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 732
INTRODUCER:	Senator Flores
SUBJECT:	Office Surgery
DATE:	March 8, 2019
REVISED:	

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

I. Summary:

SB 732 revises the definition of "ambulatory surgical center" to remove the exclusion of physician offices, and the bill relocates the requirements that a person who seeks to operate an office surgery center must register with the Department of Health (DOH) and pay registration costs to new statutory sections. The bill:

- Prohibits a physician from practicing allopathic or osteopathic medicine in a center that is not registered with the DOH;
- Creates ss. 458.3266 and 459.0138, F.S., regulating office surgery centers;
- Defines Level I, II and III surgical procedures and sets out additional requirements for surgeons to perform Level III procedures in an office surgery center;
- Defines surgery, office surgery, office surgery center, and five levels of anesthesia – minimal sedation, moderate sedation with analgesia or conscious sedation, deep sedation with analgesia, general anesthesia, and regional anesthesia;
- Creates a new physician type, the "designated physician," and establishes specific responsibilities for that physician in the office surgery center setting;
- Requires a physician who practices in an office surgery center to notify his or her respective board within 10 days after beginning or ending his or her practice at the office surgery center;
- Creates a duty on all physicians practicing at an office surgery center to report to the DOH any perceived noncompliance with the laws or rules that govern office surgery centers;
- Prohibits physicians from performing certain types of surgical procedures in an office surgery center;
- Directs the DOH to inspect office surgery centers annually unless the center is accredited by a board-approved, nationally-recognized accrediting agency;
- Prohibits the DOH from issuing office surgery center certificates of registration under specific circumstances;

- Authorizes the DOH to revoke an office surgery center's certificate of registration and to prohibit associated physicians from practicing at the center for failure to comply with applicable laws and rules;
- Authorizes the DOH to impose specified fines for violations of office surgery center regulations, and other specified statutes, after consideration of specified factors;
- Authorizes the DOH to adopt rules to administer the registration, inspection, and safety of office surgery centers;
- Authorizes the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) to adopt rules to specify training requirements for all licensed or certified office surgery center health care practitioners and other health care practitioners who are not regulated by any board; and
- Republishes statutes regarding the reporting of adverse incidents in office practice settings to comply with Article III, section 6, of the Florida Constitution.

The effective date of the bill is July 1, 2019.

II. Present Situation:

Regulation of Office Surgery

The practice of medicine in Florida is regulated under ch. 458, F.S., and the practice of osteopathic medicine is regulated under ch. 459, F.S. Both professions have broad authority to adopt rules to implement the provisions of their respective practice acts.[1] The BOM and the BOOM were created within the Department of Health (DOH) to ensure that every physician practicing in the state meets minimum requirements for safe practice.[2]

In Florida, surgeries performed in a doctor's office, outside a facility licensed under ch. 390 or ch. 395, F.S., are regulated by ss. 458.309(3) and 459.005(2), F.S. Both sections are identical except for the references to the BOM or the BOOM. Both require that a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level 2 procedures lasting more than five minutes, and all Level 3 surgical procedures in an office setting, to register the doctor's office with the DOH, unless that office is licensed as a facility under ch. 395, F.S. Level 2 procedures and Level 3 procedures are not defined in statutes, but the respective boards have defined three levels of office surgery by administrative rule,[3] which are subject to change by the boards through the administrative rule propagation process.

The DOH is required to inspect a registered doctor's office annually unless the office is accredited by a nationally-recognized accrediting agency or an accrediting organization approved by the BOM or the BOOM. The actual costs of registration, inspection and/or accreditation are to be paid by the person seeking to register and operate the office in which office surgeries are performed.

[1] Sections 458.309(1) and 459.005(1), F.S.
[2] Sections 458.307(1), 458.301, 459.004 and 459.001, F.S.
[3] Rules 64B8-9.009 and 64B15-14.007, F.A.C.

All other aspects of office surgeries are regulated by administrative rules promulgated by the BOM and the BOOM.

