

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:

29

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
 36 liposuction procedure in which more than 1,000 cubic centimeters
 37 of 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
 45 office seeking registration under this section before the office
 46 may be 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
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
82 | direct visualization by open exposure of the major blood vessel,
83 | except for percutaneous endovascular intervention; or

84 | 4. Be emergent or life threatening.

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

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

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

101 delegated.

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

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

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

125 (d) If a procedure in an office surgery setting results in

126 hospitalization, the incident must be reported as an adverse
127 incident pursuant to s. 458.351.

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

137 (4) REREGISTRATION.—An office that registered under this
138 section before July 1, 2024, in which a physician performs
139 liposuction procedures that include a patient being rotated 180
140 degrees or more during the procedure or in which a physician
141 performs gluteal fat grafting procedures must seek
142 reregistration with the department consistent with the
143 parameters of initial registration under subsection (1)
144 according to a schedule developed by the department. During the
145 reregistration process, if the department determines that the
146 performance of such procedures in the office creates a
147 significant risk to patient safety and that the interests of
148 patient safety would be better served if such procedures were
149 instead regulated under the requirements of ambulatory surgical
150 center licensure under chapter 395:

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

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

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

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

170 459.0138 Office surgeries.—

171 (1) REGISTRATION.—

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

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

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

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

197 ~~(h) A physician may only perform a procedure or surgery~~
198 ~~identified in paragraph (a) in an office that is registered with~~
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 204 identified in paragraph (1) (a) in a setting other than an office
 205 registered under this section or a facility licensed under
 206 chapter 390 or chapter 395, as applicable. The board shall
 207 impose a fine of \$5,000 per incident on a physician who violates
 208 this paragraph performing a gluteal fat grafting procedure in an
 209 office surgery setting shall adhere to standards of practice
 210 pursuant to this subsection and rules adopted by the board.

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

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

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 219 direct visualization by open exposure of the major blood vessel,
 220 except for percutaneous endovascular intervention; or

221 4. Be emergent or life threatening.

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

226 following:

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

231 2. Before a physician may delegate any duties during a
232 gluteal fat grafting procedure, the patient must provide
233 written, informed consent for such delegation. Any duty
234 delegated by a physician during a gluteal fat grafting procedure
235 must be performed under the direct supervision of the physician
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237 injections must be performed by the physician and may not be
238 delegated.

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

251 ultrasound or other technology is not required for other
252 portions of such procedure.

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

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

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

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

290 (b) The agency must inspect the office and determine, in
291 the interest of patient safety, whether the office is a
292 candidate for ambulatory surgical center licensure
293 notwithstanding the office's failure to meet all requirements
294 associated with such licensure at the time of inspection and
295 notwithstanding the exceptions provided under s. 395.002 (3).

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297 If the agency determines that an office is a candidate for
298 ambulatory surgical center licensure under paragraph (b), the
299 agency must notify the office and the department, and the office
300 must cease performing procedures described in this subsection.

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301 The office may not recommence performing such procedures without
302 first relinquishing its registration under this section and
303 attaining ambulatory surgery center licensure under chapter 395.

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

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