

CHAPTER 2023-307

Committee Substitute for Committee Substitute for House Bill No. 1471

An act relating to health care provider accountability; amending s. 400.022, F.S.; revising the rights of licensed nursing home facility residents; providing definitions; amending s. 408.812, F.S.; creating a cause of action for an ex parte temporary injunction against continued unlicensed activity; providing requirements for such injunction; providing construction; authorizing the Agency for Health Care Administration to provide certain records to local law enforcement and state attorneys' offices under certain circumstances; amending ss. 458.328 and 459.0138, F.S.; requiring the Department of Health to complete an inspection of any physician's office seeking registration to perform office surgeries before the office may be registered; requiring immediate suspension of a registration under specified circumstances; requiring such offices to remain closed for the duration of any suspensions; requiring a suspension to remain in effect for a specified timeframe; requiring physicians performing gluteal fat grafting procedures in an office surgery setting to adhere to specified standards of practice; specifying surgeries that may not be performed in an office surgery setting; requiring physicians performing gluteal fat grafting procedures to conduct in-person examinations of the patients; requiring the reporting of specified adverse incidents; providing requirements for the performance of gluteal fat grafting procedures; providing an effective date.

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

Section 1. Paragraph (o) of subsection (1) of section 400.022, Florida Statutes, is amended to read:

400.022 Residents' rights.—

(1) All licensees of nursing home facilities shall adopt and make public a statement of the rights and responsibilities of the residents of such facilities and shall treat such residents in accordance with the provisions of that statement. The statement shall assure each resident the following:

(o) The right to be free from mental and physical abuse, sexual abuse, neglect, exploitation, corporal punishment, extended involuntary seclusion, and ~~from~~ physical and chemical restraints, except those restraints authorized in writing by a physician for a specified and limited period of time or as are necessitated by an emergency. In case of an emergency, restraint may be applied only by a qualified licensed nurse who shall set forth in writing the circumstances requiring the use of restraint, and, in the case of use of a chemical restraint, a physician shall be consulted immediately thereafter. Restraints may not be used in lieu of staff supervision or merely for staff convenience, for punishment, or for reasons other than resident protection or

safety. For purposes of this paragraph, the terms “sexual abuse,” “neglect,” and “exploitation” have the same meanings as provided in 42 C.F.R. s. 483.5.

Section 2. Subsection (6) of section 408.812, Florida Statutes, is amended to read:

408.812 Unlicensed activity.—

(6) In addition to granting injunctive relief pursuant to subsection (2), if the agency determines that a person or entity is operating or maintaining a provider without obtaining a license and determines that a condition exists that poses a threat to the health, safety, or welfare of a client of the provider, the person or entity is subject to the same actions and fines imposed against a licensee as specified in this part, authorizing statutes, and agency rules.

(a) There is created a cause of action for an ex parte temporary injunction against continued unlicensed activity by a person or entity violating subsection (1), not to exceed 30 days.

(b) A sworn petition seeking the issuance of an ex parte temporary injunction against continued unlicensed activity shall allege all of the following:

1. The location of the unlicensed activity.
2. The names of the owners and operators of the unlicensed provider.
3. The type of services that require licensure.
4. The specific facts supporting the conclusion that the unlicensed provider is engaged in unlicensed activity, including the date, time, and location at which the unlicensed provider was notified by the agency to discontinue such activity.
5. That agency personnel have verified, through an onsite inspection, that the unlicensed provider is advertising, offering, or providing services that require licensure.
6. Whether the unlicensed provider prohibited the agency from conducting a subsequent investigation to determine current compliance with applicable laws and rules.
7. Any previous injunctive relief granted against the unlicensed provider.
8. Any previous agency determination that the unlicensed provider has been identified as engaging in unlicensed activity.

(c) A bond may not be required by the court for entry of an ex parte temporary injunction.

(d) Except as provided in s. 90.204, in a hearing to obtain an ex parte temporary injunction, evidence other than verified pleadings or affidavits by agency personnel or others with firsthand knowledge of the alleged unlicensed activity may not be used as evidence, unless the unlicensed provider appears at the hearing. A denial of a petition for an ex parte temporary injunction shall specify the grounds for denial in writing.

(e) If the court determines that the unlicensed provider is engaged in continued unlicensed activity after agency notification to cease such unlicensed activity, the court may grant the ex parte temporary injunction restraining the unlicensed provider from advertising, offering, or providing services for which licensure is required. The court may also order the unlicensed provider to provide to agency personnel access to facility personnel, records, and clients for future inspection of the unlicensed provider's premises.

(f) The agency must inspect the unlicensed provider's premises within 20 days after entry of the ex parte temporary injunction to verify compliance with such injunction. If the unlicensed provider is in compliance, the agency shall dismiss the injunction. If unlicensed activity has continued, the agency may file a petition for permanent injunction within 10 days after identifying noncompliance. The agency may also petition to extend the ex parte temporary injunction until the permanent injunction is decided.

(g) The agency may provide any inspection records to local law enforcement or a state attorney's office upon request and without redaction.

Section 3. Present subsection (2) of section 458.328, Florida Statutes, is redesignated as subsection (3), a new subsection (2) is added to that section, and paragraphs (a) and (e) of subsection (1) of that section 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 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 under chapter 390 or chapter 395.

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

(e)1. 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. The department must immediately suspend the registration of a registered office that refuses an inspection under subparagraph 1. The office must close during such suspension. The suspension must remain in effect for at least 14 consecutive days and may not terminate until the department issues a written declaration that the office may reopen following the department's completion of an inspection of the office.

(2) STANDARDS OF PRACTICE.—

(a) A physician 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)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.

(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 4. Present subsection (2) of section 459.0138, Florida Statutes, is redesignated as subsection (3), a new subsection (2) is added to that section, and paragraphs (a) and (e) of subsection (1) of that section 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 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 under chapter 390 or chapter 395.

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

(e)1. 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. The department must immediately suspend the registration of a registered office that refuses an inspection under subparagraph 1. The office must close during such suspension. The suspension must remain in effect for at least 14 consecutive days and may not terminate until the department issues a written declaration that the office may reopen following the department's completion of an inspection of the office.

(2) STANDARDS OF PRACTICE.—

(a) A physician 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)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.

(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 5. This act shall take effect July 1, 2023.

Approved by the Governor June 28, 2023.

Filed in Office Secretary of State June 28, 2023.