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:	CS/SB 732
INTRODUCER:	Health Policy Committee and Senator Flores
SUBJECT:	Office Surgery
DATE:	March 13, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 732 revises regulations pertaining to health care clinics and creates new regulations for the provision of health care services in health care settings where office surgeries are performed.

The bill amends the Health Care Clinic Act to:

- Specify that the definition of "clinic" means an entity that provides health care services to individuals and that "receives compensation" for those services, as opposed to such an entity that "tenders charges for reimbursement" for such services;
- Require that an applicant for a clinic license must provide proof that it maintains the financial responsibility to pay claims and related costs that could result from the provision of medical care and services, or the failure to provide such care and services, for physicians and osteopathic physicians who perform liposuction procedures under certain conditions in an office setting;
- Require a clinic director or medical director to ensure that the clinic complies with the standards of practice adopted by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) for office surgery; and
- Require the Agency for Health Care Administration to impose an administrative fine on a clinic not registered with the Department of Health (DOH) that performs certain office surgeries.

The bill requires the DOH to deny or revoke the registration of or impose certain penalties against any facility where certain office surgeries are performed under certain circumstances. If a

facility's registration is revoked, the DOH is authorized to deny any person named in the facility's registration documents from registering a facility to perform surgical procedures for five years after the revocation date. The DOH is also authorized to issue an emergency order suspending or restricting the registration of a facility under certain conditions upon a finding of probable cause that the facility or its surgeons are not in compliance with the standards of practice for office surgery.

The bill provides definitions for numerous terms relating to office surgery. The bill requires medical doctors and doctors of osteopathic medicine who perform certain types of office surgery, and the office in which the surgery is performed, to maintain specified levels of financial responsibility. The bill authorizes the DOH to adopt rules to administer the registration, inspection, and safety of offices that perform certain office surgery and requires the BOD and the BOOM to impose a specified fine on medical doctors and doctors of osteopathic medicine who perform certain office surgeries in an unregistered office. The bill provides that a medical doctor or doctor of osteopathic medicine performing certain office surgeries in an unregistered office constitutes grounds for denial of a license or disciplinary action.

The bill provides that a certified registered nurse anesthetist may provide services in an office registered to perform office surgery within the framework of an established protocol with a licensed anesthesiologist.

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

II. Present Situation:

Health Care Clinic Act

The Agency for Health Care Administration (AHCA) is created in s. 20.42, F.S. The AHCA is the chief health policy and planning entity for the state and is responsible for, among other things, health care clinic licensure, inspection, and regulatory enforcement.[1] Part X of ch. 400, F.S., is known as the Health Care Clinic Act (the Act). The purpose of the Act is to provide for the licensure, establishment, and enforcement of basic standards for health care clinics and to provide administrative oversight to the AHCA.[2]

"Clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and portable equipment provider.[3] Health care clinics in the state must be licensed by the AHCA;[4] however, there are numerous exclusions from the definition of "clinic" in s. 400.9905, F.S.,[5] and from the requirement to obtain a license as a clinic. The definition of "clinic" includes only entities that "tender charges for reimbursement." The AHCA interprets this phrase to include only entities that bill third parties, such as Medicare, Medicaid, and insurance companies. Entities that

[1] *See* Agency for Health Care Administration, *Division of Health Quality Assurance*, available at http://ahca.myflorida.com/MCHQ/index.shtml (last visited Mar. 12, 2019).
[2] Section 400.990, F.S.
[3] Section 400.9905(4)
[4] Section 400.991, F.S.
[5] Section 400.9905(4)(a)-(n), F.S.

provide health care services and accept "cash only" for services are excluded from the definition of "clinic" and are not subject to licensure by the AHCA.[6]

Clinic License Application

In order to obtain a clinic license, an applicant must file an application with the AHCA and pay a fee not to exceed $2,000.[7] The Act defines "applicant" to mean an individual owner, corporation, partnership, firm, business, association, or other entity that owns or controls, directly or indirectly, 5 percent or more of an interest in the clinic and that applies for a clinic license.[8]

