HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/HB 1561 Office Surgeries
SPONSOR(S): Health & Human Services Committee, Busatta Cabrera and others
TIED BILLS: **IDEN./SIM. BILLS:**

FINAL HOUSE FLOOR ACTION: 111 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 1561 passed the House on March 1, 2024. The bill was amended in the Senate on March 4, 2024, and returned to the House. The House concurred and passed the House Bill on March 5, 2024.

Current law requires a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed to register his or her office with DOH. The bill requires physicians to register regardless of whether the fat is temporarily or permanently removed.

Under current law a physician may only perform 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, in an office that is registered with DOH. Current law authorizes DOH to impose a fine of $5,000 per day on a physician who performs such a procedure or surgery in an office that is not registered with DOH. The bill changes the fine to $5,000 per incident, to allow DOH to fine a physician for multiple offenses committed during the same day.

The bill requires physician offices in which gluteal fat grafting procedures are performed to establish financial responsibility by one of the following methods:

- Obtaining and maintaining professional liability coverage of at least $250,000 per claim, with a minimum annual aggregate of at least $750,000 from an authorized insurer, surplus lines insurer, risk retention group, joint underwriting association, or through a plan of self-insurance; or
- Obtaining and maintaining an unexpired, irrevocable letter of credit of at least $250,000 per claim, with a maximum aggregate credit availability of at least $750,000.

The bill has no fiscal impact on state or local government.

The bill was approved by the Governor on May 10, 2024, ch. 2024-181, L.O.F., and became effective on that date.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Gluteal Fat Grafting

Gluteal fat grafting, commonly known as a "Brazilian butt lift" or BBL, is the fastest-growing plastic surgery procedure in the U.S.[1] The procedure involves liposuction in areas where fat removal will improve the contour of the body. Typically, fat is harvested from two or more regions which may include the flanks (love handles), abdomen, or back. The harvested fat is purified to optimize the viability of fat cells and stem cells before it is injected into the subcutaneous layer (below the skin, but above the muscle) of the buttocks.[2]

The rate of fatal complications from gluteal fat grafting is higher than any other cosmetic procedure.[3] South Florida carries the highest BBL mortality rate by far in the nation with 25 deaths occurring between 2010 and 2022.[4] According to a study on the deaths that occurred in South Florida, the surgical setting and the short surgical times for these cases were the most significant contributing factors to the deaths.[5] Of the 25 deaths, 23 of the surgeries were performed at high-volume, low budget clinics. These clinics employ a practice model based on high-volume and minimal-patient-interaction. All of the deaths resulted from pulmonary fat embolism, which occurs when a vein wall is injured during the injection process allowing fat to enter the pulmonary vessels.[6]

Regulation of Physician Offices and Office Surgery

The Board of Medicine and the Board of Osteopathic Medicine (collectively, boards) have authority to adopt rules to regulate practice of medicine and osteopathic medicine, respectively.[7] The boards have authority to establish, by rule, standards of practice and standards of care for particular settings.[8] Such standards may include education and training, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.[9]

Adverse Incident Reporting

A physician must report any adverse incident that occurs in an office practice setting to DOH within 15 days after the occurrence any adverse incident.[10] An adverse incident in an office setting is defined as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[11]

- The death of a patient;
- Brain or spinal damage to a patient;

[1] Pat Pazmiño, Onelio Garcia, *Brazilian Butt Lift–Associated Mortality: The South Florida Experience*, Aesthetic Surgery Journal, Volume 43, Issue 2, February 2023, Pages 162–178, https://doi.org/10.1093/asj/sjac224 (last visited January 25, 2024).
[2] O'Neill RC, Abu-Ghname A, Davis MJ, Chamata E, Rammos CK, Winocour SJ. *The Role of Fat Grafting in Buttock Augmentation*, Seminars in Plastic Surgery (February 15, 2020) available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7023974/#:~:text=First%2C%20fat%20is%20harvested%20from,figure%20with%20an%20augmented%20buttock (last visited January 25, 2024).
[3] *Supra* note 1.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic medicine.
[8] Ss. 458.331(v) and 459.015(z), F.S.
[9] *Id.*
[10] Ss. 458.351 and 459.026, F.S.
[11] Ss. 458.351(4) and 459.026(4), F.S.

