The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 1188

INTRODUCER: Senator Garcia

SUBJECT: Office Surgeries

DATE: February 5, 2024 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Pre-meeting**
2.			AHS	
3.			FP	

I. Summary:

SB 1188 provides additional enforcement authority to the Department of Health (DOH) over physician offices in which physicians perform certain liposuction procedures or gluteal fat grafting procedures, also known as Brazilian Butt Lifts (BBLs).

The bill requires that, in addition to other circumstances that require office registration:

- Physicians must register their offices with the DOH if they perform liposuction procedures in their offices in which more than 1,000 cc of supernatant fat is temporarily or permanently removed. Current law does not specify temporarily or permanently.
- Physicians must register their offices with the DOH if they perform gluteal fat grafting procedures in their offices. Current law does not expressly require registration for the performance of such procedures by name.
- Physicians must register their offices with the DOH if they perform liposuction procedures in their offices during which the patient is rotated 180 degrees or more.

The bill modifies the penalty for performing surgery in an unregistered office, if the surgery requires office registration, from a fine of $5,000 per day to $5,000 per incident, to allow the DOH to fine a physician for multiple offenses committed during the same day.

The bill requires that physicians who have registered their offices prior to July 1, 2024, must re-register, in accordance with a schedule developed by the DOH, if the physician performs gluteal fat grafting procedures or liposuction procedures in which the patient is rotated 180 degrees or more.

The bill requires that if, during the re-registration process, the DOH determines that the procedures being performed in the office create a significant risk to patient safety and the interests of patient safety would be better served if the office were licensed and regulated as an ambulatory surgical center (ASC), then the DOH must notify the Agency for Health Care Administration (AHCA) and the AHCA must inspect the office and determine, in the interests of

patient safety, whether the office is a candidate for ASC licensure. If the AHCA determines the office is a candidate for ASC licensure, then the bill requires the AHCA to notify the office and the DOH. The bill requires that such an office must cease performing procedures that require re-registration and prohibits such procedures from being performed there until the office relinquishes its registration and obtains an ASC license.

The bill takes effect upon becoming law.

II. Present Situation:

Regulation of Office Surgeries

The Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) (collectively, the boards)[1], within the DOH[2], have authority to adopt rules to regulate practice of medicine and osteopathic medicine, respectively. The boards have authority to establish, by rule, standards of practice for particular settings.[3] Such standards may include education and training; medications, including anesthetics; assistance of and delegation to other personnel; sterilization; performance of complex or multiple procedures; records; informed consent; and policy and procedures manuals.[4]

The boards set forth the standards of practice 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.[5] There are several levels of office surgeries governed by rules adopted by the boards, which set forth 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

A physician is required to register his or her office with the 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.[6]

Each registered office must designate a physician who is responsible for complying with all laws and regulations establishing safety requirements for such offices.[7] The designated physician is required to notify the DOH within 10 days of hiring any new recovery or surgical team

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[1]Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic medicine.
[2] The Dept. of Health, Division of Medical Quality Assurance (MQA), serves as the principle administrative unit for the Board of Medicine and the Board of Osteopathic Medicine.
[3] Sections 458.331(v) and 459.015(z), F.S.
[4] *Id.*
[5] Fla. Admin. Code Rs. 64B8-9.009(1)(d) and 64B15-14.007(1)(d), (2023). Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgery centers, mobile surgical facilities, and certain intensive residential treatment programs.
[6] Sections 458.328(1) and 459.0138(1), F.S.
[7] Fla Admin. Code Rs. 64B8-9.0091(1) and 64B15-14.0076(1), (2023).

personnel.[8] The office must notify the DOH within 10 calendar days after the termination of a designated physician relationship.[9]

The DOH must inspect any office where office surgeries will be done before the office is registered.[10] 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 the 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.[11]

The 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.[12]

The DOH's license verification web page indicates there are 1,816 office surgery registrations.[13]

Standards of Practice

Prior to performing any surgery, a physician must evaluate the risks of anesthesia and the surgical procedure to be performed.[14] A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[15] 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.[16]

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:[17]

- 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;

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[8] *Id.*
[9] *Id.*
[10] *Supra* note 5.
[11] *Id.*
[12] *Id.*
[13] Florida Agency for Health Care Administration, House Bill 1561, 2024 Agency Legislative Bill Analysis (Jan. 18, 2024) (on file with the Senate Committee on Health Policy).
[14] Fla. Admin. Code Rs. 64B8-9.009(2) and 64B15-14.007(2), (2023).
[15] *Id.* A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.
[16] *Id.* A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.
[17] Fla. Admin. Code Rs. 64B8-9.009(2)(a) and 64B15-14.007(2)(a), (2023).

