2. The physician performing the surgery must have staff  
1930 privileges at a licensed hospital to perform the same procedure  
1931 in that hospital as that being performed in the office surgery  
1932 setting or must be able to document satisfactory completion of  
1933 training, such as board certification or board eligibility by a  
1934 board approved by the American Board of Medical Specialties or  
1935 any other board approved by the Board of Medicine, or must be  
1936 able to establish comparable background, training, and  
1937 experience. Such board certification or comparable background,  
1938 training, and experience must also be directly related to and  
1939 include the procedures being performed by the physician in the  
1940 office surgery facility.

1941 3. One assistant must be currently certified in basic life  
1942 support.

1943 4. The physician performing the surgery must be currently  
1944 certified in advanced cardiac life support.

1945 5. A complete and current crash cart must be available at  
1946 all times at the location where the anesthesia is being  
1947 administered. The designated physician of an office surgery is  
1948 responsible for ensuring that the crash cart is replenished  
1949 after each use, the expiration dates for the crash cart's  
1950 medications are checked weekly, and crash cart events are  
1951 documented in the cart's logs. Medicines must be stored per the  
1952 manufacturer's recommendations, and multi-dose vials must be  
1953 dated once opened and checked daily for expiration. The crash



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1954 cart must, at a minimum, include the following intravenous or  
1955 inhaled medications:  
1956 a. Adenosine, 18 mg.  
1957 b. Albuterol, 2.5 mg with a small volume nebulizer.  
1958 c. Amiodarone, 300 mg.  
1959 d. Atropine, 3 mg.  
1960 e. Calcium chloride, 1 gram.  
1961 f. Dextrose, 50 percent; 50 ml.  
1962 g. Diphenhydramine, 50 mg.  
1963 h. Dopamine, 200 mg, minimum.  
1964 i. Epinephrine, 1 mg, in 10 ml.  
1965 j. Epinephrine, 1 mg in 1 ml vial, 3 vials total.  
1966 k. Flumazenil, 1 mg.  
1967 l. Furosemide, 40 mg.  
1968 m. Hydrocortisone, 100 mg.  
1969 n. Lidocaine appropriate for cardiac administration, 100  
1970 mg.  
1971 o. Magnesium sulfate, 2 grams.  
1972 p. Naloxone, 1.2 mg.  
1973 q. A beta blocker class drug.  
1974 r. Sodium bicarbonate, 50 mEq/50 ml.  
1975 s. Paralytic agent that is appropriate for use in rapid  
1976 sequence intubation.  
1977 t. A calcium channel blocker class drug.  
1978 u. If nonneuraxial regional blocks are performed,  
1979 Intralipid, 20 percent, 500 ml solution.  
1980 v. Any additional medication the board determines by rule  
1981 is warranted for patient safety and by the evolution of  
1982 technology and medical practice.



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- 1983           6. In the event of a drug shortage, the designated  
1984 physician is authorized to substitute a therapeutically  
1985 equivalent drug that meets the prevailing practice standards.
- 1986           7. The designated physician is responsible for ensuring  
1987 that the office maintains documentation of its unsuccessful  
1988 efforts to obtain the required drug.
- 1989           8. The designated physician is responsible for ensuring  
1990 that the following are present in the office surgery:
- 1991           a. A benzodiazepine.
- 1992           b. A positive pressure ventilation device, such as Ambu,  
1993 plus oxygen supply.
- 1994           c. An end-tidal carbon dioxide detection device.
- 1995           d. Monitors for blood pressure, electrocardiography, and  
1996 oxygen saturation.
- 1997           e. Emergency intubation equipment that must, at a minimum,  
1998 include suction devices, endotracheal tubes, working  
1999 laryngoscopes, oropharyngeal airways, nasopharyngeal airways,  
2000 and bag valve mask apparatus that are sized appropriately for  
2001 the specific patient.
- 2002           f. A working defibrillator with defibrillator pads or  
2003 defibrillator gel, or an automated external defibrillator unit.
- 2004           g. Sufficient backup power to allow the physician  
2005 performing the surgery to safely terminate the procedure and to  
2006 allow the patient to emerge from the anesthetic, all without  
2007 compromising the sterility of the procedure or the environment  
2008 of care.
- 2009           h. Working sterilization equipment cultured weekly.
- 2010           i. Sufficient intravenous solutions and equipment for a  
2011 minimum of a week's worth of surgical cases.



