By the Committees on Fiscal Policy; and Health Policy; and Senator Garcia

594-03650-24 20241188c2

A bill to be entitled

An act relating to office surgeries; amending ss. 458.328 and 459.0138, F.S.; revising the types of procedures for which a medical office must register with the Department of Health to perform office surgeries; specifying inspection procedures for such offices seeking registration with the department; requiring that certain offices seeking registration provide proof to the department that they have met specified requirements and rules; requiring the department to inspect such offices to ensure that certain equipment and procedures are present or in place; requiring the department to notify the Agency for Health Care Administration if an applicant is unable to provide certain proof to the department and to request that the agency inspect and consult with the office; deleting obsolete language; providing that the department may not register and must seek an emergency suspension of an office under specified circumstances; requiring that each office, as a condition of registration, list certain medical personnel and thereafter notify the department of the addition or termination of such personnel within a specified timeframe; providing for disciplinary action for failure to comply; revising the materials that the department must review when inspecting a registered office; requiring offices already registered with the department as of a specified date to provide a registration update within a specified timeframe;

specifying requirements for such registration update process; revising requirements for the standards of practice for office surgeries; providing an administrative penalty; revising rulemaking requirements; creating ss. 458.3281 and 459.0139, F.S.; providing construction; defining terms; specifying general requirements for office surgeries; specifying standards of practice for office surgeries, delineated by the level of surgery being performed; providing an exemption; authorizing the Board of Medicine and the Board of Osteopathic Medicine, as applicable, to adopt additional standards of practice by rule; amending s. 456.074, F.S.; correcting a cross-reference; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 458.328, Florida Statutes, is amended to read:

458.328 Office surgeries.—

(1) REGISTRATION.—

(a)~~1.~~ An office in which a physician performs or intends to perform a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed, a liposuction procedure during which the patient is rotated between the supine, lateral, and prone positions, a Level II office surgery, or a Level III office surgery must register with the department. ~~unless the office is licensed as~~ A facility licensed under chapter 390 or chapter 395 may not be

registered under this section.

(b) ~~2.~~ The department must complete an inspection of any office seeking registration under this section before the office may be registered.

1. The inspection of the office seeking registration under this section must include inspection for compliance with the standards of practice set out in this section and s. 458.3281 and any applicable board rules for the levels of office surgery and procedures listed on the application which any physician practicing at the office performs or intends to perform. The application must be updated within 10 calendar days before any additional surgical procedures or levels of office surgery are to be performed at the office. Failure to timely update the application for any such additional surgical procedures or levels of office surgery is a violation of this section and subject to discipline under ss. 456.072 and 458.331.

2. The department must immediately suspend the registration process of an office that refuses an inspection under subparagraph 1., and the applicant must be required to reapply for registration.

3. If the department determines that an office seeking registration under this section is one in which a physician may perform, or intends to perform, liposuction procedures that include a patient being rotated between the supine, lateral, and prone positions during the procedure, or in which a physician may perform, or intends to perform, gluteal fat grafting procedures, the office must provide proof to the department that it has met the applicable requirements of s. 469 of the Florida Building Code, relating to office surgery suites, and s.

458.3281 and the applicable rules adopted thereunder, and the department must inspect the office to ensure that all of the following are present or in place:

a. Equipment and a procedure for measuring and documenting in a log the amount of supernatant fat removed, both temporarily and permanently, from a particular patient, including tissue disposal procedures.

b. A procedure for measuring and documenting the amount of lidocaine injected for tumescent liposuction, if used.

c. Working ultrasound guidance equipment or other guidance technology authorized under board rule which equals or exceeds the quality of ultrasound guidance.

d. The office procedure for obtaining blood products.

e. Documentation on file at the office demonstrating that any physician performing these procedures has privileges to perform such procedures in a hospital no more than 30 minutes away.

f. Procedures for emergency resuscitation and transport to a hospital.

g. Procedures for anesthesia and surgical recordkeeping.

h. Any additional inspection requirements, as set by board rule.

4. If an applicant is required under subparagraph 3. to provide proof to the department that the office is in compliance with the applicable requirements of s. 469 of the Florida Building Code, relating to office surgery suites, or s. 458.3281 and the applicable rules adopted thereunder, but is unable to provide such proof, the department must notify the Agency for Health Care Administration and request the agency to inspect the

office and consult with the office about the process to apply for ambulatory surgical center licensure under chapter 395 and how the office may seek qualification for such licensure, notwithstanding the office's failure to meet all requirements associated with such licensure at the time of inspection and notwithstanding any pertinent exceptions provided under s. 395.002(3).