Specifically, the BOM and the BOOM may establish by rule standards of practice and standards of care for particular practice settings, including but not limited to:

- Education and training;
- Equipment and supplies;
- Medications, including anesthetics;
- Assistance of and delegation to other personnel;
- Transfer agreements;
- Sterilization;
- Records;
- Performance of complex or multiple procedures;
- Informed consent; and
- Policy and procedure manuals.[4]

The BOM rule relating to the standard of care for office surgery was initially adopted in February 1994; the BOOM in November 2001, and both have been amended numerous times.[5]

The current BOM and BOOM rules are very similar, with only three substantive differences. The BOOM's rule requires the following, and the BOM's rule does not require, that:

- If a surgeon is unavailable to provide post-operative care, the surgeon must notify the patient, prior to the procedure, of his or her unavailability after the procedure;[6]
- When Level II, IIA, or III procedures are performed, the surgeon is responsible for providing the patient, in writing, prior to the procedure, the name and location of the hospital where the surgeon has privileges to perform the same procedure as that being performed in the outpatient setting, or the name and location of the hospital where the surgeon or facility has a transfer agreement;7 and
- The surgeon performing Level I procedures in an office setting must hold a current certification in an Advanced Cardiac Life Support (ACLS) course with didactic and skills components, approved by Pacific Medical Training (PMT), the American Heart Association (AHA), or the American Safety and Health Institute (ASHI).[8]

The BOM and BOOM rules regarding levels of office surgeries (I, II. IIA and III) differentiate each level primarily by the level of sedation and anesthesia required for the procedure and patient risk.

[4] Sections 458.331(1)(v) and 459.015(1)(z), F.S.
[5] See the Florida Administrative Code, History Note for Rule 64B8-9.009, *available at* https://www.flrules.org/gateway/ruleNo.asp?id=64B8-9.009 (last visited Feb. 14, 2019).
[6] Rule 64B15-14.007(2)(h), F.A.C.
[7] Rule 64B15-14.007(2)(o), F.A.C.
[8] Rule 64B15-14.003(3)(b)1., F.A.C. The BOM recommends the surgeon have Basic Life Support Certification, but it is not required. *See* 64B8-9.009(3)(b)1., F.A.C.

As the BOM and the BOOM general requirements for all office surgery,[9] as well as specific standards for the levels of office surgery, are virtually identical, other than the three substantive differences noted above, further reference to the rules in this analysis will pertain to BOM Rule 64B8-9.009, F.A.C.

General Office Surgery Practice Standards

Rule 64B-9.009(2), F.A.C., requires the surgeon[10] to examine the patient immediately before the surgery to evaluate the patient's risk of anesthesia and the surgical procedure to be performed. The surgeon may delegate the preoperative heart and lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol. The surgeon must maintain complete records[11] of each surgical procedure, including:

- Anesthesia records;
- A written informed consent from the patient reflecting the patient's knowledge of:
  - Identified risks;
  - Consent to the procedure;[12]
  - Type of anesthesia;
  - Anesthesia provider; and
  - The availability of a choice of anesthesia provider, including an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.[13]

The rule further requires the surgeon to maintain a log of all Level II and Level III surgical procedures performed, which must include:

- 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;

[9] "Office surgery" is defined by the BOM and the BOOM, as surgery which is performed outside of any facility licensed under ch. 390, F.S., (an abortion clinic) or ch. 395, F.S., (a hospital or ambulatory surgical center). *See* Rules 64B8-9.009(1)(d) and 64B15-14.007(d), F.A.C.

[10] Rules 64B8-9.009(d) and 64B15-14.007(d), F.A.C., define a "surgeon" as a licensed physician performing any procedure included within the definition of surgery.

[11] *See* Rules 64B8-9.003 and 64B-15.007, F.A.C.

[12] A written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa. *See* Rule 64B8-9.009(2)(b), F.A.C.

[13] Rule 64B8-9.009(2), F.A.C.

- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

The log and all surgical records must be provided to the DOH investigators upon request.