- 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 logs must be maintained for at least six years from the last patient contact and must be provided to the DOH investigators upon request.[18]

For elective cosmetic and plastic surgery procedures performed in a physician's office:[19]
- 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 ten 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[20]; or
- Being emergent or life threatening.

Levels of Office Surgeries

Level I

Level I involves the most minor of surgeries, which require minimal sedation[21] or local or topical anesthesia, and have a remote chance of complications requiring hospitalization.[22] Level I procedures include:[23]

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[18] *Id.*
[19] Fla. Admin. Code Rs. 64B8-9.009(2)(f) and 64B15-14.007(2)(f), (2023).
[20] Such treatment addresses conditions such as peripheral artery disease and other arterial blockages.
[21] Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are not impaired. Controlled substances are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
[22] Fla. Admin. Code Rs. 64B8-9.009(3) and 64B15-14.007(3), (2023).
[23] *Id.*

- 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 other than minimal pre-operative tranquilization of the patient;
- Liposuction involving the removal of less than 4,000 cc supernatant fat; and
- Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cryptoscopic procedures, and closed reduction of simple fractures or small joint dislocations (e.g., finger and toe joints).

Level II

Level II office surgeries involve moderate sedation[24] and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.[25] Level II office surgeries, include but are not limited to:[26]

- Hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4,000 cc supernatant fat; and
- Any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

A physician performing a Level II office surgery must:[27]

- Have staff privileges at a licensed hospital to perform the same procedure in that hospital as the surgery being performed in the office setting;
- Demonstrate to the appropriate board that he or she has successfully completed training directly related to and include the procedure being performed, such as board certification or eligibility to become board-certified; or
- Demonstrate comparable background, training, or experience.

A physician, or a facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within a reasonable proximity[28] if the physician performing the procedure does not have staff privileges to perform the same procedure at a licensed hospital within a reasonable proximity.

Anesthesiology must be performed by an anesthesiologist, a certified registered nurse anesthetist (CRNA), or a qualified physician assistant (PA). An appropriately-trained physician, PA, or registered nurse with experience in post-anesthesia care, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.[29]

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[24] Moderate sedation or conscious sedation is a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulations. No interventions are needed to manage the patient's airway and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.

[25] Fla. Admin. Code Rs. 64B8-9.009(4) and 64B15-14.007(4), (2023).

[26] *Id.*

[27] *Id.*

[28] Transport time to the hospital must be 30 minutes of less.

[29] *Id.* The assisting practitioner must be trained in advanced cardiovascular life support, or for pediatric patients, pediatric advanced life support.

Level IIA

Level IIA office surgeries are those Level II surgeries with a maximum planned duration of five minutes or less and in which chances of complications requiring hospitalization are remote.[30] A physician, physician assistant, registered nurse, or licensed practical nurse must assist the surgeon during the procedure and monitor the patient in the recovery room until the patient is recovered from anesthesia.[31] The assisting health care practitioner must be appropriately certified in advanced cardiac life support, or in the case of pediatric patients, pediatric advanced life support.[32]

Level III

Level III office surgeries are the most complex and require deep sedation or general anesthesia.[33] A physician performing the surgery must have staff privileges to perform the same procedure in a hospital.[34] The physician must also have knowledge of the principles of general anesthesia.

Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II[35] are appropriate candidates for Level III office surgery. For all ASA Class II patients above the age of 50, the surgeon must obtain a complete work-up performed prior to the performance of Level III surgery in a physician office setting.[36] If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative electrocardiogram and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.[37] All Level III surgeries on patients classified as ASA III[38] and higher must be performed in a hospital or an ambulatory surgery center.

