

## CHAPTER 2024-181

### Committee Substitute for House Bill No. 1561

An act relating to office surgeries; amending ss. 458.328 and 459.0138, F.S.; revising the types of procedures for which a medical office must register with the Department of Health to perform office surgeries; deleting obsolete language; making technical and clarifying changes; requiring medical offices performing specified office surgeries to demonstrate to the department that they have established financial responsibility in a specified manner; revising standards of practice for office surgeries; amending s. 456.074, F.S.; correcting a cross-reference; providing an effective date.

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

Section 1. Paragraphs (a), (b), (c), and (h) of subsection (1) and subsection (2) of section 458.328, Florida Statutes, are amended to read:

458.328 Office surgeries.—

(1) REGISTRATION.—

(a)1. An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed, a Level II office surgery, or a Level III office surgery must register with the department, ~~unless the office is licensed as A facility licensed~~ under chapter 390 or chapter 395 may not be registered under this section.

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

(b) ~~By January 1, 2020,~~ Each office registered under this section or s. 459.0138 must designate a physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may suspend the registration of an office if the office fails to comply with the requirements of this paragraph.

(c) As a condition of registration, each office must establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320 and 459.0085. An office in which a physician performs a gluteal fat grafting procedure must also establish financial responsibility by

demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320(2)(b) or (c) and 459.0085(2)(b) or (c), as applicable. Each physician practicing at an office registered under this section or s. 459.0138 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as applicable.

~~(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of \$5,000 per day on a physician who performs a procedure or surgery in an office that is not registered with the department.~~

(2) STANDARDS OF PRACTICE.—

~~(a) A physician may not perform any surgery or procedure identified in paragraph (1)(a) in a setting other than an office surgery setting registered under this section or a facility licensed under chapter 390 or chapter 395, as applicable. The board shall impose a fine of \$5,000 per incident on a physician who violates this paragraph performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice pursuant to this subsection and rules adopted by the board.~~

(b) Office surgeries may not:

1. Be a type of surgery that generally results in blood 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 and be performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or
4. Be emergent or life threatening.

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

1. A physician performing a gluteal fat grafting procedure must conduct an in-person examination of the patient while physically present in the same room as the patient no later than the day before the procedure.
2. Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent for such delegation. Any duty delegated by a physician during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing such procedure. Fat extraction and gluteal fat injections must be performed by the physician and may not be delegated.

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

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

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

~~(e) 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. 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.~~

Section 2. Paragraphs (a), (b), (c), and (h) of subsection (1) and subsection (2) of section 459.0138, Florida Statutes, are amended to read:

459.0138 Office surgeries.—

(1) REGISTRATION.—

(a)1. An office in which a physician performs a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed, a Level II office surgery, or a Level III office surgery must register with the department, ~~unless the office is licensed as A facility licensed under chapter 390 or chapter 395 may not be registered under this section.~~

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

(b) ~~By January 1, 2020,~~ Each office registered under this section or s. 458.328 must designate a physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may suspend a registration for an office if the office fails to comply with the requirements of this paragraph.

(c) As a condition of registration, each office must establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320 and 459.0085. An office in which a physician performs a gluteal fat grafting procedure must also establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320(2)(b) or (c) and 459.0085(2)(b) or (c), as applicable. Each physician practicing at an office registered under this section or s. 458.328 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as applicable.

~~(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of \$5,000 per day on a physician who performs a procedure or surgery in an office that is not registered with the department.~~

## (2) STANDARDS OF PRACTICE.—

~~(a) A physician may not perform any surgery or procedure identified in paragraph (1)(a) in a setting other than an office surgery setting registered under this section or a facility licensed under chapter 390 or chapter 395, as applicable. The board shall impose a fine of \$5,000 per incident on a physician who violates this paragraph performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice pursuant to this subsection and rules adopted by the board.~~

(b) Office surgeries may not:

1. Be a type of surgery that generally results in blood 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 and be performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or

4. Be emergent or life threatening.

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

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

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

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

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

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

~~(e) 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. 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.~~

Section 3. Subsection (6) of section 456.074, Florida Statutes, is amended to read

456.074 Certain health care practitioners; immediate suspension of license.—

(6) The department must issue an emergency order suspending or restricting the registration of an office registered under s. 458.328 or s. 459.0138 ~~s. 459.0139~~ upon a finding of probable cause that the office or a physician practicing in the office is not in compliance with the standards of practice for office surgery adopted by the boards pursuant to s. 458.328 or s. 459.0138, as applicable, or is in violation of s. 458.331(1)(v) or s. 459.015(1)(z), and that such noncompliance or violation constitutes an immediate danger to the public.

Section 4. This act shall take effect upon becoming a law.

Approved by the Governor May 10, 2024.

Filed in Office Secretary of State May 10, 2024.