The BOM has set out the general requirements for all office surgery in Rule 64B8-9.009(2), F.A.C.,[14] which are as follows:

- The surgeon must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed.[15]
- The surgeon must maintain complete records of each surgical procedure, as set forth in Rule 64B8-9.003, F.A.C., including anesthesia records, when applicable and the records shall contain written informed consent from the patient reflecting 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, i.e., anesthesiologist, anesthesiologist assistant, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant.
- The requirement set forth above for written informed consent is not necessary for minor Level I procedures that are limited to the skin and mucosa.
- The surgeon must maintain a log of all liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and Level III surgical procedures performed The log and all surgical records shall be provided to investigators of the DOH upon request and must be maintained for six years from the last patient contact.
- For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined must not exceed eight hours.
- Except for elective cosmetic and plastic surgery, the surgeon must not keep patients past midnight in a physician's office.
- For elective cosmetic and plastic surgical procedures, the patient must be discharged within 24 hours of presenting to the office for surgery. An overnight stay is permitted in the office provided the total time the patient is at the office does not exceed 23 hours and 59 minutes, including the surgery time. An overnight stay in a physician's office for elective cosmetic and plastic surgery shall be strictly limited to the physician's office. If the patient has not recovered sufficiently to be safely discharged within the timeframes set forth, the patient must be transferred to a hospital for continued post-operative care.

Rule 64B8-9.009, F.A.C.,[16] defines the three levels of office surgery as follows:

Level I Office Surgery[17] 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

[14] See Rule 64B-15.007(2), F.A.C.
[15] The surgeon may delegate the preoperative heart lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol. Rule 64B8-9.009(2) and 64B15-14.007(7), F.A.C.
[16] *See also* Rule 64B-14.007, F.A.C., for the BOOM rule.
[17] Rule 64B8-9.009(3), F.A.C.

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 4000cc supernatant fat;
- Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cystoscopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints);
- The patient's level of sedation is that of minimal sedation and anxiolysis[18] and the chances of complications requiring hospitalization are remote. Minimal sedation and anxiolysis is a defined as a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilation and cardiovascular functions are unaffected. Controlled substances, as defined in ss. 893.02 and 893.03, F.S., are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain; and
- Chances of complication requiring hospitalization are remote.

Level II Office Surgery[19] includes, but is not limited to:
- Hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4,000cc supernatant fat;
- Any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. Moderate sedation and analgesia or conscious sedation is defined as a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response;
- The physician, or the facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within reasonable proximity if the physician performing the procedure does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity; and "Reasonable proximity" is defined as not to exceed 30 minutes transport time to the hospital.

Level III Office Surgery, includes:
- Surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. Deep sedation and analgesia is defined as a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response. General anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a

[18] "Anxiolysis" is defined as a state of mild sedation obtained with minor tranquilizers or antianxiety medication. See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1993866/
[19] Rule 64B8-9.009(4) and (5), F.A.C.

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 shall be considered Level III;

- Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery, and require:
  - All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center; and
  - For all ASA II patients above the age of 50, the surgeon must obtain a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative EKG 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.
- In addition to the standards for Level II Office Surgery, the surgeon must:
  - Have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. Such Board certification or comparable background, training and experience must also be directly related to and include the procedure(s) being performed by the physician in the office surgery facility. In addition, the surgeon must have knowledge of the principles of general anesthesia;
  - Have one assistant who is currently certified by an American Heart Association, American Safety and Health Institute, American Red Cross, Pacific Medical Training approved Basic Life Support course with didactic and skills components, or ACLS Certification Institute Basic Life Support course with didactic and skills components, and the surgeon must be currently certified by an American Heart Association, American Safety and Health Institute, Pacific Medical Training approved Advanced Cardiac Life Support course with didactic and skills components, or ACLS Certification Institute Advanced Cardiac Life Support course with didactic and skills components;
- Have emergency policies and procedures related to serious anesthesia complications must be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location. Topics to be covered shall include the following:
  - Airway Blockage (foreign body obstruction),
  - Allergic Reactions,
  - Bradycardia,
  - Bronchospasm,
  - Cardiac Arrest,
  - Chest Pain,
  - Hypoglycemia,
  - Hypotension,
  - Hypoventilation,
  - Laryngospasm,

- Local Anesthetic Toxicity Reaction; and,
- Malignant Hyperthermia.