(c) ~~(b)~~ To be ~~By January 1, 2020, each office~~ registered under this section or s. 459.0138, an office must, at the time of application, list a designated ~~designate a~~ physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the department of the designation of another physician to serve as the designated physician. The department may not register an office if the office fails to comply with this requirement at the time of application and must seek an emergency suspension of ~~suspend~~ the registration of an office pursuant to s. 456.074(6) if the office fails to timely notify the department of its new designated physician within 10 calendar days after the termination of the previous designated physician relationship ~~comply with the requirements of this paragraph~~.

(d) As a condition of registration, each office must, at the time of application, list all medical personnel who will be practicing at the office, including all of the following:

1. Physicians who intend to practice surgery or assist in surgery at the office seeking registration, including their respective license numbers and practice addresses.

2. Anesthesia providers, including their license numbers.

3. Nursing personnel licensed under chapter 464, including their license numbers unless already provided under subparagraph 2.

4. Physician assistants, including their respective license numbers and supervising physicians.

The office must notify the department of the addition or termination of any of the types of medical personnel specified under this paragraph within 10 calendar days before such addition or after such termination. Failure to timely notify the department of such addition or termination is a violation of this section and subject to discipline under ss. 456.072 and 458.331.

(e) ~~(c)~~ As a condition of registration, each office must establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320 and 459.0085. Each physician practicing at an office registered under this section or s. 459.0138 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as applicable.

(f) ~~(d)~~ Each physician practicing or intending to practice at an office registered under this section or s. 459.0138 must ~~shall~~ advise the board, in writing, within 10 calendar days before ~~after~~ beginning or after ending his or her practice at a

registered office, as applicable.

(g) ~~(e)1.~~ The department shall inspect a registered office at least annually, including a review of patient records, anesthesia logs, surgery logs, and liposuction logs, to ensure that the office is in compliance with this section and rules adopted hereunder unless the office is accredited in office-based surgery by the Joint Commission or other ~~a~~ nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of an office that meets the description of a clinic specified in s. 458.3265(1)(a)3.h., and those wholly owned and operated physician offices described in s. 458.3265(1)(a)3.g. which perform procedures referenced in s. 458.3265(1)(a)3.h., which must be announced.

(h) ~~2.~~ The department must immediately suspend the registration of a registered office that refuses an inspection under paragraph (g) ~~subparagraph 1~~. The office must close during such suspension. The suspension must remain in effect for at least 14 consecutive days and may not terminate until the department issues a written declaration that the office may reopen following the department's completion of an inspection of the office.

(i) ~~(f)~~ The department may suspend or revoke the registration of an office in which a procedure or surgery identified in paragraph (a) is performed for failure of any of its physicians, owners, or operators to comply with this section and rules adopted hereunder or s. 459.0138 and rules adopted thereunder. If an office's registration is revoked for any reason, the department may deny any person named in the

registration documents of the office, including the persons who own or operate the office, individually or as part of a group, from registering an office to perform procedures or office surgeries pursuant to this section or s. 459.0138 for 5 years after the revocation date.

(j) ~~(g)~~ The department may impose any penalty set forth in s. 456.072(2) against the designated physician for failure of the office to operate in compliance with the office health and safety requirements of this section and rules adopted hereunder or s. 459.0138 and rules adopted thereunder.

~~(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of $5,000 per day on a physician who performs a procedure or surgery in an office that is not registered with the department.~~

(k) ~~(i)~~ The actual costs of registration and inspection or accreditation must ~~shall~~ be paid by the person seeking to register and operate the office in which a procedure or surgery identified in paragraph (a) will be performed.

(2) REGISTRATION UPDATE.—

(a) An office that registered under this section before July 1, 2024, in which a physician performs liposuction procedures that include a patient being rotated between the supine, lateral, and prone positions during the procedure or in which a physician performs gluteal fat grafting procedures must provide a registration update to the department consistent with the requirements of the initial registration under subsection (1) no later than 30 days before the office surgery's next annual inspection.

(b) Registration update inspections required under subsection (1) must be performed by the department on the date of the office surgery's next annual inspection.