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[30] Fla. Admin. Code Rs. 64B-9.009(5) and 64B15-14.007(5), (2023).
[31] *Id.*
[32] *Id.*
[33] Deep sedation is a drug-induced depression of consciousness during which a patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. A patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. General anesthesia is a drug-induced loss of consciousness during which a patient is not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. The use of spinal or epidural anesthesia is considered Level III.
[34] Fla. Admin. Code Rs. 64B8-9.009(6) and 64B15-14.007(6), (2023). The physician may also document satisfactory completion of training directly related to and include the procedure being performed.
[35] An ASA Class I patient is a normal, healthy, non-smoking patient, with no or minimal alcohol use. An ASA Class II patient is a patient with mild systemic disease without substantive functional limitations. Examples include current smoker, social alcohol drinker, pregnancy, obesity, well-controlled hypertension with diabetes, or mild lung disease. *See* American Society of Anesthesiologists, *ASA Physical Status Classification System*, (Oct. 15, 2014, last amended Dec. 13, 2020), available at https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system (last visited on Feb. 2, 2024).
[36] *Id.*
[37] *Id.*
[38] An ASA Class III patient is a patient with severe systemic disease who has substantive functional limitations and/or one or more moderate to severe diseases. This may include poorly controlled diabetes or hypertension, chronic obstructive pulmonary disease, morbid obesity, active hepatitis, alcohol dependence or abuse, implanted pacemaker, premature infant, recent history of myocardial infarction, cerebrovascular disease, transient ischemic attack, or coronary artery disease.

During the procedure, the physician must have one assistant who has current certification in advanced cardiac life support. Additionally, the physician must have emergency policies and procedures related to serious anesthesia complications, which address:

- Airway blockage (foreign body obstruction);
- Allergic reactions;
- Bradycardia;
- Bronchospasm;
- Cardiac arrest;
- Chest pain;
- Hypoglycemia;
- Hypotension;
- Hypoventilation;
- Laryngospasm;
- Local anesthetic toxicity reaction; and
- Malignant hypothermia.

Gluteal Fat Grafting Procedure

Gluteal fat grafting (a.k.a. the Brazilian Butt Lift or BBL) is a surgical procedure that takes supernatant fat from one part of a person's body by liposuction, usually from the waist, back, or abdomen, purifies the supernatant fat, and then injects the supernatant fat in tiny droplets back into the patient's buttocks. The amount of supernatant fat that is temporarily removed from one part of the body and then transferred to the buttocks varies greatly between patients, and the patient may be turned 180 degrees while under general anesthesia following harvesting of the supernatant fat.[39]

When a surgeon performs a gluteal fat grafting procedure in an office setting, supernatant fat is removed from various parts of the patient's body but may only be injected into the subcutaneous space of the buttocks and must never cross the gluteal muscle fascia. Intramuscular or submuscular fat injections are prohibited.[40]

The risks associated with a gluteal fat grafting procedure include:[41]

- Excessive bleeding;
- Fat embolism, or fat that gets stuck in a vein and then in the lungs;
- Seroma, or fluid build-up under the skin;
- Necrosis, or large volumes of supernatant fat cells that fail to survive transfer;
- Significant scarring;
- Undesirable results; and
- Death.

[39] McLintock, Kaitlyn, *Your Comprehensive Guide To The Brazilian Butt Lift,* (Oct. 29, 2021) available at https://plasticsurgerypractice.com/treatment-solutions/innovations/industry-trends/your-comprehensive-guide-to-the-brazilian-butt-lift/ (last visited Feb. 2,, 2024).
[40] Fla. Admin. Code Rs. 64B8-9.009(2)(c) and 64B15-14.007(2)((c) (2023).
[41] Cleveland Clinic, *Fat Transfer*, available at https://my.clevelandclinic.org/health/treatments/24027-fat-transfer (last visited Feb. 2, 2024).

