

LEGISLATIVE ACTION

Senate Comm: RCS 03/28/2023 House

The Committee on Health Policy (Garcia) recommended the following:

Senate Amendment (with title amendment)

Between lines 374 and 375

insert:

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Section 5. 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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(e)<u>1. An office seeking registration under this section</u> <u>must be inspected by the department before the office may be</u> <u>registered. If a registered office refuses any subsequent</u> <u>inspection under subparagraph 2., the office's registration must</u> <u>be immediately suspended and may not be reinstated before</u> <u>completion of an inspection by the department. Completion of an</u> <u>inspection under this subparagraph does not guarantee a</u> <u>registration or reinstatement of a registration.</u>

20 2. 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 physician offices described in s. 458.3265(1)(a)3.g. which 28 29 perform procedures referenced in s. 458.3265(1)(a)3.h., which 30 must be announced.

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(2) GLUTEAL FAT GRAFTING PROCEDURES.-

(a) Physicians performing gluteal fat grafting procedures in an office surgery setting must adhere to standards of practice prescribed under this subsection. The board may adopt rules to prescribe additional requirements for the safe performance of gluteal fat grafting procedures, provided such rules do not conflict with this subsection.

38 (b) An office in which a physician performs gluteal fat 39 grafting procedures must at all times maintain a ratio of one

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40	physician to one patient during all phases of the procedure,
41	beginning with the administration of anesthesia to the patient
42	and concluding with the extubation of the patient. A physician
43	is not limited in the number of gluteal fat grafting procedures
44	that he or she may safely perform in accordance with the
45	applicable standard of care and as prescribed in this
46	subsection. However, after a physician has commenced, and while
47	he or she is engaged in, a gluteal fat grafting procedure, the
48	physician may not commence or engage in another gluteal fat
49	grafting procedure or any other procedure with another patient
50	at the same time.
51	(c) Before a physician may delegate any duties during a
52	gluteal fat grafting procedure, the patient must provide
53	written, informed consent to such delegation. Any duties
54	delegated during a gluteal fat grafting procedure must be
55	performed under the direct supervision of the physician
56	performing the procedure. Gluteal fat extractions and injections
57	must be performed by the physician performing the procedure and
58	may not be delegated.
59	(d) Only the physician performing the gluteal fat grafting
60	procedure may extract gluteal fat from, or inject gluteal fat
61	into, the patient. The gluteal fat may be injected only into the
62	subcutaneous space of the patient and may not cross the fascia
63	overlying the gluteal muscle. Intramuscular and submuscular fat
64	injections are prohibited.
65	(e) When the physician performing a gluteal fat grafting
66	procedure injects gluteal fat into the subcutaneous space of the
67	patient, the physician must use ultrasound guidance during the
68	placement and navigation of a cannula to ensure that the fat is

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69	placed into the subcutaneous space of the patient above the
70	fascia overlying the gluteal muscle. Ultrasound guidance is not
71	required for other portions of the procedure.
72	(3) STANDARDS OF PRACTICESurgeries performed in an office
73	registered under this section may not:
74	(a) Result in blood loss of more than 10 percent of
75	estimated blood volume in a patient with a normal hemoglobin
76	level;
77	(b) Require major or prolonged intracranial, intrathoracic,
78	abdominal, or joint replacement procedures, except for
79	laparoscopic procedures;
80	(c) Involve major blood vessels performed with direct
81	visualization by open exposure of the major blood vessel, except
82	for percutaneous endovascular intervention; or
83	(d) Be emergent or life threatening.
84	Section 6. Present subsection (2) of section 459.0138,
85	Florida Statutes, is redesignated as subsection (4), a new
86	subsection (2) and subsection (3) are added to that section, and
87	paragraph (e) of subsection (1) of that section is amended, to
88	read:
89	459.0138 Office surgeries
90	(1) REGISTRATION
91	(e) 1. An office seeking registration under this section
92	must be inspected by the department before the office may be
93	registered. If a registered office refuses any subsequent
94	inspection under subparagraph 2., the office's registration must
95	be immediately suspended and may not be reinstated before
96	completion of an inspection by the department. Completion of an
97	inspection under this subparagraph does not guarantee a



98 registration or reinstatement of a registration.

