

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1561 Office Surgeries

**SPONSOR(S):** Busatta Cabrera

**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1188

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	16 Y, 0 N	Guzzo	McElroy
2) Health Care Appropriations Subcommittee	15 Y, 0 N	Smith	Clark
3) Health & Human Services Committee			

### SUMMARY ANALYSIS

The bill provides additional enforcement authority to the Department of Health (DOH) over offices in which physicians perform certain liposuction procedures, including gluteal fat grafting procedures.

Current law requires a physician to register their office with DOH if they perform liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed. The bill requires them to register if the fat is temporarily or permanently removed, thus removing a loophole from registration because gluteal fat grafting procedures involve removing (temporarily) and then reinserting the fat in the patient.

The bill requires physicians to register their office with DOH if they perform gluteal fat grafting procedures. Additionally, the bill requires a physician to register their office with DOH if they perform a liposuction procedure in which the patient is rotated 180 degrees or more during the procedure.

Further, the bill requires physicians who have already registered their offices prior to July 1, 2024, to reregister their offices, in accordance with a schedule developed by DOH, if they perform gluteal fat grafting procedures, or if they perform liposuction procedures in which the patient is rotated 180 degrees or more. If during the reregistration process, DOH determines that the procedures being performed in such an office create a significant risk to patient safety and that the office should be licensed and regulated as an ambulatory surgical center (ASC), DOH must notify the Agency for Health Care Administration (AHCA) and AHCA must inspect the office to confirm that the office should be licensed as an ASC. If AHCA determines that the office should be licensed as an ASC, they must notify the office and DOH, and the office must cease performing procedures that require registration. The office is prohibited from performing such procedures until it relinquishes its registration and obtains an ASC license. The bill requires DOH to complete reregistration by December 1, 2024.

Current law authorizes DOH to impose a fine of \$5,000 per day on a physician who performs a gluteal fat grafting procedure 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 has an indeterminate, yet likely insignificant, fiscal impact on AHCA and DOH and no impact on local government.

The bill is effective upon becoming law.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED 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. 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.<sup>1</sup>

The rate of fatal complications from gluteal fat grafting is higher than any other cosmetic procedure.<sup>2</sup> South Florida carries the highest BBL mortality rate by far in the nation with 25 deaths occurring between 2010 and 2022.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup>

##### Regulation of Office Surgeries

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.<sup>6</sup> The boards have authority to establish, by rule, standards of practice and standards of care for particular settings.<sup>7</sup> 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.<sup>8</sup>

The boards establish the standards of care that must be met 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.<sup>9</sup> 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.

##### Registration

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<sup>1</sup> 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).

<sup>2</sup> 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).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic medicine.

<sup>7</sup> Ss. 458.331(v) and 459.015(z), F.S.

<sup>8</sup> *Id.*

<sup>9</sup> 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.

A physician is required to register their office 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.<sup>10</sup>

Each registered office must designate a physician who is responsible for complying with all laws and regulations establishing safety requirements for such offices.<sup>11</sup> The designated physician is required to notify DOH within 10 days of hiring any new recovery or surgical team personnel.<sup>12</sup> The office must notify DOH within 10 calendar days after the termination of a designated physician relationship.<sup>13</sup>

DOH must inspect any office where office surgeries will be done before the office is registered.<sup>14</sup> If the office refuses such inspection, it will not be registered until the inspection can be completed. If an office that has already been registered with DOH refuses inspection its registration will be immediately suspended and remain suspended until the inspection is completed, and the office must close for 14 days.<sup>15</sup>

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.<sup>16</sup>

Currently, there are 724 offices registered with DOH.<sup>17</sup>

### Standards of Care

Prior to performing any surgery, a physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.<sup>18</sup> A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.<sup>19</sup> 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.<sup>20</sup>

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,<sup>21</sup> which includes:<sup>22</sup>

- 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;

<sup>10</sup> Ss. 458.328(1) and 459.0138(1), F.S.

<sup>11</sup> Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Supra* note 10.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> Department of Health, *License Verification – Office Surgery Registration, Practicing Statuses Only*, March 21, 2023, available at <https://mqa-internet.doh.state.fl.us/MQA/SearchServices/HealthCareProviders> (last visited January 25, 2024).

<sup>18</sup> Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.

<sup>19</sup> *Id.* A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.

<sup>20</sup> *Id.* A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.

<sup>21</sup> Level I office surgeries involves the most minor of surgeries, which require minimal sedation or local or topical anesthesia, and have a remote chance of complications requiring hospitalization. Level II office surgeries involve moderate sedation and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office. 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. Rules 64B8-9.009(3)-(6) and 64B15-14.007(3)-(6), F.A.C.

<sup>22</sup> Rules 64B8-9.009(2)(c) and 64B15-14.007(2)(c), F.A.C.

- 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.<sup>23</sup>

For elective cosmetic and plastic surgery procedures performed in a physician's office:<sup>24</sup>

- 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.

Office surgeries are prohibited from:

- Resulting in blood loss greater than 10 percent of blood volume in a patient with normal hemoglobin;
- Requiring major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, excluding laparoscopy;
- Involving a major blood vessel with direct visualization by open exposure of the vessel, not including percutaneous endovascular treatment<sup>25</sup>; or
- Being emergent or life threatening.

