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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/06/2024	.	
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	.	
	.	

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

Senate Amendment (with title amendment)

Delete lines 47 - 293

and insert:

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



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11 department determines that the performance of such procedures in
12 the office would create a significant risk to patient safety and
13 the interests of patient safety would be better served if such
14 procedures were instead regulated under the requirements of
15 ambulatory surgical center licensure under chapter 395:

16 a. The department must notify the Agency for Health Care
17 Administration of its determination.

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

24 c. If the agency determines that an office is a candidate
25 for ambulatory surgical center licensure under sub-subparagraph
26 b., the agency must notify the office and the department, and
27 the office may not register under this section and must instead
28 attain ambulatory surgical center licensure under chapter 395
29 before such surgeries may be conducted in the office.

30 d. If the agency determines that an office is not a
31 candidate for ambulatory surgical center licensure under sub-
32 subparagraph b., the agency must notify the office and the
33 department, and the department shall resume the office's
34 registration process.

35 (b) ~~By January 1, 2020,~~ Each office registered under this
36 section or s. 459.0138 must designate a physician who is
37 responsible for the office's compliance with the office health
38 and safety requirements of this section and rules adopted
39 hereunder. A designated physician must have a full, active, and



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40 unencumbered license under this chapter or chapter 459 and shall
41 practice at the office for which he or she has assumed
42 responsibility. Within 10 calendar days after the termination of
43 a designated physician relationship, the office must notify the
44 department of the designation of another physician to serve as
45 the designated physician. The department may suspend the
46 registration of an office if the office fails to comply with the
47 requirements of this paragraph.

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

53 (2) STANDARDS OF PRACTICE.—

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

62 (b) Office surgeries may not:

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

66 2. Require major or prolonged intracranial, intrathoracic,
67 abdominal, or joint replacement procedures, except for
68 laparoscopic procedures;



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

72 4. Be emergent or life threatening.

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

77 1. A physician performing a gluteal fat grafting procedure
78 must conduct an in-person examination of the patient while
79 physically present in the same room as the patient no later than
80 the day before the procedure.

81 2. Before a physician may delegate any duties during a
82 gluteal fat grafting procedure, the patient must provide
83 written, informed consent for such delegation. Any duty
84 delegated by a physician during a gluteal fat grafting procedure
85 must be performed under the direct supervision of the physician
86 performing such procedure. Fat extraction and gluteal fat
87 injections must be performed by the physician and may not be
88 delegated.

89 3. Fat may only be injected into the subcutaneous space of
90 the patient and may not cross the fascia overlying the gluteal
91 muscle. Intramuscular or submuscular fat injections are
92 prohibited.

93 4. When the physician performing a gluteal fat grafting
94 procedure injects fat into the subcutaneous space of the
95 patient, the physician must use ultrasound guidance, or guidance
96 with other technology authorized under board rule which equals
97 or exceeds the quality of ultrasound, during the placement and



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98 navigation of the cannula to ensure that the fat is injected
99 into the subcutaneous space of the patient above the fascia
100 overlying the gluteal muscle. Such guidance with the use of
101 ultrasound or other technology is not required for other
102 portions of such procedure.

103 5. An office in which a physician performs gluteal fat
104 grafting procedures must at all times maintain a ratio of one
105 physician to one patient during all phases of the procedure,
106 beginning with the administration of anesthesia to the patient
107 and concluding with the extubation of the patient. After a
108 physician has commenced, and while he or she is engaged in, a
109 gluteal fat grafting procedure, the physician may not commence
110 or engage in another gluteal fat grafting procedure or any other
111 procedure with another patient at the same time.

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

115 ~~(c) An office in which a physician performs gluteal fat~~
116 ~~grafting procedures must at all times maintain a ratio of one~~
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 (4) REREGISTRATION.—An office that registered under this
125 section before July 1, 2024, in which a physician performs
126 liposuction procedures that include a patient being rotated 180



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127 degrees or more during the procedure or in which a physician
128 performs gluteal fat grafting procedures must seek
129 reregistration with the department consistent with the
130 parameters of initial registration under subsection (1)
131 according to a schedule developed by the department. During the
132 reregistration process, if the department determines that the
133 performance of such procedures in the office creates a
134 significant risk to patient safety and that the interests of
135 patient safety would be better served if such procedures were
136 instead regulated under the requirements of ambulatory surgical
137 center licensure under chapter 395:

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

140 (b) The agency must inspect the office and determine, in
141 the interest of patient safety, whether the office is a
142 candidate for ambulatory surgical center licensure,
143 notwithstanding the office's failure to meet all requirements
144 associated with such licensure at the time of inspection and
145 notwithstanding any pertinent exceptions provided under s.
146 395.002(3).

147
148 If the agency determines that an office is a candidate for
149 ambulatory surgical center licensure under paragraph (b), the
150 agency must notify the office and the department, and the office
151 must cease performing procedures described in this subsection.
152 The office may not recommence performing such procedures without
153 first relinquishing its registration under this section and
154 attaining ambulatory surgical center licensure under chapter
155 395.