- The performance of a surgical procedure on the wrong patient;
- If the procedure results in death; brain or spinal damage; permanent disfigurement; the fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory functions; or any condition that required the transfer of a patient, the performance of:
    - A wrong-site surgical procedure;
    - A wrong surgical procedure; or
    - A surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed consent process;
- A procedure to remove unplanned foreign objects remaining from a surgical procedure; or
- Any condition that required the transfer of a patient to a hospital from an ASC or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[12]

Office Surgeries

The boards also establish the standards of care physicians must meet for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390, F.S., or ch. 395, F.S.[13] There are several levels of office surgeries governed by rules adopted by the boards, which establish the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery. The levels of office surgeries include Level I, Level II, Level IIA, Level III, and Liposuction Procedures where more than 1,000 cubic centimeters of supernatant fat is removed.[14]

Prior to performing any surgery, a physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.[15] A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[16] The written consent must reflect the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists.[17]

[12] Ss. 458.351(5) and 459.026(5), F.S.
[13] Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ASCs, mobile surgical facilities, and certain intensive residential treatment programs. Office surgery is a surgery performed at an office that primarily serves as the doctor's office where he or she regularly performs consultations, presurgical exams, and postoperative observation and care, and where patient medical records are maintained and available.
[14] Rule 64B8-9.009(3)-(6) and 64B15-14.007(3)-(6), F.A.C. Level I office surgery includes minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness (liposuction involving the removal of less than 4000cc supernatant fat is permitted). Level II office surgeries involve moderate sedation and include hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4000cc supernatant fat. Level IIA office surgeries are those Level II surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote. Level III office surgeries are the most complex and require deep sedation or general anesthesia.
[15] Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.
[16] *Id.* A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.
[17] *Id.* A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.

Current law prohibits physicians from performing surgeries in office settings which:[18]

- Result in blood loss greater than 10 percent of blood volume in a patient with normal hemoglobin;
- Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, excluding laparoscopy;
- Involve a major blood vessel with direct visualization by open exposure of the vessel, not including percutaneous endovascular treatment[19]; or
- Are emergent or life threatening.

Office Surgeries – Level II, Level IIA, Level III, and Liposuction Procedures

Physicians performing office surgeries must maintain a log of all liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed and Level II and Level III surgical procedures performed, which includes:[20]

- A confidential patient identifier;
- The time the patient arrives in the operating suite;
- The name of the physician who provided medical clearance;
- The surgeon's name;
- The diagnosis;
- The CPT Codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;
- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;
- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

Such log must be maintained for at least six years from the last patient contact and must be provided to DOH investigators upon request.[21]

Additional standards apply to elective cosmetic and plastic surgery procedures performed in a physician's office:[22]

- The maximum planned duration of all planned procedures cannot exceed eight hours.
- A physician must discharge the patient within 24 hours, and overnight stay may not exceed 23 hours and 59 minutes.
- The overnight stay is strictly limited to the physician's office.
- If the patient has not sufficiently recovered to be safely discharged within the 24-hour period, the patient must be transferred to a hospital for continued post-operative care.

[18] Ss. 458.328(2)(b) and 459.0138(2)(b), F.S.
[19] Such treatment addresses conditions such as peripheral artery disease and other arterial blockages.
[20] Rules 64B8-9.009(2)(c) and 64B15-14.007(2)(c), F.A.C.
[21] *Id*.
[22] Rules 64B8-9.009(2)(g) and 64B15-14.007(2)(g), F.A.C.

Registration

Current law requires physicians to register their offices with DOH to perform liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, a level II office surgery, or a level III office surgery.[23]

Each registered office must designate a physician who is responsible for complying with all laws and regulations establishing safety requirements for such offices.[24] The designated physician is required to notify DOH within 10 days of hiring any new recovery or surgical team personnel.[25] The office must notify DOH within 10 calendar days after the termination of a designated physician relationship.[26]

DOH must inspect any office where office surgeries will be done before the office is registered.[27] If the office refuses such inspection, it will not be registered until the inspection can be completed. DOH is required to immediately suspend the registration of an office that refuses an inspection. The office must close during the suspension, which must remain in effect for at least 14 consecutive days. Upon completion of an inspection of the office, DOH may lift the suspension by issuing a written declaration that the office may reopen.[28]

DOH must inspect each registered office annually unless the office is accredited by a nationally recognized accrediting agency approved by the respective board. Such inspections may be unannounced.[29]

Currently, 724 offices are registered with DOH.[30]

Enforcement Authority

DOH may deny or revoke an office registration if any of its physicians, owners, or operators do not comply with any office surgery laws or rules. Also, DOH may deny a person applying for a facility registration if he or she was named in the registration document of an office whose registration is revoked for five years after the revocation date.

DOH may impose penalties on the designated physician if the registered office is not in compliance with safety requirements, including:[31]

- Suspension or permanent revocation of a license;
- Restriction of license;
- Imposition of an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.;
- Issuance of a reprimand or letter of concern.
- Placement of the licensee on probation for a period of time and subject to such conditions as the board;
- Corrective action;
- Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights;

[23] Ss. 458.328(1) and 459.0138(1), F.S.
[24] Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.
[25] *Id.*
[26] *Id.*
[27] *Supra* note 23.
[28] *Id.*
[29] *Id.*
[30] Department of Health, *License Verification – Office Surgery Registration, Practicing Statuses Only*, March 21, 2023, available at https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited January 25, 2024).
[31] S. 456.072(2), F.S.

- Refund of fees billed and collected from the patient or a third party on behalf of the patient; or
- Requirement that the licensee undergo remedial education.