Liposuction Procedures in an Office Setting

Liposuction is the surgical removal of subcutaneous fat by means of an aspiration cannula introduced through small skin incisions, assisted by suction. Synonyms used in literature include liposuction surgery, suction-assisted lipectomy, suction lipoplasty, fat suction, blunt suction lipectomy, and liposculpture.[20]

History of Liposuction

Liposuction was initially developed in the late seventies in Italy and France. At that time, liposuction was performed under general anesthesia without any introduction of fluid, hence, called "dry liposuction." Later, a small amount of fluid was introduced into the fat (the "wet technique"). These methods were associated with much blood loss, and patients frequently required blood transfusions.

In 1985, Dr. Jeffrey A. Klein, a dermatologist in California, revolutionized liposuction surgery when he developed the tumescent technique, which permits liposuction totally by local anesthesia and with minimal surgical blood loss. Further modifications such as power liposuction and ultrasonic liposuction have been introduced with variable results. Despite these advances, the tumescent technique remains the worldwide standard of care for liposuction.[21]

Liposuction is one of the most commonly performed cosmetic procedures and is performed by general surgeons, plastic surgeon, and dermatologists. Dermatologists now perform about one third of these procedures in the United States and have pioneered many of the advances in liposuction, especially in the fields of ambulatory surgery and local anesthesia.[22]

The BOM, in rule 64B8-9.009(2)(b) through (e), F.A.C.,[23] sets the general requirements for all liposuction procedures in an office setting as follows:

- The surgeon must maintain a log of all liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, documentation of completion of the medical clearance as performed by the anesthesiologist or the operating physician, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, and any adverse incidents, as identified in s. 458.351, F.S.
- In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.

[20] Venkataram, Jayashree, Journal of Cutaneous and Aesthetic Surgery, *Tumescent Liposuction: A Review* July – December, 2008, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2840906/ (last visited Feb. 27, 2019).
[21] Id.
[22] *Supra* note 17.
[23] *See* also Rule 64B15-14.007(2), F.A.C.

- Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operation, only in the following circumstances:
  - When combined with abdominoplasty, liposuction may not exceed 1000cc of supernatant fat;
  - When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000 cc of supernatant fat; and
  - Major liposuction in excess of 1000cc supernatant fat may not be performed in a remote location from any other procedure.

III. Effect of Proposed Changes:

Section 1 - Definition of Ambulatory Surgical Center

The bill amends the definition of an "ambulatory surgical center," in s. 395.002, F.S., to remove the exclusion of physician offices.

Sections 2, 3, 5, and 6 – Office Surgery Centers

The bill strikes from ss. 458.309(3) and 459.005(2), F.S., regulations for allopathic and osteopathic physicians who perform liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level 2 procedures lasting more than 5 minutes, and all Level 3 surgical procedures in an office setting. The bill also strikes a physician's duty to register his or her office with the DOH if he or she performs the above noted procedures in his or her office unless the office is licensed as a facility under ch. 395, F.S.

The bill relocates both these requirements to new statutes ss. 458.3266 and 459.0138, F.S., to regulate all facilities, offices, or office surgery centers, other than facilities licensed under chs. 390 or 395, F.S., where allopathic and osteopathic physicians perform Level I, II, or III surgical procedures.

The bill defines "office surgery" as any manual or operative procedure, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, or relieving suffering or any elective procedure for aesthetic, reconstructive, or cosmetic purposes, to include, but not be limited to:

- Use of lasers;
- Incision or curettage of tissue or an organ;
- Suture or other repair of tissue or an organ, including both a closed and open reduction of a fracture;
- Extraction of tissue, including premature extraction of the products of conception from the uterus;
- Insertion of natural or artificial implants; or
- Endoscopic procedures with use of local or general anesthetic.

The bill requires a physician who practices in an office surgery center to notify his or her respective board in writing within 10 days after beginning or ending his or her practice at the office surgery center. The bill creates a duty on all physicians practicing at the surgery center to

report to the DOH any perceived noncompliance with the office surgery center statutory requirements. The bill prohibits a physician from performing surgical procedures in an office surgery center which may:

- Result in blood loss of more than 10 percent of estimated blood volume in a patient having a normal hemoglobin level;
- Require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; or
- Involve major blood vessels, when such procedure is performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or are generally emergent or life threatening in nature.