#### *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.<sup>26</sup> 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:<sup>27</sup>

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

<sup>23</sup> *Id.*

<sup>24</sup> Rules 64B8-9.009(2)(g) and 64B15-14.007(2)(g), F.A.C.

<sup>25</sup> Such treatment addresses conditions such as peripheral artery disease and other arterial blockages.

<sup>26</sup> Ss. 458.351 and 459.026, F.S.

<sup>27</sup> Ss. 458.351(4) and 459.026(4), F.S.

- 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.<sup>28</sup>

#### *Office Surgeries – Gluteal Fat Procedures*

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. 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.

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.

#### *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:<sup>29</sup>

- 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;
- 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

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<sup>28</sup> Ss. 458.351(5) and 459.026(5), F.S.

<sup>29</sup> S. 456.072(2), F.S.

- 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 adopt rules establishing the standards of practice for physicians who perform office surgery. The boards must fine physicians who perform office surgeries in an unregistered facility \$5,000 per day. Lastly, performing office surgery in a facility that is not registered with DOH is grounds for disciplinary action against a physician's license.

In 2023, the Legislature provided further enforcement authority to DOH and the boards to regulate offices in which certain liposuction procedures and office surgeries.<sup>30</sup>

### Ambulatory Surgical Centers

An ambulatory surgical center, or ASC, is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within 24 hours.<sup>31</sup> If a provider anticipates or knows that they will be discharging patients beyond 24 hours, they must self-designate as an ASC by applying for ASC licensure with the Agency for Health Care Administration (AHCA).<sup>32</sup>

ASCs are licensed and regulated by AHCA under the same regulatory framework as hospitals.<sup>33</sup> Currently, there are 520 licensed ASCs in Florida.<sup>34</sup>

### **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 if the fat is temporarily or permanently removed, thus removing a loophole from registration because gluteal fat grafting procedures involve temporarily removing the fat and then reinserting it into the patient.

The bill requires physicians to register their office with DOH if they perform gluteal fat grafting procedures. Additionally, the bill requires a physician to register their office with DOH if they perform a liposuction procedure in which the patient is rotated 180 degrees or more during the procedure.

Further, the bill requires physicians who have already registered their offices prior to July 1, 2024, to reregister their offices, in accordance with a schedule developed by DOH, if they perform gluteal fat grafting procedures, or if they perform liposuction procedures in which the patient is rotated 180 degrees or more. The bill requires DOH to complete reregistration by December 1, 2024.

If during the reregistration process, DOH determines that the procedures being performed in such an office create a significant risk to patient safety and that the office should be licensed and regulated as an ASC, DOH must notify AHCA and AHCA must inspect the office to confirm whether the office should be licensed as an ASC. If AHCA determines that the office should be licensed as an ASC, they must notify the office and DOH and the office must cease performing procedures that require registration. The office is prohibited from performing such procedures until it relinquishes its registration and obtains an ASC license.

Current law authorizes DOH to impose a fine of \$5,000 per day on a physician who performs a gluteal fat grafting procedure 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.

<sup>30</sup> Ch.23-307, Laws of Fla.

<sup>31</sup> S. 395.002(3), F.S.

<sup>32</sup> Agency for Health Care Administration, Agency Analysis of HB 1561 (Jan. 18, 2024).

<sup>33</sup> SS. 395.001-.1065, F.S., and Part II, Chapter 408, F.S.

<sup>34</sup> *Supra* note 32.

The bill is effective upon becoming law.

**B. SECTION DIRECTORY:**

**Section 1:** Amends s. 458.328, F.S., relating to office surgeries.

**Section 2:** Amends s. 459.0138, F.S., relating to office surgeries.

**Section 3:** In an unnumbered section of law, requires DOH to develop a schedule for reregistration of medical offices affected by the bill, to be completed by a specified date.

**Section 4:** Provides the bill is effective upon becoming law.

**II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

**A. FISCAL IMPACT ON STATE GOVERNMENT:**

1. Revenues:

The bill would have an indeterminate, positive fiscal impact on the DOH Medical Quality Assurance Trust Fund, to the extent the number of annual office incidents exceeds one per day.

2. Expenditures:

The bill has an indeterminate, yet likely insignificant, negative fiscal impact on AHCA for additional staff to conduct survey inspections of physician offices. According to AHCA, the number of additional surveys is unknown, so it is unknown if additional staff would be needed to cover the workload.<sup>35</sup>

DOH will experience a non-recurring increase in workload and costs associated with updating the Licensing and Enforcement Information Database System (LEIDS) and Iron Data Mobile (IDM) inspection software to update inspection requirements; DOH will also experience a non-recurring workload increase to update the artificial intelligence virtual agent (ELI) for voice and web, Search Services application, data reporting, and board and DOH websites. Additionally, DOH may be required to create data exchange services with the AHCA.<sup>36</sup> The workload and costs associated with the bill can be absorbed within existing resources.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

**C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

None.

**D. FISCAL COMMENTS:**

None.

**III. COMMENTS**

**A. CONSTITUTIONAL ISSUES:**

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

<sup>35</sup> *Id.*

<sup>36</sup> Department of Health, 2024 Agency Legislative Bill Analysis: SB 1188, (Jan. 11, 2024)

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

#### **IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES**