

By Senator Garcia

36-01129-24

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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; deleting obsolete language; making
7 technical and clarifying changes; revising standards
8 of practice for office surgeries; requiring medical
9 offices already registered with the department to
10 perform certain office surgeries as of a specified
11 date to reregister if such offices perform specified
12 procedures; specifying notification and inspection
13 procedures for the department and the Agency for
14 Health Care Administration in the event that, during
15 the reregistration process, the department determines
16 that the performance of specified procedures in an
17 office creates a risk of patient safety such that the
18 office should instead be regulated as an ambulatory
19 surgical center; requiring an office to cease
20 performing the specified procedures and relinquish its
21 office surgery registration and instead seek licensure
22 as an ambulatory surgical center under such
23 circumstances; requiring the department to develop a
24 schedule for reregistration of medical offices
25 affected by this act, to be completed by a specified
26 date; providing an effective date.

27
28 Be It Enacted by the Legislature of the State of Florida:
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30 Section 1. Paragraphs (a), (b), and (h) of subsection (1)
31 and subsection (2) of section 458.328, Florida Statutes, are
32 amended, and subsection (4) is added to that section, to read:

33 458.328 Office surgeries.—

34 (1) REGISTRATION.—

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

44 2. The department must complete an inspection of any office
45 seeking registration under this section before the office may be
46 registered.

47 (b) ~~By January 1, 2020,~~ Each office registered under this
48 section or s. 459.0138 must designate a physician who is
49 responsible for the office's compliance with the office health
50 and safety requirements of this section and rules adopted
51 hereunder. A designated physician must have a full, active, and
52 unencumbered license under this chapter or chapter 459 and shall
53 practice at the office for which he or she has assumed
54 responsibility. Within 10 calendar days after the termination of
55 a designated physician relationship, the office must notify the
56 department of the designation of another physician to serve as
57 the designated physician. The department may suspend the
58 registration of an office if the office fails to comply with the

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59 requirements of this paragraph.

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

65 (2) STANDARDS OF PRACTICE.—

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

74 (b) Office surgeries may not:

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

78 2. Require major or prolonged intracranial, intrathoracic,
79 abdominal, or joint replacement procedures, except for
80 laparoscopic procedures;

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

84 4. Be emergent or life threatening.

85 (c) A physician performing a gluteal fat grafting procedure
86 in an office surgery setting shall adhere to standards of
87 practice under this subsection and rules adopted by the board,

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88 which include, but are not limited to, all of the following:

89 1. A physician performing a gluteal fat grafting procedure
90 must conduct an in-person examination of the patient while
91 physically present in the same room as the patient no later than
92 the day before the procedure.

93 2. Before a physician may delegate any duties during a
94 gluteal fat grafting procedure, the patient must provide
95 written, informed consent for such delegation. Any duty
96 delegated by a physician during a gluteal fat grafting procedure
97 must be performed under the direct supervision of the physician
98 performing such procedure. Fat extraction and gluteal fat
99 injections must be performed by the physician and may not be
100 delegated.

101 3. Fat may only be injected into the subcutaneous space of
102 the patient and may not cross the fascia overlying the gluteal
103 muscle. Intramuscular or submuscular fat injections are
104 prohibited.

105 4. When the physician performing a gluteal fat grafting
106 procedure injects fat into the subcutaneous space of the
107 patient, the physician must use ultrasound guidance, or guidance
108 with other technology authorized under board rule which equals
109 or exceeds the quality of ultrasound, during the placement and
110 navigation of the cannula to ensure that the fat is injected
111 into the subcutaneous space of the patient above the fascia
112 overlying the gluteal muscle. Such guidance with the use of
113 ultrasound or other technology is not required for other
114 portions of such procedure.

115 5. An office in which a physician performs gluteal fat
116 grafting procedures must at all times maintain a ratio of one

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117 physician to one patient during all phases of the procedure,
118 beginning with the administration of anesthesia to the patient
119 and concluding with the extubation of the patient. After a
120 physician has commenced, and while he or she is engaged in, a
121 gluteal fat grafting procedure, the physician may not commence
122 or engage in another gluteal fat grafting procedure or any other
123 procedure with another patient at the same time.

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

127 ~~(e) An office in which a physician performs gluteal fat~~
128 ~~grafting procedures must at all times maintain a ratio of one~~
129 ~~physician to one patient during all phases of the procedure,~~
130 ~~beginning with the administration of anesthesia to the patient~~
131 ~~and concluding with the extubation of the patient. After a~~
132 ~~physician has commenced, and while he or she is engaged in, a~~
133 ~~gluteal fat grafting procedure, the physician may not commence~~
134 ~~or engage in another gluteal fat grafting procedure or any other~~
135 ~~procedure with another patient at the same time.~~

136 (4) REREGISTRATION.—An office that registered under this
137 section before July 1, 2024, in which a physician performs
138 liposuction procedures that include a patient being rotated 180
139 degrees or more during the procedure or in which a physician
140 performs gluteal fat grafting procedures must seek
141 reregistration with the department consistent with the
142 parameters of initial registration under subsection (1)
143 according to a schedule developed by the department. During the
144 reregistration process, if the department determines that the
145 performance of such procedures in the office creates a

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146 significant risk to patient safety and that the interests of
147 patient safety would be better served if such procedures were
148 instead regulated under the requirements of ambulatory surgical
149 center licensure under chapter 395:

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

152 (b) The agency must inspect the office and determine, in
153 the interest of patient safety, whether the office is a
154 candidate for ambulatory surgical center licensure
155 notwithstanding the office's failure to meet all requirements
156 associated with such licensure at the time of inspection and
157 notwithstanding the exceptions provided under s. 395.002(3).

