A bill to be entitled 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 inspect specified offices before registration and refuse to register a new office or immediately suspend the registration of a registered office that refuses an inspection for a specified timeframe; prohibiting the department from registering specified facilities; providing suspension requirements; providing standard of practice requirements for office surgeries; providing definitions; prohibiting certain office surgeries; providing physician, office, and procedure requirements; providing an effective date.

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

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

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400.022 Residents' rights.-

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(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

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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 exparte 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.

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- 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

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order	the	unlicense	ed provider	to provi	de to	agency	pers	sonnel	
access	to	facility	personnel,	records,	and	clients	for	future	
inspection of the unlicensed provider's premises.									

- cf) 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. Subsection (2) of section 458.328, Florida Statutes, is renumbered as subsection (3), paragraphs (a) and (e) of subsection (1) are amended, and a new subsection (2) is added to that section, to read:
  - 458.328 Office surgeries.—
  - (1) REGISTRATION. -
- (a) 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

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unless the office is licensed as a facility under chapter 390 or chapter 395. The department must inspect any such office before registration. The department may not register a facility that must be licensed under chapter 390 or chapter 395.

- 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. The department must refuse to register a new office or must immediately suspend the registration of a registered office that refuses an inspection for 14 days. Such office must be closed during the period of suspension. The suspension must remain in effect until the department has completed its inspection.
  - (2) STANDARD OF PRACTICE.
  - (a) For purposes of this section, the term:
- 1. "Office surgery" means a surgery performed at an office that primarily serves as a physician's office at which a physician regularly performs consultations with surgical

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151	patients, presurgical examinations, and postoperative monitoring
152	and care related to office surgeries and at which patient
153	records are readily maintained and available.

- 2. "Physician" means a physician or surgeon licensed to practice under this chapter.
- (b) 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.
  - (c) Office surgeries may not:
- 1. Result 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 performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or
  - 4. Be emergent or life threatening.
- (d)1. A physician performing a gluteal fat grafting procedure must have sufficient training, as determined by the board, to perform gluteal fat grafting procedures safely and effectively.
  - 2. A physician performing a gluteal fat grafting procedure

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- must conduct an in-person examination of the patient no later than the day before the procedure.
  - 3. Any duty delegated by a physician, with a patient's informed consent, to be performed 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.
  - 4. Gluteal 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.
  - 5. When the physician performing a gluteal fat grafting procedure injects fat into the subcutaneous space of the patient, the physician must use ultrasound guidance during the placement and navigation of the canula to ensure that the fat is injected into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. The board may establish minimum technical standards for such ultrasound guidance.

    Ultrasound guidance is not required for other portions of such procedure.
  - (e) If a procedure in an office surgery setting results in hospitalization, the type of procedure performed and the location at which the procedure was performed, if known, must be included in the hospital intake information for the purpose of

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adverse incident reporting.

(f) 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.

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

459.0138 Office surgeries.—

- (1) REGISTRATION. -
- (a) 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. The department must inspect any such office before registration. The department may not register a facility that must be licensed under chapter 390 or chapter 395.
  - (e) The department shall inspect a registered office at

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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. The department must refuse to register a new office or immediately suspend the registration of a registered office that refuses an inspection for 14 days. Such office must be closed during the period of suspension. The suspension must remain in effect until the department has completed its inspection.

- (2) STANDARD OF PRACTICE.
- (a) For purposes of this section, the term:
- 1. "Office surgery" means a surgery performed at an office that primarily serves as a physician's office at which a physician performs surgeries as permitted under this section.

  The physician's office must be an office at which such physician regularly performs consultations with surgical patients, presurgical examinations, and postoperative monitoring and care related to office surgeries and at which patient records are readily maintained and available.

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251	2.	"Phys	ician"	means	а	physician	or	surgeon	licensed	to
252	practic	e under	this	chapter	<u>.</u>					

- (b) 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.
  - (c) Office surgeries may not:
- 1. Result 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 performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or
  - 4. Be emergent or life threatening.
- (d)1. A physician performing a gluteal fat grafting procedure must have sufficient training, as determined by the board, to perform gluteal fat grafting procedures safely and effectively.
- 2. Any duty delegated by a physician, with a patient's informed consent, to be performed during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing such procedure. Fat extraction and gluteal

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- fat injections must be performed by the physician and may not be delegated.
  - 4. Gluteal 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.
  - 5. When the physician performing a gluteal fat grafting procedure injects fat into the subcutaneous space of the patient, the physician must use ultrasound guidance during the placement and navigation of the canula to ensure that the fat is injected into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. The board may establish minimum technical standards for such ultrasound guidance.

    Ultrasound guidance is not required for other portions of such procedure.
  - (e) If a procedure in an office surgery setting results in hospitalization, the type of procedure performed and the location at which the procedure was performed, if known, must be included in the hospital intake information for the purpose of adverse incident reporting.
    - Section 5. This act shall take effect July 1, 2023.

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