DOH can also issue an emergency order suspending or restricting the registration of a facility if there is probable cause that:

- The office or its physicians are not in compliance with the board rule on the standards of practice; or
- The licensee or registrant is practicing or offering to practice beyond the scope allowed by law or beyond his or her competence to perform; and
- Such noncompliance constitutes an immediate danger to the public.

The boards must fine physicians who perform office surgeries in an unregistered facility $5,000 per day.[32]

Office Surgeries – Gluteal Fat Grafting Procedures

Current law requires physicians to register their offices to perform gluteal fat grafting procedures. However, they are not required to indicate to DOH that they perform such procedures. According to DOH, physician offices registered to perform level I, level II, and level III office surgeries are performing gluteal fat grafting procedures, the majority of which are registered to perform level III office surgeries.

Current law establishes standards of practice for physicians performing gluteal fat grafting procedures in office surgery settings. A physician providing gluteal fat grafting procedures must adhere to the standards of practice in statute and in rule.[33]

A physician or osteopathic physician performing such procedures must conduct an in-person exam of the patient, while physically present in the same room as the patient, no later than the day before the procedure.[34]

Any duty delegated by the physician and performed during the gluteal fat grafting procedure must be completed under the direct supervision of the physician. Gluteal fat injections and fat extraction may not be delegated. Gluteal fat injections must be done under ultrasound guidance, or guidance with other technology authorized by rule that equals or exceeds the quality of ultrasound, to ensure the fat is injected into the subcutaneous space. Gluteal fat may only be injected into the subcutaneous space and may not cross the fascia covering gluteal muscle. Intramuscular and submuscular fat injections are prohibited.[35]

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.[36]

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

[32] Ss. 458.328(1)(h) and 459.0138(1)(h), F.S.
[33] Ss. 458.328(2) and 459.0138(2), F.S.
[34] *Id.*
[35] *Id.*
[36] *Id.*

commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.[37]

Physician Financial Responsibility

Current law requires physicians, as a condition of licensure, to demonstrate financial responsibility to the board of their ability to pay claims and costs arising out of the rendering of, or the failure to render, medical care or services. A physician may demonstrate financial responsibility by one of the following methods:[38]

- Establishing and maintaining an escrow account consisting of sufficient cash or assets to cover $100,000 per claim with a minimum annual aggregate of $300,000;
- Obtaining or maintaining professional liability coverage of at least $100,000 per claim, with a minimum annual aggregate of at least $300,000 from an authorized insurer, surplus lines insurer, risk retention group, joint underwriting association, or through a plan of self-insurance; or
- Obtaining and maintaining an unexpired, irrevocable letter of credit of at least $100,000 per claim, with a minimum aggregate credit availability of at least $300,000.

A physician is prohibited from using the escrow account, professional liability coverage, or irrevocable letter of credit to pay for litigation costs or attorney's fees for the defense of any medical malpractice claim.[39]

Physicians who perform surgery in ambulatory surgical centers are required to establish additional financial responsibility by one of the following methods:[40]

- Establishing and maintaining an escrow account consisting of sufficient cash or assets to cover $250,000 per claim with a minimum annual aggregate of $750,000;
- Obtaining or maintaining professional liability coverage of at least $250,000 per claim, with a minimum annual aggregate of at least $750,000 from an authorized insurer, surplus lines insurer, risk retention group, joint underwriting association, or through a plan of self-insurance; or
- Obtaining and maintaining an unexpired, irrevocable letter of credit of at least $250,000 per claim, with a maximum aggregate credit availability of at least $750,000.

A physician is prohibited from using the escrow account, professional liability coverage, or irrevocable letter of credit to pay for litigation costs or attorney's fees for the defense of any medical malpractice claim.[41]

Current law does not require physicians who perform surgery in office settings to establish additional, or greater, financial responsibility than that generally required for all physicians.

Current law does not require registered office surgeries to carry liability covergage, or establish other financial responsibility.

Effect of the Bill

Current law requires a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed to register his or her office with DOH. The bill requires physicians to register regardless of whether the fat is temporarily or permanently removed.

[37] *Id.*
[38] Ss. 458.320(1) and 459.0085(1), F.S.
[39] *Id.*
[40] Ss. 458.320(2) and 459.0085(2), F.S.
[41] *Id.*

Under current law a physician must register his or her office with DOH in order to perform 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. Current law authorizes DOH to impose a fine of $5,000 per day on a physician who performs such a procedure or surgery in an unregistered office. The bill changes the fine to $5,000 per incident, to allow DOH to fine a physician for multiple offenses committed during the same day.

The bill requires physician offices in which gluteal fat grafting procedures are performed to establish financial responsibility by one of the following methods:

- Obtaining and maintaining professional liability coverage of at least $250,000 per claim, with a minimum annual aggregate of at least $750,000 from an authorized insurer, surplus lines insurer, risk retention group, joint underwriting association, or through a plan of self-insurance; or
- Obtaining and maintaining an unexpired, irrevocable letter of credit of at least $250,000 per claim, with a maximum aggregate credit availability of at least $750,000.

The bill is effective upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.