HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 933 Clinics and Office Surgery
SPONSOR(S): Health Care Appropriations Subcommittee, Health Quality Subcommittee, Rodriguez, A.
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 732

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	10 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee	11 Y, 0 N, As CS	Mielke	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Under current law, the Board of Medicine and the Board of Osteopathic Medicine (collectively, "boards") oversee surgical procedures performed by their respective licensees in office surgery settings. The boards have established the standards of care that must be met for office surgeries, including certain liposuction procedures, Level II surgical procedures that last more than five minutes, and all Level III procedures.

CS/CS/HB 933 revises requirements and enforcement authority of the Department of Health (DOH) and the boards to regulate physician offices in which certain office surgeries are performed. The bill requires physicians and offices, if separate legal entities, to meet financial responsibility requirements for registration to designate a physician who is responsible for ensuring the office's compliance with laws and regulations.

The bill authorizes DOH to adopt rules related to the registration, inspection, and safety of office surgery centers. The bill requires DOH to annually inspect each registered office and authorizes such inspections to be unannounced. The bill also authorizes the boards to adopt rules to establish standards of practice for physicians performing office surgeries.

The bill provides DOH with the authority to suspend, revoke, or impose other penalties on the registration of a facility in which office surgeries are performed. DOH may also deny the registration application of an applicant who was affiliated with a facility whose registration was previously revoked. The bill also authorizes the boards to discipline the license of a physician who performs surgery in an unregistered facility.

The bill has an insignificant positive and negative fiscal impact on DOH, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill provides that the act shall take effect July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Regulation of Office Surgeries

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

The Boards set forth the standards of care that must be met for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390, F.S., or ch. 395, F.S.[4] There are several levels of office surgeries that are governed by rules adopted by the Boards, which sets forth the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery.

Registration

The Boards require a licensed physician who performs liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed, Level II procedures planned to last more than five minutes, and Level III procedures to register the office with DOH.[5] A physician who performs surgery in an office setting must ensure that the office is registered with DOH, regardless of whether other physicians practice in the office or the office is not owned by a physician.[6] The registration requires a physician to document compliance with transfer agreement[7] and training requirements. DOH must annually inspect registered offices or the office must be accredited by a national accreditation organization approved by the respective board.[8] Currently, there are 587 offices registered with DOH.[9]

Standards of Care

Prior to performing any surgery, a physician must evaluate the risk of anesthesia and of the surgical procedure to be performed.[10] A physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.[11] The written consent must reflect the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists.[12]

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[1] Chapter 458, F.S., regulates the practice of allopathic medicine, and ch. 459, F.S., regulates the practice of osteopathic medicine.
[2] Sections 458.331(v) and 459.015(z), F.S.
[3] Id.
[4] Rules 64B8-9.009(1)(d) and 64B15-14.007(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgery centers, mobile surgical facilities, and certain intensive residential treatment programs.
[5] Sections 458.309(3) and 459.005(2), F.S. *See also* r. 64B8-9.0091 and 64B15-14.0076, F.A.C.
[6] Rule 64B8-9.0091(1) and 64B15-14.0076(1), F.A.C.
[7] A physician or the facility where a surgical procedure is being performed must have a transfer agreement with a licensed hospital within a reasonable proximity or within 30 minutes transport time to the hospital. *See* Rules 64B8-9.009 and 64B15-14.007, F.A.C.
[8] *Supra* note 5.
[9] E-mail correspondence with DOH, dated March 19, 2019 (on file with the Health Quality Subcommittee).
[10] Rules 64B8-9.009(2) and 64B15-14.007(2), F.A.C.
[11] Id. A physician does not need to obtain written informed consent for minor Level I procedures limited to the skin and mucosa.
[12] Id. A patient may use an anesthesiologist, anesthesiologist assistant, another appropriately trained physician, certified registered nurse anesthetist, or physician assistant.

Any physician performing office surgeries must maintain a log of all liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed and Level II and Level III surgical procedures performed, which includes:[13]

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

Such log must be maintained for at least six years from the last patient contact and must be provided to DOH investigators upon request.[14]

For elective cosmetic and plastic surgery procedures performed in a physician's office:[15]

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

Levels of Office Surgeries

Level I Office Surgery

Level I involves the most minor of surgeries, which require minimal sedation[16] or local or topical anesthesia, and have a remote the chance of complications requiring hospitalization.[17] Level I procedures include:[18]

- 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;

[13] Rules 64B8-9.009(2)(a) and 64B15-14.007(2)(a), F.A.C.
[14] Id.
[15] Rules 64B8-9.009(2)(f) and 64B15-14.007(2)(f), F.A.C.
[16] Minimal sedation is a drug-induced state during which the patient responds normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are not impaired. Controlled substances are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.
[17] Rules 64B8-9.009(3) and 64B15-14.007(3), F.A.C.
[18] Id.

- Liposuction involving the removal of less than 4000cc supernatant fat; and
- 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).