Any physician who violates the above is subject to disciplinary action by his or her respective board.

The bill creates a "designated physician," and defines him or her as a physician licensed under chs. 458 or 459, F.S., who practices at the office surgery center and who is responsible for the center's compliance with applicable regulatory statutes and board rules.

The bill directs the designated physician of an office surgery center to:

- Ensure that the center maintains an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies at the facility, alerts the designated physician to identify and resolve recurring problems, and provides opportunities for the center to improve its performance and enhance and improve the quality of care provided to the public;
- Establish and document compliance with the quality assurance program, and that effort must include at least the following components:
  - Identification, investigation, and analysis of the frequency and causes of incidents;
  - Identification of trends or patterns of adverse incidents; and
  - Development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients.
- Review, at least quarterly, the quality assurance program;
- Report all adverse incidents to the DOH; and
- Notify the applicable board in writing of the designated physician's termination of employment within 10 days after such termination.

The bill defines an "office surgery center" as any facility or office surgery setting, other than a facility licensed under chs. 390 or 395, F.S., where a physician performs any of the following surgical procedures:

- A Level I procedure;
- A Level II procedure lasting more than five minutes; or
- A Level III procedure.

The bill defines the three levels of office surgery as follows:

- "Level I procedures" are procedures in which the patient's level of sedation is that of minimal sedation, and controlled substances, as defined in ss. 893.02 and 893.03, F.S., are

limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain. The term includes:
  - Minor procedures such as:
    - Excision of skin lesions, moles, warts, cysts, and lipomas;
    - Repair of lacerations; or
    - Surgery limited to the skin and subcutaneous tissue performed under topical or regional anesthesia not involving drug-induced alteration of consciousness other than minimal preoperative tranquilization of the patient;
    - Incision and drainage of superficial abscesses;
    - Limited endoscopies such as proctoscopies;
    - Skin biopsies;
    - Arthrocentesis;
    - Thoracentesis;
    - Paracentesis;
    - Dilation of urethra;
    - Cystoscopic procedures: and
    - Closed reduction of simple fractures or small joint dislocations, including, but not limited to, finger and toe joints.
- "Level II procedures" are any surgery in which the patient's level of sedation is:
  - Moderate sedation and analgesia; or
  - Conscious sedation.

  The term includes, but is not limited to:
    - Hemorrhoidectomy;
    - Hernia repair;
    - Large joint dislocations;
    - Colonoscopy; and
    - Liposuction involving the removal of up to 1,000 cubic centimeters of supernatant fat.
- "Level III procedures" are any surgery in which the patient's level of sedation is:
  - Deep sedation with analgesia;
  - General anesthesia;
  - Spinal anesthesia;
  - Regional anesthesia; or
  - Epidural anesthesia.

The bill further directs that the following additional requirements be in place for all Level III office surgeries:
- An anesthesiologist[24] must by physically present at the center and available at the time of the procedure;
- The center must have a written patient transfer agreement with a hospital within reasonable proximity to the center which includes the transfer of the patient's medical records and the treating physician to the licensed hospital; or the surgeon performing the procedure must have admitting privileges at a hospital within reasonable proximity to the center;
- The patient must be classified as a Class I or II under the American Society of Anesthesiologists' (ASA) Physical Status Classification System;

[24] *See* ss. 458.3475 and 459.023, F.S.

- All ASA Class II patients above the age of 50 must have:
  - A complete medical workup performed by the surgeon before surgery; and
  - If the patient has a cardiac history or has other complicating health conditions, he or she must have a preoperative EKG; and
    - A referral to an appropriate consultant for medical optimization of the complicating conditions; or
    - An evaluation by the anesthesiologist to administer or supervise the patient's anesthesia.
- The surgeon must have staff privileges at a licensed hospital to perform the same Level III procedure in the hospital; or must be able to document satisfactory completion of training, such as board certification or board qualification by a board approved by the American Board of Medical Specialties or any other board approved by the his or her respective board.

