

1 A bill to be entitled
 2 An act relating to office surgery standards of
 3 practice; providing a short title; amending ss.
 4 458.328 and 459.0138, F.S.; providing a registration
 5 requirement for offices that perform specified
 6 surgeries; revising the standards of practice for
 7 office surgeries and health care professionals who
 8 practice at such offices; providing liability
 9 requirements; providing an effective date.

10
 11 Be It Enacted by the Legislature of the State of Florida:

12
 13 **Section 1.** This act may be cited as "Hillary's Law."

14 **Section 2.** **Subsection (3) of section 458.328, Florida**
 15 **Statutes, is renumbered as subsection (4), paragraph (e) of**
 16 **subsection (1) and subsection (2) are amended, and a new**
 17 **subsection (3) is added to that section, to read:**

18 458.328 Office surgeries.—

19 (1) REGISTRATION.—

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

39 | 3. As a condition of registration, each office must also
40 | be inspected by the Joint Commission on Accreditation of
41 | Healthcare Organizations (JCAHO) and conform to the JCAHO
42 | standards for a stand-alone ambulatory surgery center and meet
43 | any other requirements set by JCAHO.

44 | (2) STANDARDS OF PRACTICE.—

45 | (a) A physician may not perform any surgery or procedure
46 | identified in paragraph (1)(a) in a setting other than an office
47 | surgery setting registered under this section or a facility
48 | licensed under chapter 390 or chapter 395, as applicable. The
49 | board shall impose a fine of \$5,000 per incident on a physician
50 | who violates this paragraph.

51 (b) Office surgeries may not:

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

55 2. Require major or prolonged intracranial, intrathoracic,
56 abdominal, or joint replacement procedures, except for
57 laparoscopic procedures;

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

61 4. Be emergent or life threatening.

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

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

70 2. Before a physician may delegate any duties during a
71 gluteal fat grafting procedure, the patient must provide
72 written, informed consent for such delegation. Any duty
73 delegated by a physician during a gluteal fat grafting procedure
74 must be performed under the direct supervision of the physician
75 performing such procedure. Fat extraction and gluteal fat

76 injections must be performed by the physician and may not be
77 delegated.

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

82 4. When the physician performing a gluteal fat grafting
83 procedure injects fat into the subcutaneous space of the
84 patient, the physician must use ultrasound guidance, or guidance
85 with other technology authorized under board rule which equals
86 or exceeds the quality of ultrasound, during the placement and
87 navigation of the cannula to ensure that the fat is injected
88 into the subcutaneous space of the patient above the fascia
89 overlying the gluteal muscle. Such guidance with the use of
90 ultrasound or other technology is not required for other
91 portions of such procedure.

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

- 101 (d) A physician may not:
- 102 1. Perform a minor or major surgery on an immediate family
103 member. As used in this subparagraph, the term "immediate family
104 member" means a parent, spouse, child, or sibling.
- 105 2. Alter or change an informed consent form for a
106 procedure after the consent has been signed, or after any
107 sedative drugs are administered to the patient.
- 108 (e) All health care professionals performing duties at a
109 registered office must be:
- 110 1. Licensed or certified, and may not perform surgeries or
111 procedures outside the scope of his or her license or
112 certification.
- 113 2. Certified in advanced cardiac life support and maintain
114 certification through continuing education every 2 years.
- 115 (f) A registered office may only perform procedures or
116 surgeries during regular office hours and must have:
- 117 1. Appropriate staff on premises for procedures and
118 surgeries and administrative duties.
- 119 2. On the premises at all times a functioning automated
120 external defibrillator device as defined in s. 768.1325(2)(b)
121 and all necessary critical care equipment and medications.
- 122 3. Preoperative guidelines, intraoperative protocols, and
123 postoperative recovery guidelines in place that meet the
124 standards of any stand-alone ambulatory surgery center for each
125 surgery and procedure, and any followup surgeries and

126 procedures, for every patient.

127 4. A certified registered nurse anesthetist onsite, who is
128 supervised by a board-certified anesthesiologist offsite, to
129 properly administer and oversee anesthesia gases including
130 nitrous oxide, sedatives, narcotic analgesics, intravenous local
131 anesthetics, and the antidote to local anesthetic overdose,
132 which must be kept onsite and accessible during a procedure or
133 surgery.

134 5. Proper protocols in place for storing, accessing,
135 administering, and dispensing sedatives and drugs listed in
136 Schedule II, Schedule III, or Schedule IV of s. 893.03.

137 (f) ~~(d)~~ If a procedure in an office surgery setting results
138 in hospitalization, the incident must be reported as an adverse
139 incident pursuant to s. 458.351 within 48 hours after its
140 occurrence. If an adverse incident occurs due to a local
141 anesthetic, all vials related to the local anesthetic and its
142 constitution that were administered must be saved as evidence
143 for the department and the sheriff's office or municipal police
144 department.

145 (g) A registered office having to undergo any type of
146 construction or refurbishment of its structure may not perform
147 any surgeries or procedures in the building until completion of
148 the construction or refurbishment.

149 (h) An oversight committee shall be created by the
150 department that oversees any violations of this section and

151 reports such violations to the department.

152 (3) LIABILITY.—A physician must maintain medical
153 malpractice insurance or provide proof of financial
154 responsibility in an amount of at least \$1 million.

155 **Section 3. Subsection (3) of section 459.0138, Florida**
156 **Statutes, is renumbered as subsection (4), paragraph (e) of**
157 **subsection (1) and subsection (2) are amended, and a new**
158 **subsection (3) is added to that section, to read:**

159 459.0138 Office surgeries.—

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162 least annually, including a review of patient records, to ensure
163 that the office is in compliance with this section and rules
164 adopted hereunder unless the office is accredited by a
165 nationally recognized accrediting agency approved by the board.
166 The inspection may be unannounced, except for the inspection of
167 an office that meets the description of a clinic specified in s.
168 459.0137(1)(a)3.h., and those wholly owned and operated
169 physician offices described in s. 459.0137(1)(a)3.g. which
170 perform procedures referenced in s. 459.0137(1)(a)3.h., which
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173 registration of a registered office that refuses an inspection
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175 suspension. The suspension must remain in effect for at least 14

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247 | procedure after the consent has been signed, or after any
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255 certification through continuing education every 2 years.

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291 department that oversees any violations of this section and
292 reports such violations to the department.

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294 malpractice insurance or provide proof of financial
295 responsibility in an amount of at least \$1 million.

296 **Section 4.** This act shall take effect July 1, 2025.