

By Senator Gaetz

1-01021B-25

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1 A bill to be entitled
2 An act relating to office surgery standards of
3 practice; providing a short title; amending ss.
4 458.328 and 459.0138, F.S.; prohibiting physicians
5 from performing level II or level III surgeries on
6 immediate family members in an office surgery setting,
7 with exceptions; defining the term "immediate family
8 member"; prohibiting physicians from altering or
9 changing a consent form for a surgical procedure after
10 the patient has signed the form or after sedative
11 drugs have been administered to the patient;
12 specifying requirements for health care professionals
13 performing duties at a registered office which require
14 licensure or certification; specifying practice
15 standards for office surgeries; requiring office
16 surgeries to report adverse incidents to the
17 Department of Health within a specified timeframe;
18 specifying requirements if an adverse incident occurs
19 due to a local anesthetic; prohibiting office
20 surgeries from performing surgical procedures
21 concurrently with any construction or refurbishment
22 that interferes with the safe performance of such
23 procedures until it is safe to do so; requiring the
24 department to create an oversight committee for
25 specified purposes; requiring physicians performing
26 surgeries in office surgery settings to comply with
27 specified financial responsibility requirements;
28 providing an effective date.
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1-01021B-25

2025424__

30 Be It Enacted by the Legislature of the State of Florida:

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32 Section 1. This act may be cited as "Hillary's Law."

33 Section 2. Present subsection (3) of section 458.328,
34 Florida Statutes, is redesignated as subsection (4), a new
35 subsection (3) is added to that section, and subsection (2) is
36 amended, to read:

37 458.328 Office surgeries.—

38 (2) STANDARDS OF PRACTICE.—

39 (a) A physician may not perform any surgery or procedure
40 identified in paragraph (1)(a) in a setting other than an office
41 surgery setting registered under this section or a facility
42 licensed under chapter 390 or chapter 395, as applicable. The
43 board shall impose a fine of \$5,000 per incident on a physician
44 who violates this paragraph.

45 (b) Office surgeries may not:

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

49 2. Require major or prolonged intracranial, intrathoracic,
50 abdominal, or joint replacement procedures, except for
51 laparoscopic procedures;

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

55 4. Be emergent or life threatening.

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

1-01021B-25

2025424__

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

60 1. A physician performing a gluteal fat grafting procedure
61 must conduct an in-person examination of the patient while
62 physically present in the same room as the patient no later than
63 the day before the procedure.

64 2. Before a physician may delegate any duties during a
65 gluteal fat grafting procedure, the patient must provide
66 written, informed consent for such delegation. Any duty
67 delegated by a physician during a gluteal fat grafting procedure
68 must be performed under the direct supervision of the physician
69 performing such procedure. Fat extraction and gluteal fat
70 injections must be performed by the physician and may not be
71 delegated.

72 3. Fat may only be injected into the subcutaneous space of
73 the patient and may not cross the fascia overlying the gluteal
74 muscle. Intramuscular or submuscular fat injections are
75 prohibited.

76 4. When the physician performing a gluteal fat grafting
77 procedure injects fat into the subcutaneous space of the
78 patient, the physician must use ultrasound guidance, or guidance
79 with other technology authorized under board rule which equals
80 or exceeds the quality of ultrasound, during the placement and
81 navigation of the cannula to ensure that the fat is injected
82 into the subcutaneous space of the patient above the fascia
83 overlying the gluteal muscle. Such guidance with the use of
84 ultrasound or other technology is not required for other
85 portions of such procedure.

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

1-01021B-25

2025424__

88 physician to one patient during all phases of the procedure,
89 beginning with the administration of anesthesia to the patient
90 and concluding with the extubation of the patient. After a
91 physician has commenced, and while he or she is engaged in, a
92 gluteal fat grafting procedure, the physician may not commence
93 or engage in another gluteal fat grafting procedure or any other
94 procedure with another patient at the same time.