Level II Office Surgeries

Level II office surgeries involve moderate sedation[19] and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.[20] Level II office surgeries, include but is not limited to:[21]

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

A physician performing a Level II office surgery must:[22]

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

A physician, or a facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within a reasonable proximity[23] if the physician performing the procedure does not have staff privileges to perform the same procedure at a licensed hospital within a reasonable proximity.[24]

Anesthesiology must be performed by an anesthesiologist, a certified registerd nurse anesthetist (CRNA), or a qualified physician assistant (PA). An appropriately-trained physician, PA, or RN with experience in post-anesthesia care, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.[25]

Level IIA Office Surgeries

Level IIA office surgeries are those Level II surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote.[26] A physician, physician assistant, registered nurse, or licensed practical nurse must assist the surgeon during the procedure and monitor the patient in the recovery room until the patient is recovered from anesthesia.[27]

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[19] Moderate sedation or conscious sedation is a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulations. No interventions are needed to manage the patient's airway and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.
[20] Rules 64B8-9.009(4) and 64B15-14.007(4), F.A.C.
[21] Id.
[22] Id.
[23] Transport time to the hospital must be 30 minutes of less.
[24] *Supra* note 20.
[25] Id. The assisting practitioner must be trained in advanced cardiovascular life support, or for pediatric patients, pediatric advanced life support.
[26] Rules 64B-9.009(5) and 64B15-14.007(5), F.A.C.
[27] Id.

The assisting health care practitioner must be appropriately certified in advanced cardiac life support, or in the case of pediatric patients, pediatric advanced life support.[28]

Level III Office Surgeries

Level III office surgeries are the most complex and require deep sedation or general anesthesia.[29] A physician performing the surgery must have staff privileges to perform the same procedure in a hospital.[30] The physician must also have knowledge of the principles of general anesthesia.

Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II[31] are appropriate candidates for Level III office surgery.[32] For all ASA Class 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.[33] 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.[34] All Level III surgeries on patients classified as ASA III[35] and higher must be performed in a hospital or an ambulatory surgery center.[36]

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

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

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[28] Id.

[29] Deep sedation is a drug-induced depression of consciousness during which a patient cannot be easily aroused but responds purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. A patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. General anesthesia is a drug-induced loss of consciousness during which a patient is not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. The use of spinal or epidural anesthesia is considered Level III.

[30] Rules 64B8-9.009(6) and 64B15-14.007(6), F.A.C. The physician may also document satisfactory completion of training directly related to and include the procedure being performed.

[31] An ASA Class I patient is a normal, healthy, non-smoking patient, with no or minimal alcohol use. An ASA Class II patient is a patient with mild systemic disease without substantive functional limitations. Examples include current smoker, social alcohol drinker, pregnancy, obesity, well-controlled hypertension with diabetes, or mild lung disease. *See* American Society of Anesthesiologists, *ASA Physical Status Classification System*, (Oct. 15, 2014), available at https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system (last visited March 21, 2019).

[32] *Supra* note 30.

[33] Id.

[34] Id.

[35] An ASA Class III patient is a patient with severe systemic disease who has substantive functional limitations and/or one or more moderate to severe diseases. This may include poorly controlled diabetes or hypertension, chronic obstructive pulmonary disease, morbid obesity, active hepatitis, alcohol dependence or abuse, implanted pacemaker, premature infant, recent history of myocardial infarction, cerebrovascular disease, transient ischemic attack, or coronary artery disease.

[36] *Supra* note 30.

Adverse Incident Reporting

A physician must report any adverse incident that occurs in an office practice setting to DOH within 15 days after the occurrence any adverse incident.[37] An adverse incident in an office setting is defined as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[38]

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

DOH must review each adverse incident report to determine if discipline against the practitioner's license is warranted.[39]

Effect of Proposed Legislation

Office Surgery

CS/CS/HB 933 provides DOH and the Boards of Medicine and Osteopathic Medicine additional enforcement authority for physician offices that are registered to perform certain surgical procedures.

Registration

The bill retains the requirement that physician offices that perform liposuction procedures in which more than 1,000 cubic centimeters of supernatant fat is removed and Level III office surgeries[40] register with DOH. The bill expands the registration requirement to make all Level II office surgeries[41] subject to the requirement and not just those surgeries lasting more than five minutes.

The bill requires that any physician who registers to perform surgical procedures in an office setting, as well as the office, if it is a separate legal entity, to maintain financial responsibility at the same level as currently required for physicians. Currently, a physician must maintain liability coverage, an escrow account, or an irrevocable letter of credit of at least $100,000 per claim, with a minimum aggregate

[37] Sections 458.351 and 459.026, F.S.
[38] Sections 458.351(4) and 459.026(4), F.S.
[39] Sections 458.351(5) and 459.026(5), F.S.
[40] The bill defines "Level III office surgery" as any surgery in which the patient's level of sedation is that of deep sedation and analgesia, including any surgery that uses spinal anesthesia or epidural anesthesia.
[41] The bill defines "Level II office surgery" as any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation.

availability of $300,000.[42] Physicians meeting certain requirements may choose not to carry any liability coverage.

