

**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 Health Regulation Committee

**BILL:** CS/SB 544

**INTRODUCER:** Health Regulation and Senator Sobel

**SUBJECT:** Health Care

**DATE:** December 7, 2011      **REVISED:** \_\_\_\_\_

|    | ANALYST   | STAFF DIRECTOR | REFERENCE | ACTION        |
|----|-----------|----------------|-----------|---------------|
| 1. | Davlantes | Stovall        | HR        | <b>Fav/CS</b> |
| 2. |           |                | BC        |               |
| 3. |           |                |           |               |
| 4. |           |                |           |               |
| 5. |           |                |           |               |
| 6. |           |                |           |               |

**Please see Section VIII. for Additional Information:**

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|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes        |
| B. AMENDMENTS.....           | <input type="checkbox"/>            | Technical amendments were recommended   |
|                              | <input type="checkbox"/>            | Amendments were recommended             |
|                              | <input type="checkbox"/>            | Significant amendments were recommended |

**I. Summary:**

The bill provides that any physician who performs liposuction procedures in which more than 1000 cubic centimeters (cc) of fat is removed must register his or her office with the Department of Health (the department), unless the office is licensed as a facility under ch. 395, F.S., (hospitals, ambulatory surgical centers, and mobile surgical facilities). Identical changes are made to the statutes concerning allopathic and osteopathic physicians.

The bill will take effect on January 3, 2013.

This bill substantially amends ss. 458.309 and 459.005, F.S.

**II. Present Situation:**

***Definitions***

According to rules<sup>1</sup> adopted for the practice of medicine and osteopathic medicine, surgery is defined as any operative procedure, including the use of lasers, performed upon the body of a

<sup>1</sup> Rule 64B8-9.009, F.A.C., relates to allopathic physicians and is materially similar to Rule 64B15-14.007, F.A.C., which concerns osteopathic physicians.

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. Only licensed physicians are allowed to perform surgery under these rules.

Office surgery is defined as surgery which is performed outside any facility licensed under ch. 390, F.S., relating to abortion clinics, or ch. 395, F.S., relating to hospitals, ambulatory surgical centers, and mobile surgical facilities. Office surgical procedures may not be of a type that generally result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; directly involve major blood vessels; or are generally emergent or life threatening in nature.<sup>2</sup>

### ***Levels of Office Surgery***

Surgical procedures are divided by rule into three different levels based on the invasiveness of the procedure and the level of anesthesia required.<sup>3</sup> Each level of surgery has its own equipment and personnel requirements. However, nothing in these designations relieves the surgeon of the responsibility for making the medical determination that the office is an appropriate forum for the particular procedures to be performed on the particular patient. Each patient's medical history and comorbid health problems must be considered individually to maximize patient safety and reduce operative complications.

Level I office surgery consists of minor procedures in which the chances of complications requiring hospitalization are remote. Such procedures include excisions or repairs of lacerations limited to the skin or subcutaneous tissue, liposuction involving removal of less than 4000 cc of fat, various endoscopic imaging procedures, closed reduction of simple fractures or dislocations, and needle drainage of certain body fluids. Only local or topical anesthesia and minimal pre-operative tranquilization of the patient is permitted. Surgeons performing Level I office surgeries are required to complete continuing medical education courses concerning regional anesthesia and are recommended to be certified in basic life support (BLS). No surgical assistants are necessary, and specific lifesaving equipment and medications are required to be on hand during the procedure.

Level II office surgery encompasses more invasive procedures which require peri-operative sedation and monitoring. Such procedures include hemorrhoid removal, hernia repair, breast biopsies, colonoscopies, and liposuction involving the removal of up to 4000 cc of fat.<sup>4</sup> The level of sedation allowed under Level II office surgery is such that the patient remains able to maintain adequate cardiorespiratory function and to respond purposefully to verbal commands or tactile stimulation. Surgeons performing Level II office surgeries must be able to document satisfactory

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<sup>2</sup> Rule 64B8-9.009(1), F.A.C. Identical provisions are found in Rule 64B15-14.007(1), F.A.C.

<sup>3</sup> Rule 64B8-9.009(3)-(6), F.A.C. Similar provisions are found in Rule 64B15-14.007(3)-(6), F.A.C.

<sup>4</sup> Liposuction involving the removal of up to 4000 cc of fat can be classified as a Level I or Level II office surgery procedure depending on the level of anesthesia used.

background, training, and experience to perform procedures under sedation and must also be trained in advanced cardiac life support (ACLS). The surgeon must be assisted by a qualified anesthesia provider<sup>5</sup> and at least one assistant<sup>6</sup> who is BLS-certified. An ACLS-certified physician, nurse, or physician assistant must be available to monitor the patient during his or her recovery from anesthesia. Specific lifesaving medications and equipment are also required to be on hand during the procedure and recovery.

Level IIA office surgeries are those Level II office surgeries with a maximum planned duration of 5 minutes or less and in which the chances of complications requiring hospitalization are remote. The same standards apply as for Level II procedures except that the assistance of a qualified anesthesia provider is not required.

Level III office surgery involves procedures which require general anesthesia. Only patients designated as Class I or II under the American Society of Anesthesiologists' (ASA) risk criteria are appropriate candidates for office surgery.<sup>7</sup> Specific pre-operative diagnostic tests and medical clearance must be obtained on ASA Class II patients older than 40. Surgeons and their assistants must demonstrate the same training, experience, and certification requirements as for Level II office surgeries, and surgeons must also have knowledge of the principles of general anesthesia. A qualified anesthesia provider is required to administer anesthesia, and a registered nurse, licensed practical nurse, physician assistant, or operating room technician must assist with the surgery. The surgical team must be familiar with emergency protocols for serious anesthesia complications, and specific lifesaving medications and equipment must be immediately available for use on the patient at all times. The same personnel needed for Level II office surgeries must be present to monitor the patient during recovery from anesthesia.

#### ***Rules and Regulations Governing Office Surgery***

Subsection 458.309(3), F.S., relating to allopathic physicians, and s. 459.005(2), F.S., relating to osteopathic physicians, require that all physicians who perform Level II procedures lasting more than 5 minutes and all Level III surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility pursuant to ch. 395, F.S. The language, which is identical in both statutes, also provides for annual inspection of such offices.

In addition to submitting a registration application, each physician who performs specified Level II and Level III surgeries in an office setting must pay the department a one-time registration fee of \$150 and an annual inspection fee of \$1500 for each practice location.<sup>8</sup> The inspection and inspection fee may be waived for offices which undergo inspections as part of the accreditation process for the American Association for Accreditation of Ambulatory Surgery

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<sup>5</sup> Qualified anesthesia providers include anesthesiologists, certified registered nurse assistants, registered nurses, or physician assistants qualified under Rule 64B8-30.012(2)(b)6. or 64B15-6.010(2)(b)6., F.A.C. An anesthesia provider may not function in any other capacity during the procedure.

<sup>6</sup> Additional assistance may only be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician.

<sup>7</sup> ASA Class I includes normal, healthy patients without any significant medical conditions. ASA Class II includes patients with a well-controlled disease of one body system and pregnant patients. ASA Classes III-VI encompass patients in increasingly severe stages of debilitation by a medical disease. (Source: ASA Physical Status Classification System, <http://www.asahq.org/clinical/physicalstatus.htm>, last visited on November 8, 2011).

<sup>8</sup> Rule 64B-4.003, F.A.C.

Facilities, the Accreditation Association for Ambulatory Health Care, or the Joint Commission on Accreditation of Healthcare Organizations.<sup>9</sup>

Each surgeon must maintain a log of all Level II and Level III surgical procedures performed, which must include certain essential data about the patient and the procedure. A policy and procedures manual as well as a risk management program must be designed, implemented, and updated annually for each surgery office. Any adverse incidents that occur within the office surgical setting must be reported to the department within 15 days.<sup>10</sup> Failure to comply with office surgery requirements may result, at the department's discretion, in probation, suspension, or revocation of office surgery registration; 50-200 hours of community service; and administrative fines of up to \$10,000.<sup>11</sup>

### ***Special Rules Relating to Liposuction***

Liposuction is classified as a Level I or Level II office surgery procedure, depending on the type of anesthesia used. In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of fat to be removed from the patient, up to a maximum of 4000 cc in the office surgical setting. Liposuction may be performed in combination with another surgical procedure during a single Level II or Level III operation if, when combined with abdominoplasty or when liposuction is associated with and directly related to another procedure, the total amount of fat removed does not exceed 1000 cc.<sup>12</sup>

Any elective or cosmetic plastic surgery procedure or combination of procedures performed in a physician's office may not last longer than 8 continuous hours, and the patient must be discharged within 24 hours of presenting to the office for surgery. If the patient has not sufficiently recovered after 24 hours has elapsed, he or she must be transferred to a hospital for continued post-operative care. For all procedures other than cosmetic surgery, the patient must be discharged from the office by midnight on the day of surgery.<sup>13</sup>

### ***Problems in South Florida***

News media has reported the deaths of several South Floridians after liposuction procedures performed by physicians without sufficient training or equipment for cosmetic surgery. Many more Floridians have been permanently disfigured or live with chronic pain as a result of botched procedures from such physicians.