95 (d) A physician may not:

96 1. Perform a level II or level III surgery on an immediate
97 family member unless the family member, due to cost or to
98 availability of alternate providers, cannot reasonably obtain
99 the surgical service from another physician. As used in this
100 subparagraph, the term "immediate family member" means a parent,
101 spouse, child, or sibling.

102 2. Alter or change an informed consent form for a procedure
103 after the consent has been signed, or after any sedative drugs
104 are administered to the patient.

105 (e) All health care professionals performing duties at a
106 registered office which require licensure or certification must
107 be:

108 1. Licensed or certified, and may not perform surgeries or
109 procedures outside the scope of his or her license or
110 certification.

111 2. Certified in advanced cardiac life support and maintain
112 certification through continuing education every 2 years.

113 (f) A registered office must have:

114 1. Appropriate staff on premises for procedures and
115 surgeries and administrative duties.

116 2. On the premises at all times a functioning automated

1-01021B-25

2025424__

117 external defibrillator device as defined in s. 768.1325(2)(b)
118 and all necessary critical care equipment and medications.

119 3. Preoperative guidelines, intraoperative protocols, and
120 postoperative recovery guidelines in place for each surgery and
121 procedure, and any follow-up surgeries and procedures, for every
122 patient.

123 4. Qualified anesthesia personnel present in the room
124 throughout the administration of all general and regional
125 anesthetics and provision of monitored anesthesia care.

126 5. Proper protocols in place for storing, accessing,
127 administering, and dispensing sedatives and drugs listed in
128 Schedule II, Schedule III, or Schedule IV of s. 893.03.

129 (g) ~~(d)~~ If a procedure in an office surgery setting results
130 in hospitalization, the incident must be reported as an adverse
131 incident pursuant to s. 458.351 within 48 hours after its
132 occurrence. If an adverse incident occurs due to a local
133 anesthetic, all vials related to the local anesthetic and its
134 constitution that were administered must be saved as evidence
135 for the department and the sheriff's office or municipal police
136 department.

137 (h) A registered office having to undergo any type of
138 construction or refurbishment that materially interferes with
139 the safe performance of a surgical procedure in the office may
140 not perform any surgeries or procedures in the building until it
141 is safe to do so.

142 (i) An oversight committee shall be created by the
143 department that oversees any violations of this section and
144 reports such violations to the department.

145 (3) LIABILITY.—Any physician performing office surgeries in

1-01021B-25

2025424__

146 an office registered under this section must comply with the
147 financial responsibility requirements set forth in s. 458.320.

148 Section 3. Present subsection (3) of section 459.0138,
149 Florida Statutes, is redesignated as subsection (4), a new
150 subsection (3) is added to that section, and subsection (2) is
151 amended, to read:

152 459.0138 Office surgeries.—

153 (2) STANDARDS OF PRACTICE.—

154 (a) A physician may not perform any surgery or procedure
155 identified in paragraph (1)(a) in a setting other than an office
156 surgery setting registered under this section or a facility
157 licensed under chapter 390 or chapter 395, as applicable. The
158 board shall impose a fine of \$5,000 per incident on a physician
159 who violates this paragraph.

160 (b) Office surgeries may not:

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

164 2. Require major or prolonged intracranial, intrathoracic,
165 abdominal, or joint replacement procedures, except for
166 laparoscopic procedures;

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

170 4. Be emergent or life threatening.

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

1-01021B-25

2025424__

175 1. A physician performing a gluteal fat grafting procedure
176 must conduct an in-person examination of the patient while
177 physically present in the same room as the patient no later than
178 the day before the procedure.

179 2. Before a physician may delegate any duties during a
180 gluteal fat grafting procedure, the patient must provide
181 written, informed consent for such delegation. Any duty
182 delegated by a physician during a gluteal fat grafting procedure
183 must be performed under the direct supervision of the physician
184 performing such procedure. Fat extraction and gluteal fat
185 injections must be performed by the physician and may not be
186 delegated.