Each registered office must designate a physician who is responsible for complying with all laws and regulations for registration and operation. The designated physician must hold an active and unencumbered Florida license to practice medicine or osteopathic medicine, and must practice at the registered office.

Within 10 days after termination of the designated physician, a registered office must notify the department of the identity of a new designated physician. If a registered office does not have a designated physician, DOH may suspend its registration.

The bill requires DOH to inspect each registered office annually unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Medicine or Board of Osteopathic Medicine, respectively. The bill also authorizes such inspections to be unannounced. However, if the registered office is a pain management clinic that is wholly owned and operated by physicians where one or more physicians are trained to perform certain interventional pain procedures, then the inspection must be announced.

The bill authorizes the Boards of Medicine and Osteopathic Medicine to adopt rules on the registration, inspections, and safety of facilities in which office surgeries are performed. The bill requires the boards to adopt rules establishing the standards of practice for physicians who perform office surgery. The bill directs the boards to fine physicians who perform office surgeries in an unregistered facility $5,000 per day.

Enforcement Authority

The bill authorizes DOH to deny or revoke the registration of, or impose penalties against, a facility where office surgery is performed if its physicians, owners, or operators do not comply with board rules. The penalties DOH may impose include:[43]

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

The bill authorizes DOH to deny a person applying for a facility registration if he or she was named in the registration document of a facility whose registration is revoked for five years after the revocation date.

[42] Sections 458.320 and 459.0085, F.S. There are a number of exceptions to this requirement, including but not limited to, physicians who work exclusively for the federal or state government, those whose practice is incidental to teaching duties, and those holding an inactive license.
[43] Section 456.072(2), F.S.

The bill authorizes DOH to issue an emergency order suspending or restricting the registration of a facility if there is probable cause that:

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

The bill also adds performing office surgery in a facility that is not registered with DOH as a ground for disciplinary against a physician's license.

The bill provides that the act shall take effect July 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.004, F.S., relating to department; powers and duties.
Section 2: Amends s. 456.074, F.S., relating to certain health care practitioners; immediate suspension of license.
Section 3: Amends s. 458.305, F.S., relating to definitions.
Section 4: Amends s. 458.309, F.S., relating to rulemaking authority.
Section 5: Amends s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 6: Amends s. 459.003, F.S., relating to definitions.
Section 7: Amends s. 459.005, F.S., relating to rulemaking authority.
Section 8: Amends s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 9: Amends s. 766.101, F.S., relating to medical review committee, immunity from liability.
Section 10: Provides that the act shall take effect upon becoming.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   DOH will experience an increase in registration revenue from the physician offices that perform Level II surgeries. It is unknown how many additional registrations there will be, though the estimated additional revenue is not expected to be significant.

2. Expenditures:

   DOH will incur insignificant, recurring costs due to the expanded physician office regulation. It is estimated that existing resources and the additional registration revenue will be sufficient to cover this cost.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A physician who performs office surgery and a facility, if it is a separate legal entity, in which office surgeries are performed, must obtain and maintain liability coverage as required by the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable.

2. Other:

B. RULE-MAKING AUTHORITY:

DOH and the boards have sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 26, 2019, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Revised the definition of “health care clinic.”
- Required health care clinics who are required to register with DOH as surgery offices to comply with Boards of Medicine and Osteopathic Medicine rules.
- Directed the Agency for Health Care Administration to impose an administrative fine on anyone who operates an unregistered office where certain office surgeries are performed.
- Directed DOH to deny or revoke the registration a surgery office if any of its physicians, owners, or operators do not comply with board rules.
- Authorized DOH to deny future office surgery registration for five years to any person who has had their office surgery registration revoked.
- Authorized DOH to issue an emergency order suspending or restricting the office surgery registration under certain circumstances.
- Expanded the registration requirement to offices who perform any Level II surgery rather than just those that last more than five minutes.
- Authorized DOH to adopt rules regarding the registration, inspection, and safety of surgery offices.
- Directed the Boards of Medicine and Osteopathic Medicine to adopt standards of practice for physicians who perform office surgeries.
- Directed the Boards of Medicine and Osteopathic Medicine to fine a physician $5,000 per day if the physician performs certain procedures in an unregistered office.
- Required a physician and the surgery office itself to maintain liability coverage.
- Established the performance of certain office surgeries in an unregistered office as a ground for discipline against a physician’s license.

On April 9, 2019, the Health Care Appropriations Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment:

- Removed provisions of the bill relating to AHCA.

- Required each registered office to designate a physician who has an unencumbered Florida license to practice medicine or osteopathic medicine and who practices at the office to be responsible for complying with all laws and regulations.
- Required the office to notify DOH within 10 days if the designated physician is terminated.
- Required DOH to annually inspect each office unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Medicine or Board of Osteopathic Medicine.

The analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.