(c) During the registration update process, the office surgery may continue to operate under the original registration.

(d) In order to provide an office surgery time to update to the requirements of subsection (1) and s. 458.3281, effective July 1, 2024, and the applicable provisions of s. 469 of the Florida Building Code, relating to office surgery suites, any office surgery registered under this section before July 1, 2024, whose annual inspection is due in July or August 2024, may request from the department, in writing, a 60-day postponement of the required annual inspection, which postponement must be granted.

(e) All other requests to the department for a postponement of the registration update inspection required under this registration update process must be in writing and be approved by the chair of the Board of Medicine for good cause shown, and such postponement may not exceed 30 days.

(3) STANDARDS OF PRACTICE.—

(a) A physician performing a procedure or surgery in an office registered under this section must comply with the applicable provisions of s. 469 of the Florida Building Code, relating to office surgery suites, and the standards of practice for office surgery set forth in this section and s. 458.3281 and any applicable rules adopted thereunder.

(b) A physician may not perform any surgery or procedure identified in paragraph (1)(a) in a setting other than an office registered under this section or a facility licensed under

chapter 390 or chapter 395, as applicable. The board shall impose a fine of $5,000 per incident on a physician who violates this paragraph ~~performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice pursuant to this subsection and rules adopted by the board~~.

(c)~~(b)~~ Office surgeries may not:

1. Be a type of surgery that generally results in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;

2. Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

3. Involve major blood vessels and be performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or

4. Be emergent or life threatening.

(d)~~(c)~~ A physician performing a gluteal fat grafting procedure in an office surgery setting must comply with the applicable provisions of s. 469 of the Florida Building Code, relating to office surgery suites, and the standards of practice under this subsection and s. 458.3281, and applicable rules adopted thereunder, including, but not limited to, all of the following standards of practice:

1. The ~~A~~ physician performing the ~~a~~ gluteal fat grafting procedure must conduct an in-person examination of the patient while physically present in the same room as the patient no later than the day before the procedure.

2. Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide

written, informed consent for such delegation. Any duty delegated by a physician during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing such procedure. Fat extraction and gluteal fat injections must be performed by the physician and may not be delegated.

3. Fat may only be injected into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular or submuscular fat injections are prohibited.

4. When the physician performing a gluteal fat grafting procedure injects fat into the subcutaneous space of the patient, the physician must use ultrasound guidance, or guidance with other technology authorized under board rule which equals or exceeds the quality of ultrasound, during the placement and navigation of the cannula to ensure that the fat is injected into the subcutaneous space of the patient above the fascia overlying the gluteal muscle. Such guidance with the use of ultrasound or other technology is not required for other portions of such procedure.

5. An office in which a physician performs gluteal fat grafting procedures shall at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

(e)~~(d)~~ If a procedure in an office surgery setting results in hospitalization, the incident must be reported as an adverse incident pursuant to s. 458.351.

~~(e) An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.~~

(4)~~(3)~~ RULEMAKING.—

(a) The board may ~~shall~~ adopt by rule additional standards of practice for physicians who perform office procedures or ~~office~~ surgeries under ~~pursuant to~~ this section, as warranted for patient safety and by the evolution of technology and medical practice.

(b) The board may adopt rules to administer the registration, registration update, inspection, and safety of offices in which a physician performs office procedures or ~~office~~ surgeries under ~~pursuant to~~ this section.

Section 2. Section 458.3281, Florida Statutes, is created to read:

458.3281 Standard of practice for office surgery.—

(1) CONSTRUCTION.—This section does not relieve a physician performing a procedure or surgery from the responsibility of making the medical determination of whether an office is an appropriate setting in which to perform that particular

procedure or surgery, taking into consideration the particular patient on which the procedure or surgery is to be performed.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Certified in advanced cardiac life support" means a person holds a current certification in an advanced cardiac life support course with didactic and skills components, approved by the American Heart Association, the American Safety and Health Institute, the American Red Cross, Pacific Medical Training, or the Advanced Cardiovascular Life Support (ACLS) Certification Institute.

(b) "Certified in basic life support" means a person holds a current certification in a basic life support course with didactic and skills components, approved by the American Heart Association, the American Safety and Health Institute, the American Red Cross, Pacific Medical Training, or the ACLS Certification Institute.

(c) "Certified in pediatric advanced life support" means a person holds a current certification in a pediatric advanced life support course with didactic and skills components approved by the American Heart Association, the American Safety and Health Institute, or Pacific Medical Training.

(d) "Continual monitoring" means monitoring that is repeated regularly and frequently in steady, rapid succession.

(e) "Continuous" means monitoring that is prolonged without any interruption at any time.

(f) "Equipment" means a medical device, instrument, or tool used to perform specific actions or take certain measurements during, or while a patient is recovering from, a procedure or surgery which must meet current performance standards according

to its manufacturer's guidelines for the specific device, instrument, or tool, as applicable.

(g) "Major blood vessels" means a group of critical arteries and veins, including the aorta, coronary arteries, pulmonary arteries, superior and inferior vena cava, pulmonary veins, and any intra-cerebral artery or vein.

(h) "Office surgery" means a physician's office in which surgical procedures are performed by a physician for the practice of medicine as authorized by this section and board rule. The office must be an office at which a physician regularly performs consultations with surgical patients, preoperative examinations, and postoperative care, as necessitated by the standard of care related to the surgeries performed at the physician's office, and at which patient records are readily maintained and available. The types of procedures or surgeries performed in an office surgery are those which need not be performed in a facility licensed under chapter 390 or chapter 395, and are not of the type that:

1. Generally result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin count;

2. Require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures;

3. Involve major blood vessels and are performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or

4. Are generally emergent or life threatening in nature.

(i) "Pediatric patient" means a patient who is 13 years of

age or younger.

(j) "Percutaneous endovascular intervention" means a procedure performed without open direct visualization of the target vessel and which requires only needle puncture of an artery or vein followed by insertion of catheters, wires, or similar devices that are then advanced through the blood vessels using imaging guidance. Once the catheter reaches the intended location, various maneuvers to address the diseased area may be performed, including, but not limited to, injection of contrast medium for imaging; treatment of vessels with angioplasty; atherectomy; covered or uncovered stenting; embolization or intentionally occluding vessels or organs; and delivering medications or radiation or other energy, such as laser, radiofrequency, or cryo.

(k) "Reasonable proximity" means a distance that does not exceed 30 minutes of transport time to the hospital.

(l) "Surgery" means any manual or operative procedure performed upon the body of a living human being, including, but not limited to, those performed with the use of lasers, for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting a deformity or defect, prolonging life, or relieving suffering, or any elective procedure for aesthetic, reconstructive, or cosmetic purposes. The term includes, but is not limited to, incision or curettage of tissue or an organ; suture or other repair of tissue or an 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.

(3) GENERAL REQUIREMENTS FOR OFFICE SURGERY.—

(a) The physician performing the surgery must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. The physician performing the surgery 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.

(b) The physician performing the surgery shall maintain complete patient records of each surgical procedure performed, which must include all of the following:

1. The patient's name, patient number, preoperative diagnosis, postoperative diagnosis, surgical procedure, anesthetic, anesthesia records, recovery records, and complications, if any.

2. The name of each member of the surgical team, including the surgeon, first assistant, anesthesiologist, nurse anesthetist, anesthesiologist assistant, circulating nurse, and operating room technician, as applicable.

(c) Each office surgery's designated physician shall ensure that the office surgery has procedures in place to verify that all of the following have occurred before any surgery is performed:

1. The patient has signed the informed consent form for the procedure reflecting the patient's knowledge of identified risks of the procedure, consent to the procedure, the type of anesthesia and anesthesia provider to be used during the procedure, and the fact that the patient may choose the type of

anesthesia provider for the procedure, such as an anesthesiologist, a certified registered nurse anesthetist, a physician assistant, an anesthesiologist assistant, or another appropriately trained physician as provided by board rule.

2. The patient's identity has been verified.

3. The operative site has been verified.

4. The operative procedure to be performed has been verified with the patient.

5. All of the information and actions required to be verified under this paragraph are documented in the patient's medical record.

(d) With respect to the requirements set forth in paragraph (c), written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.

(e) The physician performing the surgery shall maintain a log of all liposuction procedures performed at the office surgery where more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed and where Level II and Level III surgical procedures are performed. The log must, at a minimum, include all of the following:

1. A confidential patient identifier.

2. Time of arrival in the operating suite.

3. The name of the physician performing the procedure.

4. The patient's diagnosis, CPT codes used for the procedure, the patient's classification for risk with anesthesia according to the American Society of Anesthesiologists' physical status classification system, and the type of procedure and level of surgery performed.

