

By the Committee on Health Policy; and Senator Garcia

588-02981-24

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1 A bill to be entitled
2 An act relating to office surgeries; amending ss.
3 458.328 and 459.0138, F.S.; revising the types of
4 procedures for which a medical office must register
5 with the Department of Health to perform office
6 surgeries; specifying notification and inspection
7 procedures for the department and the Agency for
8 Health Care Administration if, during the registration
9 process, the department determines that the
10 performance of specified procedures in the office
11 would create a risk to patient safety such that the
12 office should instead be regulated as an ambulatory
13 surgical center; deleting obsolete language; making
14 technical and clarifying changes; revising standards
15 of practice for office surgeries; requiring medical
16 offices already registered with the department to
17 perform certain office surgeries as of a specified
18 date to reregister if such offices perform specified
19 procedures; specifying notification and inspection
20 procedures for the department and the agency in the
21 event that, during the reregistration process, the
22 department determines that the performance of
23 specified procedures in an office creates a risk of
24 patient safety such that the office should instead be
25 regulated as an ambulatory surgical center; requiring
26 an office to cease performing the specified procedures
27 and relinquish its office surgery registration and
28 instead seek licensure as an ambulatory surgical
29 center under such circumstances; requiring the

588-02981-24

20241188c1

30 department to develop a schedule for reregistration of
31 medical offices affected by this act, to be completed
32 by a specified date; providing an effective date.
33

34 Be It Enacted by the Legislature of the State of Florida:
35

36 Section 1. Paragraphs (a), (b), and (h) of subsection (1)
37 and subsection (2) of section 458.328, Florida Statutes, are
38 amended, and subsection (4) is added to that section, to read:

39 458.328 Office surgeries.—

40 (1) REGISTRATION.—

41 (a)1. An office in which a physician performs a liposuction
42 procedure in which more than 1,000 cubic centimeters of
43 supernatant fat is temporarily or permanently removed, a
44 liposuction procedure in which the patient is rotated 180
45 degrees or more during the procedure, a gluteal fat grafting
46 procedure, a Level II office surgery, or a Level III office
47 surgery must register with the department. ~~unless the office is~~
48 licensed as A facility licensed under chapter 390 or chapter 395
49 may not be registered under this section.

50 2. The department must complete an inspection of any office
51 seeking registration under this section before the office may be
52 registered.

53 3. If the department determines that an office seeking
54 registration under this section is one in which a physician is
55 likely to perform, or intends to perform, liposuction procedures
56 that include a patient being rotated 180 degrees or more during
57 the procedure or in which a physician is likely to perform, or
58 intends to perform, gluteal fat grafting procedures, and the

588-02981-24

20241188c1

59 department determines that the performance of such procedures in
60 the office would create a significant risk to patient safety and
61 the interests of patient safety would be better served if such
62 procedures were instead regulated under the requirements of
63 ambulatory surgical center licensure under chapter 395:

64 a. The department must notify the Agency for Health Care
65 Administration of its determination.

66 b. The agency must inspect the office and determine, in the
67 interest of patient safety, whether the office is a candidate
68 for ambulatory surgical center licensure, notwithstanding the
69 office's failure to meet all requirements associated with such
70 licensure at the time of inspection and notwithstanding any
71 pertinent exceptions provided under s. 395.002(3).

72 c. If the agency determines that an office is a candidate
73 for ambulatory surgical center licensure under sub-subparagraph
74 b., the agency must notify the office and the department, and
75 the office may not register under this section and must instead
76 attain ambulatory surgical center licensure under chapter 395
77 before such surgeries may be conducted in the office.

78 d. If the agency determines that an office is not a
79 candidate for ambulatory surgical center licensure under sub-
80 subparagraph b., the agency must notify the office and the
81 department, and the department shall resume the office's
82 registration process.

83 ~~(b) By January 1, 2020,~~ Each office registered under this
84 section or s. 459.0138 must 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

588-02981-24

20241188c1

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 suspend the
94 registration of an office if the office fails to comply with the
95 requirements of this paragraph.