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

159 459.0138 Office surgeries.—

160 (1) REGISTRATION.—

161 (a)1. An office in which a physician performs a liposuction
162 procedure in which more than 1,000 cubic centimeters of
163 supernatant fat is temporarily or permanently removed, a
164 liposuction procedure in which the patient is rotated 180
165 degrees or more during the procedure, a gluteal fat grafting
166 procedure, a Level II office surgery, or a Level III office
167 surgery must register with the department. ~~unless the office is~~
168 ~~licensed as~~ A facility licensed under chapter 390 or chapter 395
169 may not be registered under this section.

170 2. The department must complete an inspection of any office
171 seeking registration under this section before the office may be
172 registered.

173 3. If the department determines that an office seeking
174 registration under this section is one in which a physician is
175 likely to perform, or intends to perform, liposuction procedures
176 that include a patient being rotated 180 degrees or more during
177 the procedure or in which a physician is likely to perform, or
178 intends to perform, gluteal fat grafting procedures, and the
179 department determines that the performance of such procedures in
180 the office would create a significant risk to patient safety and
181 the interests of patient safety would be better served if such
182 procedures were instead regulated under the requirements of
183 ambulatory surgical center licensure under chapter 395:

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



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185 Administration of its determination.

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

192 c. If the agency determines that an office is a candidate
193 for ambulatory surgical center licensure under sub-subparagraph
194 b., the agency must notify the office and the department, and
195 the office may not register under this section and must instead
196 attain ambulatory surgical center licensure under chapter 395
197 before such surgeries may be conducted in the office.

198 d. If the agency determines that an office is not a
199 candidate for ambulatory surgical center licensure under sub-
200 subparagraph b., the agency must notify the office and the
201 department, and the department shall resume the office's
202 registration process.

203 ~~(b) By January 1, 2020,~~ Each office registered under this
204 section or s. 458.328 must designate a physician who is
205 responsible for the office's compliance with the office health
206 and safety requirements of this section and rules adopted
207 hereunder. A designated physician must have a full, active, and
208 unencumbered license under this chapter or chapter 458 and shall
209 practice at the office for which he or she has assumed
210 responsibility. Within 10 calendar days after the termination of
211 a designated physician relationship, the office must notify the
212 department of the designation of another physician to serve as
213 the designated physician. The department may suspend a



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214 registration for an office if the office fails to comply with
215 the requirements of this paragraph.

216 ~~(h) A physician may only perform a procedure or surgery~~
217 ~~identified in paragraph (a) in an office that is registered with~~
218 ~~the department. The board shall impose a fine of \$5,000 per day~~
219 ~~on a physician who performs a procedure or surgery in an office~~
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223 identified in paragraph (1)(a) in a setting other than an office
224 registered under this section or a facility licensed under
225 chapter 390 or chapter 395, as applicable. The board shall
226 impose a fine of \$5,000 per incident on a physician who violates
227 this paragraph performing a gluteal fat grafting procedure in an
228 office surgery setting shall adhere to standards of practice
229 pursuant to this subsection and rules adopted by the board.

230 (b) Office surgeries may not:

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

234 2. Require major or prolonged intracranial, intrathoracic,
235 abdominal, or joint replacement procedures, except for
236 laparoscopic procedures;

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

240 4. Be emergent or life threatening.

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



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

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

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

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258 the patient and may not cross the fascia overlying the gluteal
259 muscle. Intramuscular or submuscular fat injections are
260 prohibited.

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

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



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275 and concluding with the extubation of the patient. After a
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277 gluteal fat grafting procedure, the physician may not commence
278 or engage in another gluteal fat grafting procedure or any other
279 procedure with another patient at the same time.

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

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293 section before July 1, 2024, in which a physician performs
294 liposuction procedures that include a patient being rotated 180
295 degrees or more during the procedure or in which a physician
296 performs gluteal fat grafting procedures must seek
297 reregistration with the department consistent with the
298 parameters of initial registration under subsection (1)
299 according to a schedule developed by the department. During the
300 reregistration process, if the department determines that the



301 performance of such procedures in the office creates a
302 significant risk to patient safety and that the interests of
303 patient safety would be better served if such procedures were
304 instead regulated under the requirements of ambulatory surgical
305 center licensure under chapter 395:

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307 Administration of its determination;

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309 the interest of patient safety, whether the office is a
310 candidate for ambulatory surgical center licensure
311 notwithstanding the office's failure to meet all requirements
312 associated with such licensure at the time of inspection and
313 notwithstanding any pertinent exceptions provided under s.
314 395.002(3).

315
316 ===== T I T L E A M E N D M E N T =====

317 And the title is amended as follows:

318 Delete line 6

319 and insert:

320 surgeries; specifying notification and inspection
321 procedures for the department and the Agency for
322 Health Care Administration if, during the registration
323 process, the department determines that the
324 performance of specified procedures in the office
325 would create a risk to patient safety such that the
326 office should instead be regulated as an ambulatory
327 surgical center; deleting obsolete language; making