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2012 j. Any other equipment required by board rule, as warranted  
2013 by the evolution of technology and medical practice.

2014 9. The physician performing the surgery must be assisted by  
2015 a qualified anesthesia provider, which may include any of the  
2016 following types of providers:

2017 a. An anesthesiologist.

2018 b. A certified registered nurse anesthetist.

2019 c. A registered nurse, if the physician performing the  
2020 surgery is certified in advanced cardiac life support and the  
2021 registered nurse assists only with local anesthesia or conscious  
2022 sedation.

2023  
2024 An anesthesiologist assistant may assist the anesthesiologist as  
2025 provided by board rule. An assisting anesthesia provider may not  
2026 function in any other capacity during the procedure.

2027 10. If additional anesthesia assistance is required by the  
2028 specific procedure or patient circumstances, such assistance  
2029 must be provided by a physician, osteopathic physician,  
2030 registered nurse, licensed practical nurse, or operating room  
2031 technician.

2032 11. The designated physician is responsible for ensuring  
2033 that each patient is monitored in the recovery room until fully  
2034 recovered from anesthesia. Such monitoring must be provided by a  
2035 licensed physician, physician assistant, registered nurse with  
2036 postanesthesia care unit experience, or the equivalent who is  
2037 currently certified in advanced cardiac life support, or, in the  
2038 case of pediatric patients, currently certified in pediatric  
2039 advanced life support.

2040 (6) LEVEL II-A OFFICE SURGERY.-



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2041 (a) Scope.—Level II-A office surgeries are those Level II  
2042 office surgeries that have a maximum planned duration of 5  
2043 minutes or less and in which the chances of complications  
2044 requiring hospitalization are remote.

2045 (b) Standards of practice.—

2046 1. All practice standards for Level II office surgery set  
2047 forth in paragraph (5) (b) must be met for Level II-A office  
2048 surgery except for the requirements set forth in subparagraph  
2049 (5) (b) 9. regarding assistance by a qualified anesthesia  
2050 provider.

2051 2. During the surgical procedure, the physician performing  
2052 the surgery must be assisted by a licensed physician, physician  
2053 assistant, registered nurse, or licensed practical nurse.

2054 3. Additional assistance may be required by specific  
2055 procedure or patient circumstances.

2056 4. Following the procedure, a licensed physician, physician  
2057 assistant, or registered nurse must be available to monitor the  
2058 patient in the recovery room until the patient is recovered from  
2059 anesthesia. The monitoring provider must be currently certified  
2060 in advanced cardiac life support, or, in the case of pediatric  
2061 patients, currently certified in pediatric advanced life  
2062 support.

2063 (7) LEVEL III OFFICE SURGERY.—

2064 (a) Scope.—

2065 1. Level III office surgery includes those types of surgery  
2066 during which the patient's level of sedation is that of deep  
2067 sedation and analgesia or general anesthesia. As used in this  
2068 subparagraph, the term:

2069 a. "Deep sedation and analgesia" means a drug-induced





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2070 depression of consciousness during which:  
2071 (I) Patients cannot be easily aroused but respond  
2072 purposefully following repeated or painful stimulation;  
2073 (II) The ability to independently maintain ventilatory  
2074 function may be impaired;  
2075 (III) Patients may require assistance in maintaining a  
2076 patent airway and spontaneous ventilation may be inadequate; and  
2077 (IV) Cardiovascular function is usually maintained.  
2078  
2079 For purposes of this sub-subparagraph, a reflexive withdrawal  
2080 from a painful stimulus by a patient is not considered a  
2081 purposeful response.  
2082 b. "General anesthesia" means a drug-induced loss of  
2083 consciousness during which:  
2084 (I) Patients are not arousable, even by painful  
2085 stimulation;  
2086 (II) The ability to independently maintain ventilatory  
2087 function is often impaired;  
2088 (III) Patients often require assistance in maintaining a  
2089 patent airway and positive pressure ventilation may be required  
2090 because of depressed spontaneous ventilation or drug-induced  
2091 depression of neuromuscular function; and  
2092 (IV) Cardiovascular function may be impaired.  
2093 2. The use of spinal or epidural anesthesia for a procedure  
2094 requires that procedure to be considered a Level III office  
2095 surgery.  
2096 3. Only patients classified under the American Society of  
2097 Anesthesiologists' (ASA) risk classification criteria as Class I  
2098 or Class II are appropriate candidates for a Level III office