The application requires a variety of information, including, but not limited to, the name, residence and business address, phone number, social security number, and license number of the medical or clinic director. The applicant must also provide proof of compliance with the Act, including a listing of services to be provided, the number and discipline of each professional staff member to be employed and proof of financial ability to operate.[9] The AHCA requires a Level 2 background screening for applicants and personnel as required in s. 408.809(1)(e), F.S., pursuant to ch. 435 and s. 408.809, F.S.[10]

Clinic Director Responsibilities

The Act requires that each clinic must appoint a medical director or clinic director who must agree in writing to accept legal responsibility for the following activities on behalf of the clinic:[11]

- Have signs identifying the medical director or clinic director posted in a conspicuous location within the clinic readily visible to all patients;
- Ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license;
- Review any patient referral contracts or agreements executed by the clinic;
- Ensure that all health care practitioners at the clinic have active, appropriate certification or licensure for the level of care being provided;
- Serve as the clinic records owner;
- Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements;
- Conduct systematic reviews of clinic billings to ensure the billings are neither fraudulent nor unlawful;
- Refrain from referring a patient to the clinic if the referral would constitute a conflict of interest; and
- Ensure that the clinic publishes a schedule of charges for the medical services offered to patients.

[6] *See* Agency for Health Care Administration, *Senate Bill 486 Analysis* (2015) (on file with the Senate Committee on Health Policy).
[7] *Supra* note 3 and s. 400.9925(3), F.S.
[8] Section 400.9905(2), F.S.
[9] *Supra* note 3.
[10] Section 400.991(5)(b), F.S.
[11] Section 400.9935, F.S.

Unlicensed Clinics and Administrative Penalties

The Act provides that operating a clinic without a license is a third degree felony punishable as provided in ss. 775.082, 775.083, or 775.084, F.S., with each day of continued operation being a separate offense.[12] Any person found guilty of unlicensed activity a second or subsequent time commits a felony of the second degree, with each day of continued operation being a separate offense.[13] Additionally, any health care provider who is aware of the operation of an unlicensed clinic must report that facility to the AHCA. Failure to report a clinic that the provider knows or has reasonable cause to suspect is unlicensed must be reported to the provider's licensing board.[14]

The AHCA also has the authority to deny the application for a license renewal, revoke and suspend the license, and impose administrative fines of up to $5,000 per violation for violations of the requirements of the Act or rules of the AHCA.

Each day of continuing violation after the date fixed for termination of the violation constitutes an additional, separate, and distinct violation. Any action taken to correct a violation shall be documented in writing by the owner, medical director, or clinic director of the clinic and verified through follow up visits by AHCA personnel.[15]

Any licensed clinic whose owner, medical director, or clinic director concurrently operates an unlicensed clinic shall be subject to an administrative fine of $5,000 per day. Any clinic whose owner fails to apply for a change-of-ownership license and operates the clinic under the new ownership is subject to a fine of $5,000. During an inspection, the AHCA must make a reasonable attempt to discuss each violation with the owner, medical director, or clinic director, prior to written notification.[16]

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.[17] The Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) were created within the Department of Health (DOH) to ensure that every physician practicing in the state meets minimum requirements for safe practice.[18]

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

[12] Section 400.993(1), F.S.
[13] Section 400.993(2), F.S.
[14] Section 400.993(3), F.S.
[15] *Id*.
[16] *Id*.
[17] Sections 458.309(1) and 459.005(1), F.S.
[18] Sections 458.307(1), 458.301, 459.004 and 459.001, F.S.

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,[19] 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.

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.[20]

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.[21]

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;[22]
- 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;23 and

[19] Rules 64B8-9.009 and 64B15-14.007, F.A.C.
[20] Sections 458.331(1)(v) and 459.015(1)(z), F.S.
[21] *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).
[22] Rule 64B15-14.007(2)(h), F.A.C.
[23] Rule 64B15-14.007(2)(o), F.A.C.

- 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).[24]

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.

As the BOM and the BOOM general requirements for all office surgery,[25] 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[26] 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[27] 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;[28]
  - 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.[29]

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;

[24] 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.
[25] "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.
[26] 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.
[27] *See* Rules 64B8-9.003 and 64B-15.007, F.A.C.
[28] 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.
[29] Rule 64B8-9.009(2), F.A.C.