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

101 (2) STANDARDS OF PRACTICE.—

102 (a) A physician may not perform any surgery or procedure
103 identified in paragraph (1) (a) in a setting other than an office
104 registered under this section or a facility licensed under
105 chapter 390 or chapter 395, as applicable. The board shall
106 impose a fine of \$5,000 per incident on a physician who violates
107 this paragraph performing a gluteal fat grafting procedure in an
108 office surgery setting shall adhere to standards of practice
109 pursuant to this subsection and rules adopted by the board.

110 (b) Office surgeries may not:

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

114 2. Require major or prolonged intracranial, intrathoracic,
115 abdominal, or joint replacement procedures, except for
116 laparoscopic procedures;

588-02981-24

20241188c1

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

120 4. Be emergent or life threatening.

121 (c) A physician performing a gluteal fat grafting procedure
122 in an office surgery setting shall adhere to standards of
123 practice under this subsection and rules adopted by the board,
124 which include, but are not limited to, all of the following:

125 1. A physician performing a gluteal fat grafting procedure
126 must conduct an in-person examination of the patient while
127 physically present in the same room as the patient no later than
128 the day before the procedure.

129 2. Before a physician may delegate any duties during a
130 gluteal fat grafting procedure, the patient must provide
131 written, informed consent for such delegation. Any duty
132 delegated by a physician during a gluteal fat grafting procedure
133 must be performed under the direct supervision of the physician
134 performing such procedure. Fat extraction and gluteal fat
135 injections must be performed by the physician and may not be
136 delegated.

137 3. Fat may only be injected into the subcutaneous space of
138 the patient and may not cross the fascia overlying the gluteal
139 muscle. Intramuscular or submuscular fat injections are
140 prohibited.

141 4. When the physician performing a gluteal fat grafting
142 procedure injects fat into the subcutaneous space of the
143 patient, the physician must use ultrasound guidance, or guidance
144 with other technology authorized under board rule which equals
145 or exceeds the quality of ultrasound, during the placement and

588-02981-24

20241188c1

146 navigation of the cannula to ensure that the fat is injected
147 into the subcutaneous space of the patient above the fascia
148 overlying the gluteal muscle. Such guidance with the use of
149 ultrasound or other technology is not required for other
150 portions of such procedure.

151 5. An office in which a physician performs gluteal fat
152 grafting procedures must at all times maintain a ratio of one
153 physician to one patient during all phases of the procedure,
154 beginning with the administration of anesthesia to the patient
155 and concluding with the extubation of the patient. After a
156 physician has commenced, and while he or she is engaged in, a
157 gluteal fat grafting procedure, the physician may not commence
158 or engage in another gluteal fat grafting procedure or any other
159 procedure with another patient at the same time.

160 (d) If a procedure in an office surgery setting results in
161 hospitalization, the incident must be reported as an adverse
162 incident pursuant to s. 458.351.

163 ~~(e) An office in which a physician performs gluteal fat~~
164 ~~grafting procedures must at all times maintain a ratio of one~~
165 ~~physician to one patient during all phases of the procedure,~~
166 ~~beginning with the administration of anesthesia to the patient~~
167 ~~and concluding with the extubation of the patient. After a~~
168 ~~physician has commenced, and while he or she is engaged in, a~~
169 ~~gluteal fat grafting procedure, the physician may not commence~~
170 ~~or engage in another gluteal fat grafting procedure or any other~~
171 ~~procedure with another patient at the same time.~~

172 (4) REREGISTRATION.—An office that registered under this
173 section before July 1, 2024, in which a physician performs
174 liposuction procedures that include a patient being rotated 180

588-02981-24

20241188c1

175 degrees or more during the procedure or in which a physician
176 performs gluteal fat grafting procedures must seek
177 reregistration with the department consistent with the
178 parameters of initial registration under subsection (1)
179 according to a schedule developed by the department. During the
180 reregistration process, if the department determines that the
181 performance of such procedures in the office creates a
182 significant risk to patient safety and that the interests of
183 patient safety would be better served if such procedures were
184 instead regulated under the requirements of ambulatory surgical
185 center licensure under chapter 395:

186 (a) The department must notify the Agency for Health Care
187 Administration of its determination; and

188 (b) The agency must inspect the office and determine, in
189 the interest of patient safety, whether the office is a
190 candidate for ambulatory surgical center licensure,
191 notwithstanding the office's failure to meet all requirements
192 associated with such licensure at the time of inspection and
193 notwithstanding any pertinent exceptions provided under s.
194 395.002(3).