5. Documentation of completion of the medical clearance

performed by the anesthesiologist or the physician performing the surgery.

6. The name and provider type of the anesthesia provider and the type of anesthesia used.

7. The duration of the procedure.

8. Any adverse incidents as identified in s. 458.351.

9. The type of postoperative care, duration of recovery, disposition of the patient upon discharge, including the address of where the patient is being discharged, discharge instructions, and list of medications used during surgery and recovery.

All surgical and anesthesia logs must be kept at the office surgery and maintained for 6 years after the date of last patient contact and must be provided to department investigators upon request.

(f) For any liposuction procedure, the physician performing the surgery is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4,000 cubic centimeters of supernatant fat may be removed by liposuction in the office surgery setting. A maximum of 50mg/kg of lidocaine may be injected for tumescent liposuction in the office surgery setting.

(g)1. Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III surgical procedure only in the following circumstances:

a. When combined with an abdominoplasty, liposuction may not exceed 1,000 cubic centimeters of supernatant fat.

b. When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1,000 cubic centimeters of supernatant fat.

2. Major liposuction in excess of 1,000 cubic centimeters of supernatant fat may not be performed on a patient's body in a location that is remote from the site of another procedure being performed on that patient.

(h) For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined may not exceed 8 hours. Except for elective cosmetic and plastic surgery, the physician performing the surgery may 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 after presenting to the office for surgery. However, an overnight stay is allowed in the office if 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 must 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 postoperative care.

(i) The American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring are hereby adopted and incorporated by reference as the standards for anesthetic monitoring by any qualified anesthesia provider under this section.

1. These standards apply to general anesthetics, regional anesthetics, and monitored Level II and III anesthesia care.

However, in emergency circumstances, appropriate life support measures take priority. These standards may be exceeded at any time based on the judgment of the responsible supervising physician or anesthesiologist. While these standards are intended to encourage quality patient care, observing them does not guarantee any specific patient outcome. This set of standards addresses only the issue of basic anesthesia monitoring, which is only one component of anesthesia care.

2. In certain rare or unusual circumstances, some of these methods of monitoring may be clinically impractical, and appropriate use of the described monitoring methods may fail to detect adverse clinical developments. In such cases, a brief interruption of continual monitoring may be unavoidable and does not by itself constitute a violation of the standards of practice of this section.

3. Under extenuating circumstances, the physician performing the surgery or the anesthesiologist may waive the following requirements:

a. The use of an oxygen analyzer with a low oxygen concentration limit alarm, or other technology authorized under board rule which equals or exceeds the quality of the oxygen analyzer, during the administration of general anesthesia with an anesthesia machine.

b. The use of pulse oximetry with a variable pitch pulse tone and an audible low threshold alarm, or other technology authorized under board rule which equals or exceeds the quality of a pulse oximeter, and the use of adequate illumination and exposure of the patient to assess color.

c. The use of capnography, capnometry, or mass

spectroscopy, or other technology authorized under board rule which equals or exceeds the quality of capnography, capnometry, or mass spectroscopy, as a quantitative method of analyzing the end-tidal carbon dioxide for continual monitoring for the presence of expired carbon dioxide during ventilation, from the time of the endotracheal tube or supraglottic airway placement until extubation or removal or initiating transfer of the patient to a postoperative care location.

d. The use of continuous electrocardiogram display, or other technology authorized under board rule which equals or exceeds the quality of electrocardiogram display, from the beginning of anesthesia until preparing to leave the anesthetizing location.

e. The measuring of arterial blood pressure and heart rate evaluated at least every 5 minutes during anesthesia.

When any of the monitoring is waived for extenuating circumstances under this subparagraph, it must be documented in a note in the patient's medical record, including the reasons for the need to waive the requirement. These standards are not intended for the application to the care of an obstetrical patient in labor or in the conduct of pain management.

(j)1. Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel must be continuously present in the room to provide anesthesia care for the entire duration of all general anesthetics, regional anesthetics, and monitored anesthesia care conducted on the patient. In the event that there is a direct known hazard, such as radiation, to the anesthesia personnel which might require intermittent remote

observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthesia, the best judgment of the supervising physician or anesthesiologist shall be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthesia during the temporary absence.

