LEGISLATIVE ACTION Senate House Comm: RCS 03/28/2023

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

Senate Amendment (with title amendment)

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Between lines 374 and 375

4 insert:

> 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) 1. An office seeking registration under this section must be inspected by the department before the office may be registered. If a registered office refuses any subsequent inspection under subparagraph 2., the office's registration must be immediately suspended and may not be reinstated before completion of an inspection by the department. Completion of an inspection under this subparagraph does not quarantee a registration or reinstatement of a registration.
- 2. 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) 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.
- (b) An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one

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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. A physician is not limited in the number of gluteal fat grafting procedures that he or she may safely perform in accordance with the applicable standard of care and as prescribed in this subsection. 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.

- (c) 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.
- (d) 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.
- (e) 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

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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.

- (3) STANDARDS OF PRACTICE.—Surgeries performed in an office registered under this section may not:
- (a) Result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;
- (b) Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;
- (c) Involve major blood vessels performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or
 - (d) Be emergent or life threatening.

Section 6. 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 must be inspected by the department before the office may be registered. If a registered office refuses any subsequent inspection under subparagraph 2., the office's registration must be immediately suspended and may not be reinstated before completion of an inspection by the department. Completion of an inspection under this subparagraph does not guarantee a

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registration or reinstatement of a registration.

2. 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.q. which perform procedures referenced in s. 459.0137(1)(a)3.h., which must be announced.

- (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.
- (b) 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. A physician is not limited in the number of gluteal fat grafting procedures that he or she may safely perform in accordance with the applicable standard of care and as prescribed in this subsection. However, after a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the

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physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

- (c) 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.
- (d) 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.
- (e) 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.
- (3) STANDARDS OF PRACTICE.—Surgeries performed in an office registered under this section may not:
- (a) Result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;



156 (b) Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for 157 laparoscopic procedures; 158 159 (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. 163 164 ======== T I T L E A M E N D M E N T ========== 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

rules; providing an effective date.

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