- The diagnosis;
- The CPT Codes for the procedures performed;
- The patient's ASA classification;
- The type of procedure performed;
- The level of surgery;
- The anesthesia provider;
- The type of anesthesia used;
- The duration of the procedure;
- The type of post-operative care;
- The duration of recovery;
- The disposition of the patient upon discharge;
- A list of medications used during surgery and recovery; and
- Any adverse incidents.

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.,[30] 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.[31]
- 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

[30] See Rule 64B-15.007(2), F.A.C.

[31] 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.

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.,[32] defines the three levels of office surgery as follows:

Level I Office Surgery[33] includes:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness 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[34] 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[35] 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:

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[32] *See also* Rule 64B-14.007, F.A.C., for the BOOM rule.
[33] Rule 64B8-9.009(3), F.A.C.
[34] "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/
[35] Rule 64B8-9.009(4) and (5), F.A.C.

- 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 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.[36]

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.[37]

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.[38]

The BOM, in rule 64B8-9.009(2)(b) through (e), F.A.C.,[39] 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

[36] 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).
[37] Id.
[38] *Supra* note 17.
[39] *See* also Rule 64B15-14.007(2), F.A.C.

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.
- 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:

CS/SB 732 defines a "clinic" in ch. 400 F.S., to include an entity that provides health care services and "that receives compensation," expanding the definition to include more entities than those that bill third parties, such as Medicare, Medicaid, and insurance companies. The bill creates additional responsibilities for clinics to ensure that clinics comply with the standards of practice defined by the BOM and the BOOM for office surgery.

The bill directs the AHCA to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the Department of Health (DOH) as an office surgery facility. The bill directs that a clinic must maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic.

The CS/SB 732 also regulates office surgery procedures performed by physicians in an office setting. The bill amends ss. 458.305 and 459. 003, F.S., to define the following terms:

- "Surgeon" means a licensed physician performing any procedure included within the definition of surgery;
- "Surgery" means any manual or operative procedure, including the use of lasers, 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, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an 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 an endoscopic procedure with use of local or general anesthetic;

- "Office surgery" means surgery which is performed outside of any facility licensed under chapter 390 or 395, F.S., and includes:
  - "Level I Office Surgery" means surgery limited to minor procedures where anesthesia is limited to minimal sedation;
  - "Level II Office Surgery means any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation; and
  - Level III Office Surgery means surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. The use of spinal or epidural anesthesia shall be considered Level III.

The bill amends ss. 458.003 and 459.003, F.S., to define six levels of anesthesia that are used to describe the three levels of office surgery as the following:

- "Minimal sedation" means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and respiratory and cardiovascular functions are unaffected;
- "Moderate sedation and analgesia", or "conscious sedation", means 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;
- "Deep sedation and analgesia" means 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 respiratory 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" means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain respiratory 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.
- "Epidural anesthesia" means the injection of an anesthetic agent into the epidural space of the spinal cord to produce regional anesthesia resulting in loss of sensation in the lower abdominal, genital and/or pelvic areas.
- "Spinal Anesthesia" means the injection of an anesthetic agent beneath the arachnoid membrane that surrounds the spinal cord to produce a loss of sensation to the lower half of the body.

The bill amends ss. 458.309 and 459.005, F.S., to authorize the DOH to develop rules to administer the registration, inspection, and safety of an office performing office surgery; and directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians

practicing in an office registered to perform office surgery. The BOM and BOOM must impose a fine of $5,000 per day on a physician who performs certain office surgical procedures in an office that has not registered with the DOH. As a condition of registration, a physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and level III office surgeries in an office setting, and the office itself is a separate legal entity from the physician, must maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S.

The bill amends ss. 458.331 and 459. 015(1), F.S., to establish specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH.

The bill amends s. 464.012, F.S., to direct that any certified registered nurse anesthetist who provide services in an office registered under ss. 458.309(3) or 459.005(2), F.S., must do so within the framework of an established protocol with an anesthesiologist.