195
196 If the agency determines that an office is a candidate for
197 ambulatory surgical center licensure under paragraph (b), the
198 agency must notify the office and the department, and the office
199 must cease performing procedures described in this subsection.
200 The office may not recommence performing such procedures without
201 first relinquishing its registration under this section and
202 attaining ambulatory surgical center licensure under chapter
203 395.

588-02981-24

20241188c1

204 Section 2. Paragraphs (a), (b), and (h) of subsection (1)
205 and subsection (2) of section 459.0138, Florida Statutes, are
206 amended, and subsection (4) is added to that section, to read:

207 459.0138 Office surgeries.—

208 (1) REGISTRATION.—

209 (a)1. An office in which a physician performs a liposuction
210 procedure in which more than 1,000 cubic centimeters of
211 supernatant fat is temporarily or permanently removed, a
212 liposuction procedure in which the patient is rotated 180
213 degrees or more during the procedure, a gluteal fat grafting
214 procedure, a Level II office surgery, or a Level III office
215 surgery must register with the department. ~~unless the office is~~
216 licensed as A facility licensed under chapter 390 or chapter 395
217 may not be registered under this section.

218 2. The department must complete an inspection of any office
219 seeking registration under this section before the office may be
220 registered.

221 3. If the department determines that an office seeking
222 registration under this section is one in which a physician is
223 likely to perform, or intends to perform, liposuction procedures
224 that include a patient being rotated 180 degrees or more during
225 the procedure or in which a physician is likely to perform, or
226 intends to perform, gluteal fat grafting procedures, and the
227 department determines that the performance of such procedures in
228 the office would create a significant risk to patient safety and
229 the interests of patient safety would be better served if such
230 procedures were instead regulated under the requirements of
231 ambulatory surgical center licensure under chapter 395:

232 a. The department must notify the Agency for Health Care

588-02981-24

20241188c1

233 Administration of its determination.

234 b. The agency must inspect the office and determine, in the
235 interest of patient safety, whether the office is a candidate
236 for ambulatory surgical center licensure, notwithstanding the
237 office's failure to meet all requirements associated with such
238 licensure at the time of inspection and notwithstanding any
239 pertinent exceptions provided under s. 395.002(3).

240 c. If the agency determines that an office is a candidate
241 for ambulatory surgical center licensure under sub-subparagraph
242 b., the agency must notify the office and the department, and
243 the office may not register under this section and must instead
244 attain ambulatory surgical center licensure under chapter 395
245 before such surgeries may be conducted in the office.

246 d. If the agency determines that an office is not a
247 candidate for ambulatory surgical center licensure under sub-
248 subparagraph b., the agency must notify the office and the
249 department, and the department shall resume the office's
250 registration process.

251 ~~(b) By January 1, 2020,~~ Each office registered under this
252 section or s. 458.328 must designate a physician who is
253 responsible for the office's compliance with the office health
254 and safety requirements of this section and rules adopted
255 hereunder. A designated physician must have a full, active, and
256 unencumbered license under this chapter or chapter 458 and shall
257 practice at the office for which he or she has assumed
258 responsibility. Within 10 calendar days after the termination of
259 a designated physician relationship, the office must notify the
260 department of the designation of another physician to serve as
261 the designated physician. The department may suspend a

588-02981-24

20241188c1

262 registration for an office if the office fails to comply with
263 the requirements of this paragraph.

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

269 (2) STANDARDS OF PRACTICE.—

270 (a) A physician may not perform any surgery or procedure
271 identified in paragraph (1) (a) in a setting other than an office
272 registered under this section or a facility licensed under
273 chapter 390 or chapter 395, as applicable. The board shall
274 impose a fine of \$5,000 per incident on a physician who violates
275 this paragraph performing a gluteal fat grafting procedure in an
276 office surgery setting shall adhere to standards of practice
277 pursuant to this subsection and rules adopted by the board.

278 (b) Office surgeries may not:

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

282 2. Require major or prolonged intracranial, intrathoracic,
283 abdominal, or joint replacement procedures, except for
284 laparoscopic procedures;

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

288 4. Be emergent or life threatening.

