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LEGISLATIVE ACTION

Senate

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House

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

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

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

(2) STANDARDS OF PRACTICE.—

(a) Surgeries performed in an office registered under this 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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(d) Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent to such delegation. Any duties delegated during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing the procedure. Gluteal fat extractions and injections must be performed by the physician performing the procedure and may not be delegated.

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

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

Section 4. Present subsection (2) of section 459.0138, 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:

459.0138 Office surgeries.—

(1) REGISTRATION.—

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



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

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

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

(2) STANDARDS OF PRACTICE.—

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

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



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

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

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

4. Be emergent or life threatening.

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

(3) 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.

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

(c) 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. However,  
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) Before a physician may delegate any duties during a



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

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

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

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

And the title is amended as follows:

Delete lines 13 - 23

and insert:

459.0138, F.S.; requiring that a physician's office seeking registration to perform office surgeries be inspected by the Department of Health before it may be 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.