Current Florida law allows any licensed physician to perform office surgery. Physicians trained in specialties as disparate as radiology and ophthalmology are performing liposuction and other cosmetic surgeries in Florida because the field is lucrative and there is little insurance or government regulation over these elective procedures. The medical industry makes a distinction between plastic surgeons (physicians who spend at least 5 years training in nationally-accredited

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<sup>9</sup> Rule 64B8-9.0091, F.A.C. Identical provisions are found in Rule 64B15-14.0076, F.A.C.

<sup>10</sup> Rule 64B8-9.009(2), F.A.C. Identical provisions are found in Rule 64B15-14.007(2), F.A.C.

<sup>11</sup> Rule 64B8-8.001(2)(rr)9., F.A.C.

<sup>12</sup> Rule 64B8-9.009(2)(e), F.A.C. Identical provisions are found in Rule 64B15-14.007(2)(e), F.A.C.

<sup>13</sup> Rule 64B8-9.009(2)(f), F.A.C. Identical provisions are found in Rule 64B15-14.007(2)(f), F.A.C.

residency programs<sup>14</sup>) and cosmetic surgeons (physicians whose training in elective surgical procedures may take place over a weekend); however, the public is not generally aware of the difference.

Furthermore, physicians performing office surgeries under local anesthesia, including many liposuction procedures, are not required to register with or have their facilities inspected by the department. Many such unregulated cosmetic surgery facilities lack the necessary equipment to deal with emergent complications of surgical procedures and anesthesia, which has led to more negative outcomes for patients.<sup>15</sup>

### III. Effect of Proposed Changes:

**Section 1** amends s. 458.309(3), F.S., to require any allopathic physician who performs liposuction procedures in which more than 1000 cc of fat is removed to register his or her office with the department unless the office is licensed as a facility under ch. 395, F.S. As a result, the office will be inspected annually by the department unless it already receives inspections through a nationally-recognized or department-approved accrediting organization.

**Section 2** amends s. 459.005(2), F.S., to require any osteopathic physician who performs liposuction procedures in which more than 1000 cc of fat is removed to register his or her office with the department unless the office is licensed as a facility under ch. 395, F.S. As a result, the office will be inspected annually by the department unless it already receives inspections through a nationally-recognized or department-approved accrediting organization.

**Section 3** provides that the bill will take effect on January 3, 2013.

### IV. Constitutional Issues:

#### A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

#### B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

#### C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

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<sup>14</sup> Washington University School of Medicine Residency Web, *Length of Residencies*, available at <http://residency.wustl.edu.beckerproxy.wustl.edu/medadmin/resweb.nsf/0ee53e934810efcd86256a94005e5f7d/3edd4e91945f8a2b86256f850071ae49?OpenDocument> (last visited on November 8, 2011).

<sup>15</sup> USA Today, *Lack of training can be deadly in cosmetic surgery*, available at <http://www.usatoday.com/money/perfi/basics/story/2011-09-13/cosmetic-surgery-investigation/50395494/1> (last visited on November 8, 2011).

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

The bill requires physicians who perform office-based liposuction procedures in which more than 1000 cc of fat is removed to register their offices with the department. These physicians will be required to pay a \$150 registration fee and either a \$1500 annual fee for inspections or another fee to become accredited and receive inspections through any of the department-approved national accrediting organizations.

**B. Private Sector Impact:**

Physicians performing certain liposuction procedures will be subject to additional fees and regulations set by the department, including fees for registration and annual inspections.

**C. Government Sector Impact:**

The department will experience a recurring increase in workload relating to registration and inspection of additional office surgery facilities. The exact fiscal impact is indeterminate as the number of physicians who currently perform liposuction procedures removing greater than 1000 cc of fat is unknown. The department will also experience non-recurring costs for rulemaking, updating the licensure database, and processing additional non-compliance complaints, which current resources are adequate to absorb.<sup>16</sup>

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. 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 Regulation on December 7, 2011:**

The CS provides changes the effective date to January 3, 2013.

**B. Amendments:**

None.

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

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<sup>16</sup> Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 544*. A copy is on file with the Senate Health Regulation Committee.