289 (c) A physician performing a gluteal fat grafting procedure
290 in an office surgery setting shall adhere to standards of

588-02981-24

20241188c1

291 practice under this subsection and rules adopted by the board,
292 which include, but are not limited to, all of the following:

293 1. A physician performing a gluteal fat grafting procedure
294 must conduct an in-person examination of the patient while
295 physically present in the same room as the patient no later than
296 the day before the procedure.

297 2. Before a physician may delegate any duties during a
298 gluteal fat grafting procedure, the patient must provide
299 written, informed consent for such delegation. Any duty
300 delegated by a physician during a gluteal fat grafting procedure
301 must be performed under the direct supervision of the physician
302 performing such procedure. Fat extraction and gluteal fat
303 injections must be performed by the physician and may not be
304 delegated.

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306 the patient and may not cross the fascia overlying the gluteal
307 muscle. Intramuscular or submuscular fat injections are
308 prohibited.

309 4. When the physician performing a gluteal fat grafting
310 procedure injects fat into the subcutaneous space of the
311 patient, the physician must use ultrasound guidance, or guidance
312 with other technology authorized under board rule which equals
313 or exceeds the quality of ultrasound, during the placement and
314 navigation of the cannula to ensure that the fat is injected
315 into the subcutaneous space of the patient above the fascia
316 overlying the gluteal muscle. Such guidance with the use of
317 ultrasound or other technology is not required for other
318 portions of such procedure.

319 5. An office in which a physician performs gluteal fat

588-02981-24

20241188c1

320 grafting procedures must at all times maintain a ratio of one
321 physician to one patient during all phases of the procedure,
322 beginning with the administration of anesthesia to the patient
323 and concluding with the extubation of the patient. After a
324 physician has commenced, and while he or she is engaged in, a
325 gluteal fat grafting procedure, the physician may not commence
326 or engage in another gluteal fat grafting procedure or any other
327 procedure with another patient at the same time.

328 (d) If a procedure in an office surgery setting results in
329 hospitalization, the incident must be reported as an adverse
330 incident pursuant to s. 458.351.

331 ~~(e) An office in which a physician performs gluteal fat~~
332 ~~grafting procedures must at all times maintain a ratio of one~~
333 ~~physician to one patient during all phases of the procedure,~~
334 ~~beginning with the administration of anesthesia to the patient~~
335 ~~and concluding with the extubation of the patient. After a~~
336 ~~physician has commenced, and while he or she is engaged in, a~~
337 ~~gluteal fat grafting procedure, the physician may not commence~~
338 ~~or engage in another gluteal fat grafting procedure or any other~~
339 ~~procedure with another patient at the same time.~~

340 (4) REREGISTRATION.—An office that registered under this
341 section before July 1, 2024, in which a physician performs
342 liposuction procedures that include a patient being rotated 180
343 degrees or more during the procedure or in which a physician
344 performs gluteal fat grafting procedures must seek
345 reregistration with the department consistent with the
346 parameters of initial registration under subsection (1)
347 according to a schedule developed by the department. During the
348 reregistration process, if the department determines that the

588-02981-24

20241188c1

349 performance of such procedures in the office creates a
350 significant risk to patient safety and that the interests of
351 patient safety would be better served if such procedures were
352 instead regulated under the requirements of ambulatory surgical
353 center licensure under chapter 395:

354 (a) The department must notify the Agency for Health Care
355 Administration of its determination;

356 (b) The agency must inspect the office and determine, in
357 the interest of patient safety, whether the office is a
358 candidate for ambulatory surgical center licensure
359 notwithstanding the office's failure to meet all requirements
360 associated with such licensure at the time of inspection and
361 notwithstanding any pertinent exceptions provided under s.
362 395.002(3).

363

364 If the agency determines that an office is a candidate for
365 ambulatory surgical center licensure under paragraph (b), the
366 agency must notify the office and the department, and the office
367 must cease performing procedures described in this subsection.
368 The office may not recommence performing such procedures without
369 first relinquishing its registration under this section and
370 attaining ambulatory surgery center licensure under chapter 395.

371 Section 3. The Department of Health shall develop a
372 schedule for reregistration of offices affected by the
373 amendments made to s. 458.328(1) or s. 459.0138(1), Florida
374 Statutes, by this act. Registration of all such offices must be
375 completed by December 1, 2024.

376 Section 4. This act shall take effect upon becoming a law.