The bill also defines the anesthesia terms used in the description of each level of office surgery as follows:

- "Minimal sedation" includes anxiolysis and means a drug-induced state during which all of the following apply:
  - The patient may respond normally to verbal commands; and
  - The patient's cognitive function and physical coordination may be impaired, while his or her airway reflexes, ventilation, and cardiovascular functions are unaffected.
- "Moderate sedation with analgesia" or "conscious sedation" are both drug-induced depressions of consciousness and mean a state of consciousness during which all of the following apply:
  - The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation;
  - Interventions are not required to maintain a patent airway, and spontaneous ventilation is adequate;
  - Cardiovascular function is maintained; and
  - Reflex withdrawal from a painful stimulus is not considered a purposeful response.
- "Deep sedation with analgesia" means a drug-induced depression of consciousness during which all of the following apply:
  - The patient cannot be easily aroused but responds purposefully following repeated or painful stimulation;
  - The patient's ability to independently breath may be impaired;
  - The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate;
  - The patient's cardiovascular function is usually maintained; and
  - The patient's reflex withdrawal from painful stimulus is not considered a purposeful response.
- "General anesthesia" means a drug-induced loss of consciousness administered by an anesthesiologist or a certified registered nurse anesthetist during which all of the following apply:
  - The patient is not able to be aroused, even by painful stimulation;
  - The patient's ability to independently maintain ventilation function is often impaired;
  - The patient has a level of depressed neuromuscular function;

- The patient may require assistance in maintaining a patent airway, and positive pressure ventilation is required; and
- The patient's cardiovascular function may be impaired.

The bill directs that all office surgery centers must comply with the following requirements:

- Be located and operated at a publicly accessible, fixed location;
- Display a sign that clearly identifies the name, hours of operation, and street address of the center, and be prominently displayed in public view;
- Maintain and publicly list a telephone number;
- Provide emergency lighting and for emergency communications;
- Have a reception and waiting area;
- Have a restroom;
- Have an administrative area, including room for storage of medical records, supplies, and equipment;
- Have private patient examination rooms;
- Have treatment rooms, if treatment is being provided to the patients;
- Publicly display a visible printed sign in a conspicuous place in each waiting room which includes the name and contact information of the center's designated physician and the names of all physicians practicing at the center;
- Comply with the requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records[25] if the center stores and dispenses prescription drugs;
- Maintain equipment and supplies to support infection prevention and control;
- Identify infection risks based on the following:
  - Geographic location, community, and population served;
  - The nature of the provided care, treatments, and services; and
  - An analysis of the center's infection surveillance and control data; and
- Maintain written infection prevention policies and procedures that address prioritized risks and limit the following:
  - Unprotected exposure to pathogens;
  - The transmission of infections associated with procedures performed at the center;
  - The transmission of infections associated with the center's use of medical equipment, devices, and supplies;
- Maintain its structurally sound buildings and keep its grounds free from health and safety hazards;
- Keep its furniture, appliances, and equipment clean, safe, and in good repair;
- Have evacuation procedures for patients with disabilities and center employees in the event of an emergency;
- Have a written facility-specific disaster plan that specifies actions to be taken in the event of the center closing due to unforeseen disasters, including specific actions for the protection of medical records and any controlled substances;
- Have at least one employee on the premises during patient care hours who is certified in basic life support and trained in reacting to accidents and medical emergencies;

[25] *See* ss. 499.0121 and 893.07, F.S.

