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LEGISLATIVE ACTION

Senate	.	House
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Floor: 1/AD/2R	.	Floor: C
05/03/2023 10:23 AM	.	05/04/2023 03:41 PM
	.	

Senator Garcia moved the following:

Senate Amendment (with title amendment)

Delete lines 116 - 295

and insert:

Section 3. Present subsection (2) of section 458.328, Florida Statutes, is redesignated as subsection (3), a new subsection (2) is added to that section, and paragraphs (a) and (e) of subsection (1) of that section are amended, to read:

458.328 Office surgeries.—

(1) REGISTRATION.—

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



483930

12 procedure in which more than 1,000 cubic centimeters of
13 supernatant fat is removed, a Level II office surgery, or a
14 Level III office surgery must register with the department
15 unless the office is licensed as a facility under chapter 390 or
16 chapter 395.

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

20 (e)1. The department shall inspect a registered office at
21 least annually, including a review of patient records, to ensure
22 that the office is in compliance with this section and rules
23 adopted hereunder unless the office is accredited by a
24 nationally recognized accrediting agency approved by the board.
25 The inspection may be unannounced, except for the inspection of
26 an office that meets the description of a clinic specified in s.
27 458.3265(1)(a)3.h., and those wholly owned and operated
28 physician offices described in s. 458.3265(1)(a)3.g. which
29 perform procedures referenced in s. 458.3265(1)(a)3.h., which
30 must be announced.

31 2. The department must immediately suspend the registration
32 of a registered office that refuses an inspection under
33 subparagraph 1. The office must close during such suspension.
34 The suspension must remain in effect for at least 14 consecutive
35 days and may not terminate until the department issues a written
36 declaration that the office may reopen following the
37 department's completion of an inspection of the office.

38 (2) STANDARDS OF PRACTICE.—

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



41 practice pursuant to this subsection and rules adopted by the
42 board.

43 (b) Office surgeries may not:

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

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

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

53 4. Be emergent or life threatening.

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

58 2. Before a physician may delegate any duties during a
59 gluteal fat grafting procedure, the patient must provide
60 written, informed consent for such delegation. Any duty
61 delegated by a physician during a gluteal fat grafting procedure
62 must be performed under the direct supervision of the physician
63 performing such procedure. Fat extraction and gluteal fat
64 injections must be performed by the physician and may not be
65 delegated.

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



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

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

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

92 Section 4. Present subsection (2) of section 459.0138,
93 Florida Statutes, is redesignated as subsection (3), a new
94 subsection (2) is added to that section, and paragraphs (a) and
95 (e) of subsection (1) of that section are amended, to read:

96 459.0138 Office surgeries.—

97 (1) REGISTRATION.—

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



99 procedure in which more than 1,000 cubic centimeters of
100 supernatant fat is removed, a Level II office surgery, or a
101 Level III office surgery must register with the department
102 unless the office is licensed as a facility under chapter 390 or
103 chapter 395.

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

107 (e)1. The department shall inspect a registered office at
108 least annually, including a review of patient records, to ensure
109 that the office is in compliance with this section and rules
110 adopted hereunder unless the office is accredited by a
111 nationally recognized accrediting agency approved by the board.
112 The inspection may be unannounced, except for the inspection of
113 an office that meets the description of clinic specified in s.
114 459.0137(1)(a)3.h., and those wholly owned and operated
115 physician offices described in s. 459.0137(1)(a)3.g. which
116 perform procedures referenced in s. 459.0137(1)(a)3.h., which
117 must be announced.

118 2. The department must immediately suspend the registration
119 of a registered office that refuses an inspection under
120 subparagraph 1. The office must close during such suspension.
121 The suspension must remain in effect for at least 14 consecutive
122 days and may not terminate until the department issues a written
123 declaration that the office may reopen following the
124 department's completion of an inspection of the office.

125 (2) STANDARDS OF PRACTICE.—

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



128 practice pursuant to this subsection and rules adopted by the
129 board.

130 (b) Office surgeries may not:

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

134 2. Require major or prolonged intracranial, intrathoracic,
135 abdominal, or joint replacement procedures, except for
136 laparoscopic procedures;

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

140 4. Be emergent or life threatening.

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

145 2. Before a physician may delegate any duties during a
146 gluteal fat grafting procedure, the patient must provide
147 written, informed consent for such delegation. Any duty
148 delegated by a physician during a gluteal fat grafting procedure
149 must be performed under the direct supervision of the physician
150 performing such procedure. Fat extraction and gluteal fat
151 injections must be performed by the physician and may not be
152 delegated.

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154 the patient and may not cross the fascia overlying the gluteal
155 muscle. Intramuscular or submuscular fat injections are
156 prohibited.



157 4. When the physician performing a gluteal fat grafting
158 procedure injects fat into the subcutaneous space of the
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161 or exceeds the quality of ultrasound, during the placement and
162 navigation of the cannula to ensure that the fat is injected
163 into the subcutaneous space of the patient above the fascia
164 overlying the gluteal muscle. Such guidance with the use of
165 ultrasound or other technology is not required for other
166 portions of such procedure.

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

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

179
180 ===== T I T L E A M E N D M E N T =====

181 And the title is amended as follows:

182 Delete lines 14 - 23

183 and insert:

184 complete an inspection of any physician's office
185 seeking registration to perform office surgeries



186 before the office may be registered; requiring
187 immediate suspension of a registration under specified
188 circumstances; requiring such offices to remain closed
189 for the duration of any suspensions; requiring a
190 suspension to remain in effect for a specified
191 timeframe; requiring physicians performing gluteal fat
192 grafting procedures in an office surgery setting to
193 adhere to specified standards of practice; specifying
194 surgeries that may not be performed in an office
195 surgery setting; requiring physicians performing
196 gluteal fat grafting procedures to conduct in-person
197 examinations of the patients; requiring the reporting
198 of specified adverse incidents; providing requirements
199 for the performance of gluteal fat grafting
200 procedures; providing an effective date.