The bill amends s 456.004, F.S., to direct the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules; and authorized the DOH to deny future office surgery registrations for five years to any person named in office surgery registration documents, including owners and operators, of an office surgery facility that has had a registration revoked by the DOH.

The bill amends s. 456.074, F.S., to authorize the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a finding of:

- Probable cause that the office, facility. or surgeons are not in compliance with the standards of practice for office surgery adopted by the BOM and the BOOM; and
- That such noncompliance constitutes an immediate danger to the public;

The bill amends s. 400.9905, (4), F.S., to include in the definition of "clinic" a "mobile clinic and a portable equipment provider and excludes specific other entities from the definition;" and amends s. 400.9935, F.S., to direct that if the clinic is registered with the DOH to perform office surgery, the clinic must ensure that it complies with the standards of practice for office surgery promulgated by the BOM and the BOOM.

The bill amends s. 400.995, F.S., to direct AHCA to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the DOH.

The bill amends s. 400.991, F.S., to direct that a clinic maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than

1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic,

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:

None.

B. Private Sector Impact:

As a condition of registration under ss. 458.308 and 459.003, F.S., a physician who performs office surgical procedures in an office setting, and the office itself if it is a separate legal entity from the physician, must now maintain the same levels of financial responsibility required in ss. 458.320 and 459.0085, F.S. This may produce an additional cost to the physician and office if it is a separate legal entity.

C. Government Sector Impact:

The DOH, BOM and BOOM are required to promulgate rules, which may create a fiscal impact that should be absorbed within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill substantially amends the following sections of the Florida Statutes: 400.9905, 400.991, 400.9935, 400.995, 456.004, 456.074, 458.305, 458.309, 458.331, 459.003, 459.005, 459.015, 464.012, and 766.101.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 11, 2019:
The committee substitute:

- Defines a "clinic" in ch. 400 F.S., to include an entity that provides health care services "that receives compensation," expanding the definition to include more than just those that bill third parties, such as Medicare, Medicaid, and insurance companies;
- Creates additional responsibilities for clinics to ensure that clinics complies with the standards of practice defined by the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) for office surgery;
- Directs the Agency for Health Care Administration (AHCA) to impose an administrative fine of $5,000 per day on any licensed clinic whose owner, medical director, or clinic director, operates an unlicensed clinic that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgery procedures, and is not registered with the Department of Health (DOH) as an office surgery facility;
- Directs that the clinic maintain financial responsibility requirements to pay claims and costs arising out of the rendering, or failure to render, medical care and services in the manner prescribed for liposuction procedures in which more than 1,000 cc of supernatant fat is removed, Level II and Level III office surgery procedures performed in the clinic;
- Regulates office surgery procedures performed by physicians; and defines surgeon, surgery, and office surgery, and six levels of anesthesia used to describe the three levels of office surgery as: Minimal sedation; Moderate sedation with analgesia or conscious sedation; Deep sedation with analgesia; General anesthesia; Epidural anesthesia; and Spinal anesthesia.
- Directs the DOH to deny or revoke the registration of, or impose penalties against, an office or facility where a physician performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, for failure of its physicians, owners, or operators to comply with the BOM or the BOOM rules;
- Authorized the DOH to deny future office surgery registrations for five years to any person named in office surgery registration documents, including owners and

operators, of an office surgery facility that has had a registration revoked by the DOH;

- Authorizes the DOH to issue an emergency suspension, or restriction, of an office surgery registration that performs liposuction procedures in which more than 1,000 cc of supernatant fat is removed, or Level II or Level III office surgeries, upon a specific findings;
- Authorizes the DOH to develop rules to administer the registration, inspection, and safety of an office performing office surgery;
- Directs the BOM and the BOOM to adopt rules governing the standards of practice of physicians practicing in an office registered to perform office surgery;
- Directs the BOM and the BOOM to impose a fine of $5,000 per day on a physician who performs office surgical procedures in an office that has not registered;
- Establishes specific grounds for discipline against a physician's license for performing office surgical procedures in an office not registered with the DOH; and
- Directs that any certified registered nurse anesthetist who provide services in a registered office surgery facility work within the framework of an established protocol with an anesthesiologist;

B. Amendments:

None.