2. During all anesthesia, the patient's oxygenation, ventilation, circulation, and temperature must be continually evaluated to ensure adequate oxygen concentration in the inspired gas and the blood.

a. During all general anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system must be measured by an oxygen analyzer with a low oxygen concentration limit alarm used to measure blood oxygenation.

b. During all anesthesia, a quantitative method of assessing oxygenation, such as pulse oximetry, must be employed. When a pulse oximeter is used, the variable pitch pulse tone and the low threshold alarm must be audible to the qualified anesthesia provider. Adequate illumination and exposure of the patient are necessary to assess color.

c. During all anesthesia, every patient must have the adequacy of his or her ventilation continually evaluated, including, but not limited to, the evaluation of qualitative clinical signs, such as chest excursion, observation of the reservoir breathing bag, and auscultation of breath sounds. Continual monitoring for the presence of expired carbon dioxide must be performed unless invalidated by the nature of the

patient's condition, the procedure, or the equipment. Quantitative monitoring of the volume of expired gas must also be performed.

d. When an endotracheal tube or supraglottic airway is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end-tidal carbon dioxide analysis, in use from the time of endotracheal tube or supraglottic airway placement until extubation or removal or initiating transfer of the patient to a postoperative care location, must be performed using a quantitative method, such as capnography, capnometry, or mass spectroscopy, or other technology authorized under board rule which equals or exceeds the quality of capnography, capnometry, or mass spectroscopy. When capnography or capnometry is used, the end-tidal carbon dioxide alarm must be audible to the qualified anesthesia provider.

e. When ventilation is controlled by a mechanical ventilator, there must be in continuous use a device capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

f. During regional anesthesia without sedation or local anesthesia with no sedation, the adequacy of ventilation must be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation, the adequacy of ventilation must be evaluated by continual observation of qualitative clinical signs. Monitoring for the presence of exhaled carbon dioxide is recommended.

g. Every patient receiving anesthesia must have the

electrocardiogram or other technology authorized under board rule which equals or exceeds the quality of electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.

h. Every patient receiving anesthesia must have arterial blood pressure and heart rate determined and evaluated at least every 5 minutes.

i. Every patient receiving general anesthesia must have circulatory function continually evaluated by at least one of the following methods:

(I) Palpation of a pulse.

(II) Auscultation of heart sounds.

(III) Monitoring of a tracing of intra-arterial pressure.

(IV) Ultrasound peripheral pulse monitoring.

(V) Pulse plethysmography or oximetry.

(VI) Other technology authorized under board rule which equals or exceeds the quality of any of the methods listed in sub-sub-subparagraphs (I)-(V).

j. Every patient receiving anesthesia must have his or her temperature monitored when clinically significant changes in body temperature are intended, anticipated, or suspected.

(k)1. The physician performing the surgery shall ensure that the postoperative care arrangements made for the patient are adequate for the procedure being performed, as required by board rule.

2. Management of postoperative care is the responsibility of the physician performing the surgery and may be delegated as determined by board rule. If the physician performing the surgery is unavailable to provide postoperative care, the

physician performing the surgery must notify the patient of his or her unavailability for postoperative care before the procedure.

3. If there is an overnight stay at the office in relation to any surgical procedure:

a. The office must provide at least two persons to act as monitors, one of whom must be certified in advanced cardiac life support, and maintain a monitor-to-patient ratio of at least one monitor to two patients.

b. Once the physician performing the surgery has signed a timed and dated discharge order, the office may provide only one monitor to monitor the patient. The monitor must be qualified by licensure and training to administer all of the medications required on the crash cart and must be certified in advanced cardiac life support.

c. A complete and current crash cart must be present in the office surgery and immediately accessible for the monitors.

4. The physician performing the surgery must be reachable by telephone and readily available to return to the office if needed.

5. A policy and procedures manual must be maintained in the office at which Level II and Level III procedures are performed. The manual must be updated and implemented annually. The policy and procedures manual must provide for all of the following:

a. Duties and responsibilities of all personnel.

b. A quality assessment and improvement system designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and opportunities to improve performance.

c. Cleaning procedures and protocols.

d. Sterilization procedures.

e. Infection control procedures and personnel responsibilities.

f. Emergency procedures.

6. The designated physician shall establish a risk management program that includes all of the following components:

a. The identification, investigation, and analysis of the frequency and causes of adverse incidents.

b. The identification of trends or patterns of adverse incidents.

c. The development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents.

d. The documentation of such functions and periodic review of such information at least quarterly by the designated physician.