187 3. Fat may only be injected into the subcutaneous space of
188 the patient and may not cross the fascia overlying the gluteal
189 muscle. Intramuscular or submuscular fat injections are
190 prohibited.

191 4. When the physician performing a gluteal fat grafting
192 procedure injects fat into the subcutaneous space of the
193 patient, the physician must use ultrasound guidance, or guidance
194 with other technology authorized under board rule which equals
195 or exceeds the quality of ultrasound, during the placement and
196 navigation of the cannula to ensure that the fat is injected
197 into the subcutaneous space of the patient above the fascia
198 overlying the gluteal muscle. Such guidance with the use of
199 ultrasound or other technology is not required for other
200 portions of such procedure.

201 5. An office in which a physician performs gluteal fat
202 grafting procedures must at all times maintain a ratio of one
203 physician to one patient during all phases of the procedure,

1-01021B-25

2025424__

204 beginning with the administration of anesthesia to the patient
205 and concluding with the extubation of the patient. After a
206 physician has commenced, and while he or she is engaged in, a
207 gluteal fat grafting procedure, the physician may not commence
208 or engage in another gluteal fat grafting procedure or any other
209 procedure with another patient at the same time.

210 (d) A physician may not:

211 1. Perform a level II or level III surgery on an immediate
212 family member unless the family member, due to cost or to
213 availability of alternate providers, cannot reasonably obtain
214 the surgical service from another physician. As used in this
215 subparagraph, the term "immediate family member" means a parent,
216 spouse, child, or sibling.

217 2. Alter or change an informed consent form for a procedure
218 after the consent has been signed, or after any sedative drugs
219 are administered to the patient.

220 (e) All health care professionals performing duties at a
221 registered office which require licensure or certification must
222 be:

223 1. Licensed or certified, and may not perform surgeries or
224 procedures outside the scope of his or her license or
225 certification.

226 2. Certified in advanced cardiac life support and maintain
227 certification through continuing education every 2 years.

228 (f) A registered office must have:

229 1. Appropriate staff on premises for procedures and
230 surgeries and administrative duties.

231 2. On the premises at all times a functioning automated
232 external defibrillator device as defined in s. 768.1325(2)(b)

1-01021B-25

2025424__

233 and all necessary critical care equipment and medications.

234 3. Preoperative guidelines, intraoperative protocols, and
235 postoperative recovery guidelines in place for each surgery and
236 procedure, and any follow-up surgeries and procedures, for every
237 patient.

238 4. Qualified anesthesia personnel present in the room
239 throughout the administration of all general and regional
240 anesthetics and provision of monitored anesthesia care.

241 5. Proper protocols in place for storing, accessing,
242 administering, and dispensing sedatives and drugs listed in
243 Schedule II, Schedule III, or Schedule IV of s. 893.03.

244 (g) ~~(d)~~ If a procedure in an office surgery setting results
245 in hospitalization, the incident must be reported as an adverse
246 incident pursuant to s. 458.351 within 48 hours after its
247 occurrence. If an adverse incident occurs due to a local
248 anesthetic, all vials related to the local anesthetic and its
249 constitution that were administered must be saved as evidence
250 for the department and the sheriff's office or municipal police
251 department.

252 (h) A registered office having to undergo any type of
253 construction or refurbishment that materially interferes with
254 the safe performance of a surgical procedure in the office may
255 not perform any surgeries or procedures in the building until it
256 is safe to do so.

257 (i) An oversight committee shall be created by the
258 department that oversees any violations of this section and
259 reports such violations to the department.

260 (3) LIABILITY.—Any physician performing office surgeries in
261 an office registered under this section must comply with the

1-01021B-25

2025424__

262 financial responsibility requirements set forth in s. 459.0085.

263 Section 4. This act shall take effect July 1, 2025.