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2099 surgery.  
2100 a. All Level III office surgeries on patients classified as  
2101 ASA III or higher are to be performed only in a hospital or  
2102 ambulatory surgical center.  
2103 b. For all ASA II patients above the age of 50, the  
2104 physician performing the surgery must obtain a complete workup  
2105 performed before the performance of a Level III office surgery  
2106 in the office surgery setting.  
2107 c. If the patient has a cardiac history or is deemed to be  
2108 a complicated medical patient, the patient must have a  
2109 preoperative electrocardiogram and be referred to an appropriate  
2110 consultant for medical optimization. The referral to a  
2111 consultant may be waived after evaluation by the patient's  
2112 anesthesiologist.  
2113 (b) Standards of practice.—Practice standards for Level III  
2114 office surgery include all Level II office surgery standards and  
2115 all of the following requirements:  
2116 1. The physician performing the surgery must have staff  
2117 privileges at a licensed hospital to perform the same procedure  
2118 in that hospital as that being performed in the office surgery  
2119 setting or must be able to document satisfactory completion of  
2120 training, such as board certification or board qualification by  
2121 a board approved by the American Board of Medical Specialties or  
2122 any other board approved by the Board of Medicine, or must be  
2123 able to demonstrate to the accrediting organization or to the  
2124 department comparable background, training, and experience. Such  
2125 board certification or comparable background, training, and  
2126 experience must also be directly related to and include the  
2127 procedure being performed by the physician performing the



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2128 surgery in the office surgery setting. In addition, the  
2129 physician performing the surgery must have knowledge of the  
2130 principles of general anesthesia.

2131 2. The physician performing the surgery must be currently  
2132 certified in advanced cardiac life support.

2133 3. At least one operating assistant must be currently  
2134 certified in basic life support.

2135 4. An emergency policy and procedures manual related to  
2136 serious anesthesia complications must be available in the office  
2137 surgery and reviewed biannually by the designated physician,  
2138 practiced with staff, updated, and posted in a conspicuous  
2139 location in the office. Topics to be covered in the manual must  
2140 include all of the following:

2141 a. Airway blockage and foreign body obstruction.

2142 b. Allergic reactions.

2143 c. Bradycardia.

2144 d. Bronchospasm.

2145 e. Cardiac arrest.

2146 f. Chest pain.

2147 g. Hypoglycemia.

2148 h. Hypotension.

2149 i. Hypoventilation.

2150 j. Laryngospasm.

2151 k. Local anesthetic toxicity reaction.

2152 l. Malignant hyperthermia.

2153 m. Any other topics the board determines by rule are  
2154 warranted for patient safety and by the evolution of technology  
2155 and medical practice.

2156 5. An office surgery performing Level III office surgeries



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2157 must maintain all of the equipment and medications required for  
2158 Level II office surgeries and comply with all of the following  
2159 additional requirements:

2160 a. Maintain at least 720 mg of dantrolene on site if  
2161 halogenated anesthetics or succinylcholine are used.

2162 b. Equipment and medication for monitored postanesthesia  
2163 recovery must be available in the office.

2164 6. Anesthetic safety regulations must be developed, posted  
2165 in a conspicuous location in the office, and enforced by the  
2166 designated physician. Such regulations must include all of the  
2167 following requirements:

2168 a. All operating room electrical and anesthesia equipment  
2169 must be inspected at least semiannually, and a written record of  
2170 the results and corrective actions must be maintained.

2171 b. Flammable anesthetic agents may not be employed in  
2172 office surgery facilities.

2173 c. Electrical equipment in anesthetizing areas must be on  
2174 an audiovisual line isolation monitor, with the exception of  
2175 radiologic equipment and fixed lighting more than 5 feet above  
2176 the floor.