The rate of fatal complications from gluteal fat grafting is higher than any other cosmetic procedure.[42] South Florida carries the highest BBL mortality rate, by far, in the nation with 25 deaths occurring between 2010 and 2022.[43] According to a study of 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.[44] Of the 25 deaths, 23 of the surgeries were found to have been performed at what the researchers classified as high-volume, low-budget clinics. These clinics were found to have employed a practice model based on 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.[45]

360 Degree Liposuction Procedures

The 360 degree Liposuction may include liposuction of areas of body, including but not limited to the following, while under general anesthesia:
- Upper back;
- Lower back;
- Hip roll;
- Mid back;
- Flanks;
- Abdomen;
- Arms;
- Thighs; and
- Presacral triangle.

The 360 Degree Liposuction Combined with a BBL

The 360 degree liposuction with the BBL is a new popular cosmetic procedure and is actually two surgical procedures performed at the same time.[46] The 360 degree liposuction harvests excess supernatant fat from various areas of the body as noted above and involves turning the patient over 360 degrees while under general anesthesia; and then placing the patient on his or her abdomen, face down, and undergoing a BBL.[47]

The risks associated with the 360 degree liposuction with the BBL includes:
- Hemorrhage;
- Pain;
- Skin discoloration;
- Infections,

[42] Pazmiño, Pat; Garcia, Onelio, *Brazilian Butt Lift–Associated Mortality: The South Florida Experience*, Aesthetic Surgery Journal, Vol. 43, (Feb 2023), pps. 162–178, available at https://doi.org/10.1093/asj/sjac224 (last visited Feb. 2, 2024).
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] Kao, Y.-M.; Chen, K.-T.;Lee, K.-C.; Hsu, C.-C.; Chien, Y.-C., *Pulmonary Fat Embolism Following Liposuction and Fat Grafting: A Review of Published Cases.* Healthcare (May 11 2023), 11, 1391. available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10218620/pdf/healthcare-11-01391.pdf (last visited Feb. 2, 2024).
[47] McLintock, Kaitlyn, *Your Comprehensive Guide To The Brazilian Butt Lift,* (Oct. 29, 2021) available at https://plasticsurgerypractice.com/treatment-solutions/innovations/industry-trends/your-comprehensive-guide-to-the-brazilian-butt-lift/ (last visited Feb. 2, 2024).

- Fluid accumulation;
- Blood building up at the incision or underneath the buttocks;
- Skin loss; and
- Pulmonary embolism.[48]

Adding the BBL to 360 degree liposuction makes the procedure longer and potentially more dangerous, especially regarding the complication of a fat embolism and excessive blood loss, which could lead to death.[49]

The Vasovagal Response

During general anesthesia for a 360 degree liposuction and BBL there is also the possible complication of excessive vasovagal stimulation caused by turning the patient over 180 degrees or 360 degrees, creating life-threatening vasovagal syncope and triggering bradycardia, hypotension, and progressing to cardiac arrest and even death.[50] Painful stimulus of the bronchial, pharyngeal, laryngeal, esophageal mucosa and peritoneum stretch, and reduced blood volume can increase the vagal activity, leading to severe bradycardia, hypotension, and cardiac arrest. Even venous cannulation, neuraxial, and regional anesthesia techniques have been attributed to vasovagal syncope.[51]

Under Florida law, liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operations, only in the following circumstances:[52]
- When combined with abdominoplasty, liposuction may not exceed 1,000 cc of supernatant fat;
- When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1,000 cc of supernatant fat; and
- Major liposuction in excess of 1,000 cc supernatant fat may not be performed in a remote location from any other procedure.

A maximum of 4,000 cc supernatant fat may be removed by liposuction in the office setting.[53]

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[48] *Id.*
[49] Kaiser HA, Saied NN, Kokoefer AS, Saffour L, Zoller JK, Helwani MA.,PLOS ONE, (Jan. 22, 2020) Incidence and prediction of intraoperative and postoperative cardiac arrest requiring cardiopulmonary resuscitation and 30-day mortality in non-cardiac surgical patients, available at https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0225939&type=printable (last visited Feb. 2, 2024).
[50] *Id.*
[51] Hosie L, Wood JP, Thomas AN. Vasovagal syncope and anaesthetic practice. Eur. J. Anaesthesiology(Aug. 2001) available at https://journals.lww.com/ejanaesthesiology/fulltext/2001/08000/vasovagal_syncope_and_anaesthetic_practice.11.aspx (last visited Feb. 2, 2024).
[52] Fla. Admin. Code Rs. 64B8-9.009(2)(e) and 64B15-14.007(2)((e) (2023).
[53] Fla. Admin. Code Rs. 64B8-9.009(2)(d) and 64B15-14.007(2)((d) (2023).

Standards of Practice for a Gluteal Fat Grafting Procedures in Office Surgery Setting

A physician performing a gluteal fat grafting procedure in an office setting 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.[54]

If a surgeon desires to delegate any of his or her duties during a gluteal fat grafting procedure, he or she must obtain the patient's written, informed consent for the delegation. Any delegated duty must be performed under the direct supervision of the physician performing the procedure. The surgeon may not delegate the supernatant extraction or the gluteal fat injections. The supernatant fat may only be injected into the subcutaneous space of the patient's buttocks and may not cross the fascia overlying the gluteal muscle. Intramuscular or submuscular supernatant fat injections are prohibited.[55]

When the physician performing a gluteal fat grafting procedure injects the supernatant fat into the subcutaneous space of the patient's buttocks, the physician must use ultrasound guidance, or another form of guidance or technology authorized under BOM or BOOM rule, as applicable, which is equal to, or exceeds, the quality of ultrasound, during the placement and navigation of the cannula, to ensure that the supernatant fat is injected into the subcutaneous space above the fascia overlying the gluteal muscle. Ultrasound guidance is not required for other portions of the procedure.[56]

Adverse Incident Reporting

A physician must report any adverse incident that occurs in an office setting to the DOH within 15 days after the occurrence.[57] 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:[58]

- 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

[54] Sections 458.328(2)(c) and 459.0138 (2)(c), F.S.
[55] *Id.*
[56] *Id.*
[57] Sections 458.351 and 459.026, F.S.
[58] Sections 458.351(4) and 459.026(4), F.S.

- Any condition that required the transfer of a patient to a hospital from an ambulatory surgical center or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

The DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[59]

DOH Regulatory Authority of Office Surgeries

The DOH and the respective boards may deny or revoke an office surgery's registration if any of its physicians, owners, or operators do not comply with any office surgery laws or rules. The 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. The DOH may impose penalties on the designated physician if the registered office is not in compliance with safety requirements, including:[60]

- 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 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 specified by the board;
- Corrective action;
- Imposition of an administrative fine in accordance with s. 381.0261, F.S., 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.

The DOH, via the Surgeon General, 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 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 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. Performing office surgery in a facility that is not registered with the DOH is grounds for disciplinary action against a physician's license.

[59] Sections 458.351(5) and 459.026(5), F.S.
[60] Section 456.072(2), F.S.

Ambulatory Surgical Centers

An ambulatory surgical center (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.[61] If a provider anticipates or knows that he or she will be discharging patients beyond 24 hours, he or she must self-designate as an ASC by applying for ASC licensure with the Agency for Health Care Administration (AHCA). The ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.[62] Currently, there are 520 licensed ASCs in Florida.[63]

III. Effect of Proposed Changes:

SB 1188 requires physicians to register their offices with the DOH if they perform liposuction procedures in their offices in which more than 1,000 cc of supernatant fat is temporarily or permanently removed. Current law does not specify temporarily or permanently.

The bill requires physicians to register their offices with the DOH if they perform gluteal fat grafting procedures in their offices. Current law does not expressly require registration for the performance of such procedures by name.

The bill requires physicians to register their offices with the DOH if they perform liposuction procedures in their offices during which the patient is rotated 180 degrees or more.

The bill modifies the penalty for performing surgery in an unregistered office, if the surgery requires office registration, from a fine of $5,000 per day to $5,000 per incident, to allow the DOH to fine a physician for multiple offenses committed during the same day.

The bill requires that physicians who have registered their offices prior to July 1, 2024, must re-register, in accordance with a schedule developed by the DOH, if the physician performs gluteal fat grafting procedures or liposuction procedures during which a patient is rotated 180 degrees or more. The bill requires the DOH to complete the re-registration process for all affected offices by December 1, 2024.

