



324066

LEGISLATIVE ACTION

Senate

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House

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Floor: WD

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05/01/2023 10:22 AM

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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 (4), a new subsection (2) and subsection (3) are added to that section, and paragraph (e) of subsection (1) of that section is amended, to read:

458.328 Office surgeries.—

(1) REGISTRATION.—



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12           (e)1. An office seeking registration under this section  
13 must be inspected by the department before the office may be  
14 registered. The department may not register a facility until it  
15 is inspected and shall not register a facility that must be  
16 licensed under chapter 390 or chapter 395. Completion of an  
17 inspection under this subparagraph does not guarantee a  
18 registration.

19           2. If a registered office refuses any subsequent inspection  
20 under subparagraph 3., the department must immediately suspend  
21 the office's registration and may not reinstate the registration  
22 before the completion of an inspection by the department. Such  
23 office must be closed during the entire period of suspension.  
24 Completion of an inspection under this subparagraph does not  
25 guarantee a registration, reinstatement of a registration, or  
26 lifting of the suspension.

27           3. The department shall inspect a registered office at  
28 least annually, including a review of patient records, to ensure  
29 that the office is in compliance with this section and rules  
30 adopted hereunder unless the office is accredited by a  
31 nationally recognized accrediting agency approved by the board.  
32 The inspection may be unannounced, except for the inspection of  
33 an office that meets the description of a clinic specified in s.  
34 458.3265(1)(a)3.h., and those wholly owned and operated  
35 physician offices described in s. 458.3265(1)(a)3.g. which  
36 perform procedures referenced in s. 458.3265(1)(a)3.h., which  
37 must be announced.

38           (2) STANDARDS OF PRACTICE.—

39           (a) Surgeries performed in an office registered under this  
40 section may not include surgeries that:



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41 1. Are a type of surgery which generally results in blood  
42 loss of more than 10 percent of estimated blood volume in a  
43 patient with a normal hemoglobin level;

44 2. Require major or prolonged intracranial, intrathoracic,  
45 abdominal, or joint replacement procedures, except for  
46 laparoscopic procedures;

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

50 4. Are emergent or life threatening.

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

54 (3) GLUTEAL FAT GRAFTING PROCEDURES.—

55 (a) Physicians performing gluteal fat grafting procedures  
56 in an office surgery setting must adhere to standards of  
57 practice prescribed under this subsection.

58 (b) A physician performing a gluteal fat grafting procedure  
59 must conduct an in-person examination of the patient no later  
60 than the day before the procedure.

61 (c) An office in which a physician performs gluteal fat  
62 grafting procedures must at all times maintain a ratio of one  
63 physician to one patient during all phases of the procedure,  
64 beginning with the administration of anesthesia to the patient  
65 and concluding with the extubation of the patient. However,  
66 after a physician has commenced, and while he or she is engaged  
67 in, a gluteal fat grafting procedure, the physician may not  
68 commence or engage in another gluteal fat grafting procedure or  
69 any other procedure with another patient at the same time.



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70 (d) Before a physician may delegate any duties during a  
71 gluteal fat grafting procedure, the patient must provide  
72 written, informed consent to such delegation. Any duties  
73 delegated during a gluteal fat grafting procedure must be  
74 performed under the direct supervision of the physician  
75 performing the procedure. Gluteal fat extractions and injections  
76 must be performed by the physician performing the procedure and  
77 may not be delegated.

78 (e) Only the physician performing the gluteal fat grafting  
79 procedure may extract gluteal fat from, or inject gluteal fat  
80 into, the patient. The gluteal fat may be injected only into the  
81 subcutaneous space of the patient and may not cross the fascia  
82 overlying the gluteal muscle. Intramuscular and submuscular fat  
83 injections are prohibited.

84 (f) When the physician performing a gluteal fat grafting  
85 procedure injects gluteal fat into the subcutaneous space of the  
86 patient, the physician must use ultrasound guidance during the  
87 placement and navigation of a cannula to ensure that the fat is  
88 placed into the subcutaneous space of the patient above the  
89 fascia overlying the gluteal muscle. Ultrasound guidance is not  
90 required for other portions of the procedure.

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

96 459.0138 Office surgeries.—

97 (1) REGISTRATION.—

98 (e) 1. An office seeking registration under this section



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99 must be inspected by the department before the office may be  
100 registered. The department may not register a facility until it  
101 is inspected and shall not register a facility that must be  
102 licensed under chapter 390 or chapter 395. Completion of an  
103 inspection under this subparagraph does not guarantee a  
104 registration.