- Have written emergency policies and procedures related to serious anesthesia complications which must be formulated and reviewed annually, practiced, updated, and posted in a conspicuous location that address all of the following conditions:
  - Airway blockage and foreign body obstruction;
  - Allergic reactions;
  - Bradycardia;
  - Bronchospasm;
  - Cardiac arrest;
  - Chest pain;
  - Hypoglycemia;
  - Hypotension;
  - Hypoventilation;
  - Laryngospasm;
  - Local anesthetic toxicity reaction; and
  - Malignant hyperthermia;
- Have the equipment and medications to properly manage and treat a cardiac incident or arrest, including:
  - A full and current crash cart with a defibrillator, and
  - The intravenous or inhaled medications recommended by the American Heart Association Guidelines for CPR & Emergency Cardiovascular Care at the location where anesthesia is being carried out, at a minimum;
- Store medicines per the manufacturer's recommendations and note the date on multidose vials once they are opened;
- Maintain dantrolene on site if halogenated anesthetics or succinylcholine are used;
- Be comparable to a freestanding ambulatory surgical center in terms of general preparation, equipment, and supplies, including, but not limited to:
  - Patient recovery capability. and
  - Provisions for proper recordkeeping;
- Have blood pressure monitoring equipment, EKG, end-tidal CO_2 monitor, pulse oximeter, emergency intubation equipment, and a temperature monitoring device;
- Have at least one table capable of Trendelenburg,[26] lithotomy, and other positions necessary to facilitate the surgical procedure.

The bill directs the DOH to inspect each office surgery center annually, including a review of patient records, to ensure compliance with applicable statutes and board rules, unless the center is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the board. The DOH may also inspect an office surgery center as necessary to investigate a notification of noncompliance made by a physician. The actual cost of DOH inspections must be paid by the person who registered and operates the office surgery center.

[26] In Trendelenburg position the body is laid supine or flat on the back on a 15-30 degree incline with the feet elevated above the head. It is used in surgery, especially abdominal and genitourinary, and allows better access to pelvic organs as gravity pulls the intra-abdominal organs away from the pelvis. *See* Kalmar AF, Foubert L, Hendrickx JF, et al. *Influence of steep Trendelenburg position and CO(2) pneumoperitoneum on cardiovascular, cerebrovascular, and respiratory homeostasis during robotic prostatectomy*. Br J Anaesth. 2010 Apr;104(4):433–439. Epub 2010 Feb 18. *available at*: https://www.ncbi.nlm.nih.gov/pubmed/20167583 (last visited Mar. 1, 2019).

During an onsite inspection, the DOH must make a reasonable attempt to resolve each violation with the owner or designated physician before issuing a formal written notification. Any action taken to resolve a violation must be documented in writing by the owner or designated physician and submitted to the DOH. The DOH must verify all corrections of violations in a subsequent inspection.

The bill directs that anyone seeking to operate an office surgery center must register with the DOH and obtain a certificate of registration, unless the center is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows. A physician may not practice medicine in an office surgery center that is not registered with the DOH. Each office surgery center must be registered separately, regardless of whether it is operated under the same business name or management as another center. The actual costs of registration, as determined by the DOH, must be paid by the person seeking to register and operate the center.

At the time of registration, each office surgery center must identify the designated physician and, within 10 days after the resignation or termination of a center's designated physician, the center must identify to the DOH the new designated physician. The DOH may suspend a center's certificate of registration for failure to comply with this requirement. An office surgery center registration may not be transferred to a new owner. If the ownership of a registered office surgery center changes, the new owner must register the center with the DOH before beginning operation under the new ownership.

The bill directs that the DOH may not issue a certificate of registration to an office surgery center that is:

- Not fully owned by a physician, or group of physicians, licensed under chs. 458 or 459, F.S.;
- Not a health care center licensed under part X, ch. 400, F.S.; or
- Owned by or in any contractual or employment relationship with a physician licensed under chs. 458 or 459, F.S., who:
    - Has had his or her hospital privileges revoked in the last five years;
    - Does not have a clear and active license with the department; or
    - Has been the subject of disciplinary action in this state or in another jurisdiction in the last five years for an offense related to standard of care.

If the DOH determines that an office surgery center does not have a designated physician, or is owned, directly or indirectly, by a physician whose privileges, license, or disciplinary status includes any of the following, the DOH must revoke the center's certificate of registration:

- Has had his or her hospital privileges revoked in the last five years;
- Does not have a clear and active license with the department; or
- Has been the subject of disciplinary action in this state or in another jurisdiction in the last five years for an offense related to standard of care.

If the center's certificate of registration is revoked or suspended, the designated physician must ensure that as of the effective date of the suspension or revocation the center:

- Ceases to operate the facility as an office surgery center; and

- Removes any signs and symbols identifying the premises as an office surgery center.