99 2. The department shall inspect a registered office at 100 least annually, including a review of patient records, to ensure 101 that the office is in compliance with this section and rules 102 adopted hereunder unless the office is accredited by a 103 nationally recognized accrediting agency approved by the board. 104 The inspection may be unannounced, except for the inspection of 105 an office that meets the description of clinic specified in s. 459.0137(1)(a)3.h., and those wholly owned and operated 106 107 physician offices described in s. 459.0137(1)(a)3.q. which 108 perform procedures referenced in s. 459.0137(1)(a)3.h., which 109 must be announced.

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(2) GLUTEAL FAT GRAFTING PROCEDURES.-

(a) Physicians performing gluteal fat grafting procedures in an office surgery setting must adhere to standards of practice prescribed under this subsection. The board may adopt rules to prescribe additional requirements for the safe performance of gluteal fat grafting procedures, provided such rules do not conflict with this subsection.

117 (b) An office in which a physician performs gluteal fat 118 grafting procedures must at all times maintain a ratio of one 119 physician to one patient during all phases of the procedure, 120 beginning with the administration of anesthesia to the patient 121 and concluding with the extubation of the patient. A physician is not limited in the number of gluteal fat grafting procedures 122 123 that he or she may safely perform in accordance with the 124 applicable standard of care and as prescribed in this 125 subsection. However, after a physician has commenced, and while 126 he or she is engaged in, a gluteal fat grafting procedure, the

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127	physician may not commence or engage in another gluteal fat
128	grafting procedure or any other procedure with another patient
129	at the same time.
130	(c) Before a physician may delegate any duties during a
131	gluteal fat grafting procedure, the patient must provide
132	written, informed consent to such delegation. Any duties
133	delegated during a gluteal fat grafting procedure must be
134	performed under the direct supervision of the physician
135	performing the procedure. Gluteal fat extractions and injections
136	must be performed by the physician performing the procedure and
137	may not be delegated.
138	(d) Only the physician performing the gluteal fat grafting
139	procedure may extract gluteal fat from, or inject gluteal fat
140	into, the patient. The gluteal fat may be injected only into the
141	subcutaneous space of the patient and may not cross the fascia
142	overlying the gluteal muscle. Intramuscular and submuscular fat
143	injections are prohibited.
144	(e) When the physician performing a gluteal fat grafting
145	procedure injects gluteal fat into the subcutaneous space of the
146	patient, the physician must use ultrasound guidance during the
147	placement and navigation of a cannula to ensure that the fat is
148	placed into the subcutaneous space of the patient above the
149	fascia overlying the gluteal muscle. Ultrasound guidance is not
150	required for other portions of the procedure.
151	(3) STANDARDS OF PRACTICESurgeries performed in an office
152	registered under this section may not:
153	(a) Result in blood loss of more than 10 percent of
154	estimated blood volume in a patient with a normal hemoglobin
155	level;

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156	(b) Require major or prolonged intracranial, intrathoracic,
157	abdominal, or joint replacement procedures, except for
158	laparoscopic procedures;
159	(c) Involve major blood vessels performed with direct
160	visualization by open exposure of the major blood vessel, except
161	for percutaneous endovascular intervention; or
162	(d) Be emergent or life threatening.
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165	And the title is amended as follows:
166	Delete line 40
167	and insert:
168	screening requirements; amending ss. 458.328 and
169	459.0138, F.S.; requiring that a physician's office
170	seeking registration to perform office surgeries must
171	be inspected by the Department of Health before it may
172	be registered; providing for immediate suspension of a
173	registration under specified circumstances; providing
174	construction; requiring physicians performing gluteal
175	fat grafting procedures in an office surgery setting
176	to adhere to specified standards of practice;
177	authorizing the Board of Medicine and the Board of
178	Osteopathic Medicine, respectively, to adopt certain
179	rules; providing an effective date.