105 2. If a registered office refuses any subsequent inspection  
106 under subparagraph 3., the department must immediately suspend  
107 the office's registration and may not reinstate the registration  
108 before the completion of an inspection by the department. Such  
109 office must be closed during the entire period of suspension.  
110 Completion of an inspection under this subparagraph does not  
111 guarantee a registration, reinstatement of a registration, or  
112 lifting of the suspension.

113 3. The department shall inspect a registered office at  
114 least annually, including a review of patient records, to ensure  
115 that the office is in compliance with this section and rules  
116 adopted hereunder unless the office is accredited by a  
117 nationally recognized accrediting agency approved by the board.  
118 The inspection may be unannounced, except for the inspection of  
119 an office that meets the description of clinic specified in s.  
120 459.0137(1)(a)3.h., and those wholly owned and operated  
121 physician offices described in s. 459.0137(1)(a)3.g. which  
122 perform procedures referenced in s. 459.0137(1)(a)3.h., which  
123 must be announced.

124 (2) STANDARDS OF PRACTICE.—

125 (a) Surgeries performed in an office registered under this  
126 section may not:

127 1. Be a type of surgery that generally results in blood



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128 loss of more than 10 percent of estimated blood volume in a  
129 patient with a normal hemoglobin level;

130 2. Require major or prolonged intracranial, intrathoracic,  
131 abdominal, or joint replacement procedures, except for  
132 laparoscopic procedures;

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

136 4. Be emergent or life threatening.

137 (b) If a procedure in an office surgery setting results in  
138 hospitalization, the incident must be reported as an adverse  
139 incident pursuant to s. 459.026.

140 (3) GLUTEAL FAT GRAFTING PROCEDURES.—

141 (a) Physicians performing gluteal fat grafting procedures  
142 in an office surgery setting must adhere to standards of  
143 practice prescribed under this subsection.

144 (b) A physician performing a gluteal fat grafting procedure  
145 must conduct an in-person examination of the patient no later  
146 than the day before the procedure.

147 (c) An office in which a physician performs gluteal fat  
148 grafting procedures must at all times maintain a ratio of one  
149 physician to one patient during all phases of the procedure,  
150 beginning with the administration of anesthesia to the patient  
151 and concluding with the extubation of the patient. However,  
152 after a physician has commenced, and while he or she is engaged  
153 in, a gluteal fat grafting procedure, the physician may not  
154 commence or engage in another gluteal fat grafting procedure or  
155 any other procedure with another patient at the same time.

156 (d) Before a physician may delegate any duties during a



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157 gluteal fat grafting procedure, the patient must provide  
158 written, informed consent to such delegation. Any duties  
159 delegated during a gluteal fat grafting procedure must be  
160 performed under the direct supervision of the physician  
161 performing the procedure. Gluteal fat extractions and injections  
162 must be performed by the physician performing the procedure and  
163 may not be delegated.

164 (e) Only the physician performing the gluteal fat grafting  
165 procedure may extract gluteal fat from, or inject gluteal fat  
166 into, the patient. The gluteal fat may be injected only into the  
167 subcutaneous space of the patient and may not cross the fascia  
168 overlying the gluteal muscle. Intramuscular and submuscular fat  
169 injections are prohibited.

170 (f) When the physician performing a gluteal fat grafting  
171 procedure injects gluteal fat into the subcutaneous space of the  
172 patient, the physician must use ultrasound guidance during the  
173 placement and navigation of a cannula to ensure that the fat is  
174 placed into the subcutaneous space of the patient above the  
175 fascia overlying the gluteal muscle. Ultrasound guidance is not  
176 required for other portions of the procedure.

177  
178 ===== T I T L E A M E N D M E N T =====

179 And the title is amended as follows:

180 Delete lines 13 - 23

181 and insert:

182 459.0138, F.S.; requiring that a physician's office  
183 seeking registration to perform office surgeries be  
184 inspected by the Department of Health before it may be  
185 registered; providing for immediate suspension of a



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186 registration under specified circumstances; requiring  
187 such offices to remain closed for the duration of any  
188 suspensions; providing construction; specifying  
189 surgeries that may not be performed in an office  
190 surgery setting; requiring the reporting of specified  
191 adverse incidents; requiring physicians performing  
192 gluteal fat grafting procedures in an office surgery  
193 setting to adhere to specified standards of practice;  
194 providing an effective date.