The bill directs that when the DOH suspends the registration of an office surgery center, it must prescribe an appropriate period of suspension, not to exceed two years. Upon the effective date of the suspension or revocation, the designated physician must advise the DOH of the disposition of the medicinal drugs located on the premises. The disposition of the medicinal drugs[27] is subject to the supervision and approval of the DOH. If the office surgery center's registration is revoked, any person named in the registration documents of the center, including the persons who own or operate the center, may not apply, individually or as part of a group, to operate an office surgery center for a period of five years after the revocation date.

The bill directs that the DOH may revoke an office surgery center's certificate of registration and prohibit all physicians associated with the center from practicing at the center for failure to comply with this sections created by the bill and any rules promulgated under it.

The bill permits the DOH to impose an administrative fine of up to $5,000 per violation on an office surgery center for violations of this section or:
- Chapter 499, F.S., the Florida Drug and Cosmetic Act;
- 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act;
- 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act;
- Chapter 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act; or
- DOH rule.

The bill directs that the DOH consider all of the following factors in determining whether to impose a penalty on an office surgery center, and the amount of any fine:
- The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the center's actions or the actions of the physician;
- The gravity of the action or potential harm;
- The nature of the violations of applicable laws or rules;
- Any actions taken by the owner or designated physician to correct the violation;
- Whether any previous violations were committed at the center; and
- Any financial benefits derived by the center from committing or continuing to commit the violation.

The bill directs that each day a violation continues, on which the DOH has ordered a correction, constitutes an additional, separate, and distinct violation. The DOH may impose a fine and, in the case of an owner-operated office surgery center, revoke or deny the center's registration if the center's designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

[27] Medicinal drugs that are purchased or held by a surgery center that is not registered with the DOH may be deemed adulterated for purposes of s. 499.006, F.S. *See* SB 732, 2019, lines 302 – 304 and 847 - 849.

The bill direct the DOH to impose a fine of $5,000 per day on an owner or designated physician of a registered office surgery center who concurrently operates an unregistered center. The DOH is directed to impose a fine of $10,000 on a new owner of an office surgery center that requires registration who fails to register the center upon the change of ownership and who operates the unregistered center.

The bill authorizes the DOH to adopt rules to administer the registration, inspection, and safety of office surgery centers. The BOM and BOOM are also directed to adopt rules specifying training requirements for all licensed or certified office surgery center health care practitioners and other health care practitioners who are not regulated by any board.

Sections 4 and 7 - Reporting of Adverse Incidents in Office Practice Settings

The bill republishes ss. 458.351 and 459.026, F.S., regarding the reporting of adverse incidents in office practice settings to make it clear that those sections apply to the office surgery facilities and centers regulated in new ss. 458.3266 and 459.0138, F.S.; and to comply with article III, section 6 of the Florida Constitution which states that, "no law shall be revised or amended by reference to its title only."

The effective date of the bill is July 1, 2019.

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:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

Article VII, section 19 of the State Constitution requires that a new state tax or fee, as well as an increased state tax or fee, must be approved by two-thirds of the membership

of each house of the Legislature and must be contained in a separate bill that contains no other subject. Article VII, section 19(d)(1) of the State Constitution, defines "fee" to mean "any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service."

Section 1 of the SB 732 redefines the term "ambulatory surgical centers" to include an office maintained by a physician for the practice of medicine. These offices are not ambulatory surgical centers under current law. An office maintained by a physician for the practice of medicine is required to pay a registration fee under s. 395.004, F.S. This registration fee is an existing statutory fee that is not being increased; however, section 1 of the bill imposes this fee on a new type of entity, an office maintained by a physician for the practice of medicine. As such, the Florida Constitution may require that these provisions be passed in a separate bill by a two-thirds vote of the membership of each house of the Legislature.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill substantially amends the following sections of the Florida Statutes: 395.002, 458.309, and 459.005.
The bill creates the following sections of the Florida Statutes: 458.3266 and 459.0138.
The bill republishes the following sections of the Florida Statutes: 458.351 and 459.026.

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.