2177 d. Each anesthesia gas machine must have a pin-index system  
2178 or equivalent safety system and a minimum oxygen flow safety  
2179 device.

2180 e. All reusable anesthesia equipment in direct contact with  
2181 a patient must be cleaned or sterilized as appropriate after  
2182 each use.

2183 f. The following monitors must be applied to all patients  
2184 receiving conduction or general anesthesia:

2185 (I) Blood pressure cuff.



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2186 (II) A continuous temperature device, readily available to  
2187 measure the patient's temperature.

2188 (III) Pulse oximeter.

2189 (IV) Electrocardiogram.

2190 (V) An inspired oxygen concentration monitor and a  
2191 capnograph, for patients receiving general anesthesia.

2192 g. Emergency intubation equipment must be available in all  
2193 office surgery suites.

2194 h. Surgical tables must be capable of Trendelenburg and  
2195 other positions necessary to facilitate surgical procedures.

2196 i. An anesthesiologist, a certified registered nurse  
2197 anesthetist, an anesthesiologist assistant, or a physician  
2198 assistant qualified as set forth in board rule must administer  
2199 the general or regional anesthesia.

2200 j. A physician, a registered nurse, a licensed practical  
2201 nurse, a physician assistant, or an operating room technician  
2202 must assist with the surgery. The anesthesia provider may not  
2203 function in any other capacity during the procedure.

2204 k. The patient must be monitored in the recovery room until  
2205 he or she has fully recovered from anesthesia. The monitoring  
2206 must be provided by a physician, a physician assistant, a  
2207 certified registered nurse anesthetist, an anesthesiologist  
2208 assistant, or a registered nurse with postanesthesia care unit  
2209 experience or the equivalent who is currently certified in  
2210 advanced cardiac life support, or, in the case of pediatric  
2211 patients, currently certified in pediatric advanced life  
2212 support.

2213 (8) RULEMAKING.—The board may adopt by rule additional  
2214 standards of practice for physicians who perform office



2215 surgeries or procedures under this section as warranted for  
2216 patient safety and by the evolution of technology and medical  
2217 practice.

2218 Section 5. This act shall take effect upon becoming a law.  
2219

2220 ===== T I T L E A M E N D M E N T =====

2221 And the title is amended as follows:

2222 Delete everything before the enacting clause  
2223 and insert:

2224 A bill to be entitled  
2225 An act relating to office surgeries; amending ss.  
2226 458.328 and 459.0138, F.S.; revising the types of  
2227 procedures for which a medical office must register  
2228 with the Department of Health to perform office  
2229 surgeries; specifying inspection procedures for such  
2230 offices seeking registration with the department;  
2231 requiring that certain offices seeking registration  
2232 provide proof to the department that they have met  
2233 specified requirements and rules; requiring the  
2234 department to inspect such offices to ensure that  
2235 certain equipment and procedures are present or in  
2236 place; requiring the department to notify the Agency  
2237 for Health Care Administration if an applicant is  
2238 unable to provide certain proof to the department and  
2239 to request that the agency inspect and consult with  
2240 the office; deleting obsolete language; providing that  
2241 the department may not register and must seek an  
2242 emergency suspension of an office under specified  
2243 circumstances; requiring that each office, as a



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2244 condition of registration, list certain medical  
2245 personnel and thereafter notify the department of the  
2246 addition or termination of such personnel within a  
2247 specified timeframe; providing for disciplinary action  
2248 for failure to comply; revising the materials that the  
2249 department must review when inspecting a registered  
2250 office; requiring offices already registered with the  
2251 department as of a specified date to provide a  
2252 registration update within a specified timeframe;  
2253 specifying requirements for such registration update  
2254 process; revising requirements for the standards of  
2255 practice for office surgeries; providing an  
2256 administrative penalty; revising rulemaking  
2257 requirements; creating ss. 458.3281 and 459.0139,  
2258 F.S.; providing construction; defining terms;  
2259 specifying general requirements for office surgeries;  
2260 specifying standards of practice for office surgeries,  
2261 delineated by the level of surgery being performed;  
2262 authorizing the Board of Medicine and the Board of  
2263 Osteopathic Medicine, as applicable, to adopt  
2264 additional standards of practice by rule; providing an  
2265 effective date.