158
159 If the agency determines that an office is a candidate for
160 ambulatory surgical center licensure under paragraph (b), the
161 agency must notify the office and the department, and the office
162 must cease performing procedures described in this subsection.
163 The office may not recommence performing such procedures without
164 first relinquishing its registration under this section and
165 attaining ambulatory surgery center licensure under chapter 395.

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

169 459.0138 Office surgeries.—

170 (1) REGISTRATION.—

171 (a)1. An office in which a physician performs a liposuction
172 procedure in which more than 1,000 cubic centimeters of
173 supernatant fat is temporarily or permanently removed, a
174 liposuction procedure in which the patient is rotated 180

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175 degrees or more during the procedure, a gluteal fat grafting
176 procedure, a Level II office surgery, or a Level III office
177 surgery must register with the department. ~~unless the office is~~
178 ~~licensed as A facility~~ licensed under chapter 390 or chapter 395
179 may not be registered under this section.

180 2. The department must complete an inspection of any office
181 seeking registration under this section before the office may be
182 registered.

183 (b) ~~By January 1, 2020,~~ Each office registered under this
184 section or s. 458.328 must designate a physician who is
185 responsible for the office's compliance with the office health
186 and safety requirements of this section and rules adopted
187 hereunder. A designated physician must have a full, active, and
188 unencumbered license under this chapter or chapter 458 and shall
189 practice at the office for which he or she has assumed
190 responsibility. Within 10 calendar days after the termination of
191 a designated physician relationship, the office must notify the
192 department of the designation of another physician to serve as
193 the designated physician. The department may suspend a
194 registration for an office if the office fails to comply with
195 the requirements of this paragraph.

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

201 (2) STANDARDS OF PRACTICE.—

202 (a) A physician may not perform any surgery or procedure
203 identified in paragraph (1) (a) in a setting other than an office

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204 registered under this section or a facility licensed under
205 chapter 390 or chapter 395, as applicable. The board shall
206 impose a fine of \$5,000 per incident on a physician who violates
207 this paragraph ~~performing a gluteal fat grafting procedure in an~~
208 ~~office surgery setting shall adhere to standards of practice~~
209 ~~pursuant to this subsection and rules adopted by the board.~~

210 (b) Office surgeries may not:

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

214 2. Require major or prolonged intracranial, intrathoracic,
215 abdominal, or joint replacement procedures, except for
216 laparoscopic procedures;

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

220 4. Be emergent or life threatening.

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

225 1. A physician performing a gluteal fat grafting procedure
226 must conduct an in-person examination of the patient while
227 physically present in the same room as the patient no later than
228 the day before the procedure.

229 2. Before a physician may delegate any duties during a
230 gluteal fat grafting procedure, the patient must provide
231 written, informed consent for such delegation. Any duty
232 delegated by a physician during a gluteal fat grafting procedure

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233 must be performed under the direct supervision of the physician
234 performing such procedure. Fat extraction and gluteal fat
235 injections must be performed by the physician and may not be
236 delegated.

237 3. Fat may only be injected into the subcutaneous space of
238 the patient and may not cross the fascia overlying the gluteal
239 muscle. Intramuscular or submuscular fat injections are
240 prohibited.

241 4. When the physician performing a gluteal fat grafting
242 procedure injects fat into the subcutaneous space of the
243 patient, the physician must use ultrasound guidance, or guidance
244 with other technology authorized under board rule which equals
245 or exceeds the quality of ultrasound, during the placement and
246 navigation of the cannula to ensure that the fat is injected
247 into the subcutaneous space of the patient above the fascia
248 overlying the gluteal muscle. Such guidance with the use of
249 ultrasound or other technology is not required for other
250 portions of such procedure.

251 5. An office in which a physician performs gluteal fat
252 grafting procedures must at all times maintain a ratio of one
253 physician to one patient during all phases of the procedure,
254 beginning with the administration of anesthesia to the patient
255 and concluding with the extubation of the patient. After a
256 physician has commenced, and while he or she is engaged in, a
257 gluteal fat grafting procedure, the physician may not commence
258 or engage in another gluteal fat grafting procedure or any other
259 procedure with another patient at the same time.

260 (d) If a procedure in an office surgery setting results in
261 hospitalization, the incident must be reported as an adverse

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262 incident pursuant to s. 458.351.

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273 section before July 1, 2024, in which a physician performs
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277 reregistration with the department consistent with the
278 parameters of initial registration under subsection (1)
279 according to a schedule developed by the department. During the
280 reregistration process, if the department determines that the
281 performance of such procedures in the office creates a
282 significant risk to patient safety and that the interests of
283 patient safety would be better served if such procedures were
284 instead regulated under the requirements of ambulatory surgical
285 center licensure under chapter 395:

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292 associated with such licensure at the time of inspection and
293 notwithstanding the exceptions provided under s. 395.002(3).

294
295 If the agency determines that an office is a candidate for
296 ambulatory surgical center licensure under paragraph (b), the
297 agency must notify the office and the department, and the office
298 must cease performing procedures described in this subsection.
299 The office may not recommence performing such procedures without
300 first relinquishing its registration under this section and
301 attaining ambulatory surgery center licensure under chapter 395.

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

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