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CS/HB 1561, Engrossed 1

2024 Legislature

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An act relating to office surgeries; amending ss. 458.328 and 459.0138, F.S.; revising the types of procedures for which a medical office must register with the Department of Health to perform office surgeries; deleting obsolete language; making technical and clarifying changes; requiring medical offices performing specified office surgeries to demonstrate to the department that they have established financial responsibility in a specified manner; revising standards of practice for office surgeries; amending s. 456.074, F.S.; correcting a cross-reference; providing an effective date.

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

Section 1. Paragraphs (a), (b), (c), and (h) of subsection (1) and subsection (2) of section 458.328, Florida Statutes, are amended to read:

458.328 Office surgeries.—

(1) REGISTRATION.—

(a)1. An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed, a Level II office surgery, or a Level III office surgery must

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26 register with the department. ~~unless the office is licensed as A~~
 27 facility licensed under chapter 390 or chapter 395 may not be
 28 registered under this section.

29 2. The department must complete an inspection of any
 30 office seeking registration under this section before the office
 31 may be registered.

32 (b) ~~By January 1, 2020,~~ Each office registered under this
 33 section or s. 459.0138 must designate a physician who is
 34 responsible for the office's compliance with the office health
 35 and safety requirements of this section and rules adopted
 36 hereunder. A designated physician must have a full, active, and
 37 unencumbered license under this chapter or chapter 459 and shall
 38 practice at the office for which he or she has assumed
 39 responsibility. Within 10 calendar days after the termination of
 40 a designated physician relationship, the office must notify the
 41 department of the designation of another physician to serve as
 42 the designated physician. The department may suspend the
 43 registration of an office if the office fails to comply with the
 44 requirements of this paragraph.

45 (c) As a condition of registration, each office must
 46 establish financial responsibility by demonstrating that it has
 47 met and continues to maintain, at a minimum, the same
 48 requirements applicable to physicians in ss. 458.320 and
 49 459.0085. An office in which a physician performs a gluteal fat
 50 grafting procedure must also establish financial responsibility

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51 by demonstrating that it has met and continues to maintain, at a
 52 minimum, the same requirements applicable to physicians in ss.
 53 458.320(2)(b) or (c) and 459.0085(2)(b) or (c), as applicable.

54 Each physician practicing at an office registered under this
 55 section or s. 459.0138 must meet the financial responsibility
 56 requirements under s. 458.320 or s. 459.0085, as applicable.

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

62 (2) STANDARDS OF PRACTICE.—

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

72 (b) Office surgeries may not:

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

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

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

82 4. Be emergent or life threatening.

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

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

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

99 3. Fat may only be injected into the subcutaneous space of
100 the patient and may not cross the fascia overlying the gluteal

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101 muscle. Intramuscular or submuscular fat injections are
102 prohibited.

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

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

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

125 ~~(e) An office in which a physician performs gluteal fat~~

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

134 Section 2. Paragraphs (a), (b), (c), and (h) of subsection
 135 (1) and subsection (2) of section 459.0138, Florida Statutes,
 136 are amended to read:

137 459.0138 Office surgeries.—

138 (1) REGISTRATION.—

139 (a)1. An office in which a physician performs a
 140 liposuction procedure in which more than 1,000 cubic centimeters
 141 of supernatant fat is temporarily or permanently removed, a
 142 Level II office surgery, or a Level III office surgery must
 143 register with the department. ~~unless the office is licensed as A~~
 144 ~~facility~~ licensed under chapter 390 or chapter 395 may not be
 145 registered under this section.

146 2. The department must complete an inspection of any
 147 office seeking registration under this section before the office
 148 may be registered.

149 (b) ~~By January 1, 2020,~~ Each office registered under this
 150 section or s. 458.328 must designate a physician who is

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151 responsible for the office's compliance with the office health
 152 and safety requirements of this section and rules adopted
 153 hereunder. A designated physician must have a full, active, and
 154 unencumbered license under this chapter or chapter 458 and shall
 155 practice at the office for which he or she has assumed
 156 responsibility. Within 10 calendar days after the termination of
 157 a designated physician relationship, the office must notify the
 158 department of the designation of another physician to serve as
 159 the designated physician. The department may suspend a
 160 registration for an office if the office fails to comply with
 161 the requirements of this paragraph.

