

LEGISLATIVE ACTION

Senate	
Floor: 1/AD/2R	
03/04/2024 07:29 PM	

Floor: C 03/05/2024 06:41 PM

House

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Senator Garcia moved the following:
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Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

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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.-

10 (a)1. An office in which a physician performs a liposuction 11 procedure in which more than 1,000 cubic centimeters of

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12 supernatant fat is <u>temporarily or permanently</u> removed, a Level 13 II office surgery, or a Level III office surgery must register 14 with the department<u>.</u> unless the office is licensed as A facility 15 <u>licensed</u> under chapter 390 or chapter 395 <u>may not be registered</u> 16 under this section.

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

20 (b) By January 1, 2020, Each office registered under this 21 section or s. 459.0138 must designate a physician who is 22 responsible for the office's compliance with the office health 23 and safety requirements of this section and rules adopted 24 hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 459 and shall 25 26 practice at the office for which he or she has assumed 27 responsibility. Within 10 calendar days after the termination of 28 a designated physician relationship, the office must notify the 29 department of the designation of another physician to serve as 30 the designated physician. The department may suspend the 31 registration of an office if the office fails to comply with the 32 requirements of this paragraph.

(c) As a condition of registration, each office must 33 34 establish financial responsibility by demonstrating that it has 35 met and continues to maintain, at a minimum, the same 36 requirements applicable to physicians in ss. 458.320 and 37 459.0085. An office in which a physician performs a gluteal fat 38 grafting procedure must also establish financial responsibility 39 by demonstrating that it has met and continues to maintain, at a 40 minimum, the same requirements applicable to physicians in ss.

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41 <u>458.320(2)(b) or (c) and 459.0085(2)(b) or (c), as applicable.</u> 42 Each physician practicing at an office registered under this 43 section or s. 459.0138 must meet the financial responsibility 44 requirements under s. 458.320 or s. 459.0085, as applicable.

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

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(2) STANDARDS OF PRACTICE.-

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

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(b) Office surgeries may not:

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

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

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

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4. Be emergent or life threatening.

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

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

79 2. Before a physician may delegate any duties during a 80 gluteal fat grafting procedure, the patient must provide 81 written, informed consent for such delegation. Any duty delegated by a physician during a gluteal fat grafting procedure must be performed under the direct supervision of the physician 83 performing such procedure. Fat extraction and gluteal fat injections must be performed by the physician and may not be 86 delegated.

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

91 4. When the physician performing a gluteal fat grafting 92 procedure injects fat into the subcutaneous space of the 93 patient, the physician must use ultrasound guidance, or guidance 94 with other technology authorized under board rule which equals 95 or exceeds the quality of ultrasound, during the placement and 96 navigation of the cannula to ensure that the fat is injected 97 into the subcutaneous space of the patient above the fascia 98 overlying the gluteal muscle. Such guidance with the use of

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99 ultrasound or other technology is not required for other 100 portions of such procedure.

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

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

113 (e) 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, beginning with the administration of anesthesia to the patient 116 117 and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a 118 119 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.

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

459.0138 OIIICE Suigerie

126 (1) REGISTRATION.-

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(a)1. An office in which a physician performs a liposuction

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128 procedure in which more than 1,000 cubic centimeters of 129 supernatant fat is <u>temporarily or permanently</u> removed, a Level 130 II office surgery, or a Level III office surgery must register 131 with the department<u>unless the office is licensed as</u> A facility 132 <u>licensed</u> under chapter 390 or chapter 395 <u>may not be registered</u> 133 under this section.

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

137 (b) By January 1, 2020, Each office registered under this 138 section or s. 458.328 must designate a physician who is 139 responsible for the office's compliance with the office health 140 and safety requirements of this section and rules adopted 141 hereunder. A designated physician must have a full, active, and 142 unencumbered license under this chapter or chapter 458 and shall 143 practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of 144 a designated physician relationship, the office must notify the 145 146 department of the designation of another physician to serve as 147 the designated physician. The department may suspend a 148 registration for an office if the office fails to comply with 149 the requirements of this paragraph.

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

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157 minimum, the same requirements applicable to physicians in ss. 158 458.320(2)(b) or (c) and 459.0085(2)(b) or (c), as applicable. 159 Each physician practicing at an office registered under this 160 section or s. 458.328 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as applicable. 161

162 (h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with 163 the department. The board shall impose a fine of \$5,000 per day on a physician who performs a procedure or surgery in an office 166 that is not registered with the department.

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(2) STANDARDS OF PRACTICE.-

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

(b) Office surgeries may not:

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

181 2. Require major or prolonged intracranial, intrathoracic, 182 abdominal, or joint replacement procedures, except for 183 laparoscopic procedures;

184 3. Involve major blood vessels and be performed with direct 185 visualization by open exposure of the major blood vessel, except

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for percutaneous endovascular intervention; or 4. Be emergent or life threatening.

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

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

196 2. Before a physician may delegate any duties during a 197 gluteal fat grafting procedure, the patient must provide 198 written, informed consent for such delegation. Any duty delegated by a physician during a gluteal fat grafting procedure 199 200 must be performed under the direct supervision of the physician 201 performing such procedure. Fat extraction and gluteal fat 202 injections must be performed by the physician and may not be 203 delegated.

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

4. When the physician performing a gluteal fat grafting procedure injects fat into the subcutaneous space of the patient, the physician must use ultrasound guidance, or guidance with other technology authorized under board rule which equals or exceeds the quality of ultrasound, during the placement and navigation of the cannula to ensure that the fat is injected into the subcutaneous space of the patient above the fascia

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215 overlying the gluteal muscle. Such guidance with the use of 216 ultrasound or other technology is not required for other 217 portions of such procedure.

5. An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one 219 physician to one patient during all phases of the procedure, 221 beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a 223 physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

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

230 (c) 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 235 physician has commenced, and while he or she is engaged in, a 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 Section 3. Subsection (6) of section 456.074, Florida 240 Statutes, is amended to read

241 456.074 Certain health care practitioners; immediate 242 suspension of license.-

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(6) The department must issue an emergency order suspending

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244	or restricting the registration of an office registered under s.
245	458.328 or <u>s. 459.0138</u> s. 459.0139 upon a finding of probable
246	cause that the office or a physician practicing in the office is
247	not in compliance with the standards of practice for office
248	surgery adopted by the boards pursuant to s. 458.328 or s.
249	459.0138, as applicable, or is in violation of s. 458.331(1)(v)
250	or s. 459.015(1)(z), and that such noncompliance or violation
251	constitutes an immediate danger to the public.
252	Section 4. This act shall take effect upon becoming a law.
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255	And the title is amended as follows:
256	Delete everything before the enacting clause
257	and insert:
258	A bill to be entitled
259	An act relating to office surgeries; amending ss.
260	458.328 and 459.0138, F.S.; revising the types of
261	procedures for which a medical office must register
262	with the Department of Health to perform office
263	surgeries; deleting obsolete language; making
264	technical and clarifying changes; requiring medical
265	offices performing specified office surgeries to
266	demonstrate to the department that they have
267	established financial responsibility in a specified
268	manner; revising standards of practice for office
269	surgeries; amending s. 456.074, F.S.; correcting a
270	cross-reference; providing an effective date.