The bill requires that if, during the re-registration process, the DOH determines that the procedures being performed in the office create a significant risk to patient safety and the interests of patient safety would be better served if the office were licensed and regulated as an ASC, then the DOH must notify the AHCA and the AHCA must inspect the office and determine, in the interests of patient safety, whether the office is a candidate for ASC licensure, notwithstanding the office's failure to meet all requirements associated with such licensure at the time of inspection and notwithstanding the exceptions provided under s. 395.002(3).[64]

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[61] Section 395.002(3), F.S.

[62] Sections 395.001-.1065, F.S., and Part II, Chapter 408, F.S.

[63] Florida Agency for Health Care Administration, House Bill 1561, 2024 Agency Legislative Bill Analysis (Jan. 18, 2024) (on file with the Senate Committee on Health Policy).

[64] Section 395.002(3), F.S., provides that "…a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry may not be construed to be an ambulatory surgical center…"

If the AHCA determines the office is a candidate for ASC licensure, then the bill requires the AHCA to notify the office and the DOH. The bill requires that such an office must cease performing procedures that require re-registration and prohibits such procedures from being performed there until the office relinquishes its registration and obtains an ASC license.

The bill takes effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

A portion of the bill may present an unconstitutional delegation of legislative authority under Article II, Section 3 of the Florida Constitution.

During the re-registration process required under the bill, the bill requires that *"if the [DOH] determines that the performance of such procedures in the office creates a significant risk to patient safety and that the interests of patient safety would be better served if such procedures were instead regulated under the requirements of ambulatory surgical center licensure under chapter 395:"*

- The DOH must notify the AHCA of its determination;
- The AHCA must inspect the office "*and determine, in the interest of patient safety, whether the office is a candidate for ambulatory surgical center licensure notwithstanding the office's failure to meet all requirements associated with such licensure at the time of inspection and notwithstanding the exceptions provided under s. 395.002(3)";* and
- If the AHCA determines that an office is a *"candidate"* for ASC licensure, then the AHCA must notify the office and the DOH, and the office must cease performing procedures requiring re-registration.

The bill:
- Does not define *"a significant risk to patient safety;"*
- Does not provide criteria for the DOH or the AHCA inspectors to utilize in determining what *"creates a significant risk to patient safety"* such that *"the interests of patient safety would be better served"* if such procedures were instead regulated under the requirements of an ASC; and
- Does not define what is meant by *"a candidate for ambulatory surgical center licensure."*

These missing items in the bill could be interpreted to represent fundamental pieces of state policy that the Legislature may need to create instead of delegating that task to the executive branch.

As such, this portion of the bill may represent an unconstitutional delegation of legislative authority under Article II, Section 3 of the Florida Constitution. *See* Askew v. Cross Key Waterways, 372 So. 2d 913, 925 (Fla. 1978); see also Avatar Dev. Corp. v. State; 723 So. 2d 199, 202 (Fla. 1998) (citing Askew with approval). "…fundamental and primary policy decisions must be made by members of the legislature who are elected to perform those tasks, and administration of legislative programs must be pursuant to some minimal standards and guidelines ascertainable by reference to the enactment establishing the program."

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

According to the DOH, MQA 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. MQA 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, MQA may be required to create data exchange services with the AHCA.[65]

[65] Florida Department of Health, House, Senate Bill 1188, 2024 Agency Legislative Bill Analysis (Jan. 11, 2024) (on file with the Senate Committee on Health Policy).

VI. Technical Deficiencies:

On line 301, the bill references "ambulatory surgery center" instead of "ambulatory surgical center."

VII. Related Issues:

Under the bill, certain office surgery registrants need to be re-registered and inspected by December 1, 2024. The DOH advises that it currently has five OPS registered nurse consultants to complete such inspections, and it would take approximately six months to re-register and inspect all affected physician offices, if the nurse consultants do no other DOH work. Based on this, DOH requests the re-registration timeframe be extended to June 30, 2025.[66]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 458.328 and 459.0138.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

[66] *Id.*