162 (c) As a condition of registration, each office must
 163 establish financial responsibility by demonstrating that it has
 164 met and continues to maintain, at a minimum, the same
 165 requirements applicable to physicians in ss. 458.320 and
 166 459.0085. An office in which a physician performs a gluteal fat
 167 grafting procedure must also establish financial responsibility
 168 by demonstrating that it has met and continues to maintain, at a
 169 minimum, the same requirements applicable to physicians in ss.
 170 458.320(2)(b) or (c) and 459.0085(2)(b) or (c), as applicable.

171 Each physician practicing at an office registered under this
 172 section or s. 458.328 must meet the financial responsibility
 173 requirements under s. 458.320 or s. 459.0085, as applicable.

174 ~~(h) A physician may only perform a procedure or surgery~~
 175 ~~identified in paragraph (a) in an office that is registered with~~

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176 ~~the department. The board shall impose a fine of \$5,000 per day~~
 177 ~~on a physician who performs a procedure or surgery in an office~~
 178 ~~that is not registered with the department.~~

179 (2) STANDARDS OF PRACTICE.—

180 (a) A physician may not perform any surgery or procedure
 181 identified in paragraph (1) (a) in a setting other than an office
 182 surgery setting registered under this section or a facility
 183 licensed under chapter 390 or chapter 395, as applicable. The
 184 board shall impose a fine of \$5,000 per incident on a physician
 185 who violates this paragraph ~~performing a gluteal fat grafting~~
 186 ~~procedure in an office surgery setting shall adhere to standards~~
 187 ~~of practice pursuant to this subsection and rules adopted by the~~
 188 ~~board.~~

189 (b) Office surgeries may not:

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

193 2. Require major or prolonged intracranial, intrathoracic,
 194 abdominal, or joint replacement procedures, except for
 195 laparoscopic procedures;

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

199 4. Be emergent or life threatening.

200 (c) A physician performing a gluteal fat grafting

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201 procedure in an office surgery setting shall adhere to standards
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 203 which include, but are not limited to, all of the following:

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 205 must conduct an in-person examination of the patient while
 206 physically present in the same room as the patient no later than
 207 the day before the procedure.

208 2. Before a physician may delegate any duties during a
 209 gluteal fat grafting procedure, the patient must provide
 210 written, informed consent for such delegation. Any duty
 211 delegated by a physician during a gluteal fat grafting procedure
 212 must be performed under the direct supervision of the physician
 213 performing such procedure. Fat extraction and gluteal fat
 214 injections must be performed by the physician and may not be
 215 delegated.

216 3. Fat may only be injected into the subcutaneous space of
 217 the patient and may not cross the fascia overlying the gluteal
 218 muscle. Intramuscular or submuscular fat injections are
 219 prohibited.

220 4. When the physician performing a gluteal fat grafting
 221 procedure injects fat into the subcutaneous space of the
 222 patient, the physician must use ultrasound guidance, or guidance
 223 with other technology authorized under board rule which equals
 224 or exceeds the quality of ultrasound, during the placement and
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227 overlying the gluteal muscle. Such guidance with the use of
228 ultrasound or other technology is not required for other
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230 5. An office in which a physician performs gluteal fat
231 grafting procedures must at all times maintain a ratio of one
232 physician to one patient during all phases of the procedure,
233 beginning with the administration of anesthesia to the patient
234 and concluding with the extubation of the patient. After a
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236 gluteal fat grafting procedure, the physician may not commence
237 or engage in another gluteal fat grafting procedure or any other
238 procedure with another patient at the same time.

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

242 ~~(e) An office in which a physician performs gluteal fat~~
243 ~~grafting procedures must at all times maintain a ratio of one~~
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246 ~~and concluding with the extubation of the patient. After a~~
247 ~~physician has commenced, and while he or she is engaged in, a~~
248 ~~gluteal fat grafting procedure, the physician may not commence~~
249 ~~or engage in another gluteal fat grafting procedure or any other~~
250 ~~procedure with another patient at the same time.~~

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251 Section 3. Subsection (6) of section 456.074, Florida
252 Statutes, is amended to read

253 456.074 Certain health care practitioners; immediate
254 suspension of license.—

255 (6) The department must issue an emergency order
256 suspending or restricting the registration of an office
257 registered under s. 458.328 or s. 459.0138 ~~s. 459.0139~~ upon a
258 finding of probable cause that the office or a physician
259 practicing in the office is not in compliance with the standards
260 of practice for office surgery adopted by the boards pursuant to
261 s. 458.328 or s. 459.0138, as applicable, or is in violation of
262 s. 458.331(1)(v) or s. 459.015(1)(z), and that such
263 noncompliance or violation constitutes an immediate danger to
264 the public.

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