7. The designated physician shall report to the department any adverse incidents that occur within the scope of office surgeries. This report must be made within 15 days after the occurrence of an incident as required by s. 458.351.

8. The designated physician is responsible for prominently posting a sign in the office which states that the office is a doctor’s office regulated under this section and ss. 458.328, 458.3281, and 459.0138 and the applicable rules of the Board of Medicine and the Board of Osteopathic Medicine as set forth in rules 64B8 and 64B15, Florida Administrative Code. This notice must also appear prominently within the required patient informed consent form.

9. All physicians performing surgery at the office surgery must be qualified by education, training, and experience to perform any procedure the physician performs in the office surgery.

10. When Level II, Level II-A, or Level III procedures are performed in an office surgery setting, the physician performing the surgery is responsible for providing the patient, in writing, before the procedure, with the name and location of the hospital where the physician performing the surgery has privileges to perform the same procedure as the one being performed in the office surgery setting or the name and location of the hospital with which the physician performing the surgery has a transfer agreement in the event of an emergency.

(4) LEVEL I OFFICE SURGERY.—

(a) *Scope.*—Level I office surgery includes the following:

1. Minor procedures such as excision of skin lesions, moles, warts, cysts, or lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue which are performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient.

2. Liposuction involving the removal of less than 4,000 cubic centimeters of supernatant fat.

3. Incision and drainage of superficial abscesses; limited endoscopies, such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of the urethra, cystoscopic procedures, and closed reduction of simple fractures; or small joint dislocations, such as in the finger or toe joints.

4. Procedures in which anesthesia is limited to minimal sedation. The patient's level of sedation must be that of minimal sedation and anxiolysis, and the chances of complications requiring hospitalization must be remote. As used in this sub-subparagraph, the term "minimal sedation and anxiolysis" means a drug-induced state during which patients respond normally to verbal commands, and although cognitive function and physical coordination may be impaired, airway reflexes and ventilatory and cardiovascular functions remain unaffected. Controlled substances, as defined in ss. 893.02 and 893.03, must be limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.

5. Procedures for which chances of complications requiring hospitalization are remote as specified in board rule.

(b) *Standards of practice.*—Standards of practice for Level I office surgery include all of the following:

1. The medical education, training, and experience of the physician performing the surgery must include training on proper dosages and management of toxicity or hypersensitivity to regional anesthetic drugs, and the physician must be certified in advanced cardiac life support.

2. At least one operating assistant must be certified in basic life support.

3. Intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device must be available in the office surgery, along with the following medications, stored per the manufacturer's recommendation:

a. Atropine, 3 mg.

b. Diphenhydramine, 50 mg.

c. Epinephrine, 1 mg in 10 ml.

d. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

e. Hydrocortisone, 100 mg.

f. If a benzodiazepine is administered, flumazenil, 0.5 mg in 5 ml vial, 2 vials total.

g. If an opiate is administered, naloxone, 0.4 mg in 1 ml vial, 2 vials total.

4. When performing minor procedures, such as excision of skin lesions, moles, warts, cysts, or lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia in an office surgery setting, physicians performing the procedure are exempt from subparagraphs 1.-3. Current certification in basic life support is recommended but not required.

5. A physician performing the surgery need not have an assistant during the procedure unless the specific procedure being performed requires an assistant.

(5) LEVEL II OFFICE SURGERY.—

(a) *Scope.*—Level II office surgery includes, but is not limited to, all of the following procedures:

1. Hemorrhoidectomy.

2. Hernia repair.

3. Large joint dislocations.

4. Colonoscopy.

5. Liposuction involving the removal of up to 4,000 cubic centimeters of supernatant fat.

6. Any other procedure the board designates by rule as a Level II office surgery.

7. Surgeries in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. As used in this subparagraph, the term "moderate sedation and analgesia or conscious sedation" is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation; interventions are not required to maintain a patent airway; spontaneous ventilation is adequate; and cardiovascular function is maintained. For purposes of this term, reflex withdrawal from a painful stimulus is not considered a purposeful response.

(b) *Standards of practice.*—Standards of practice for Level II office surgery include, but are not limited to, the following:

1. The physician performing the surgery, or the office 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 office surgery setting at a licensed hospital within reasonable proximity. The transfer agreement required by this section must be current and have been entered into no more than 5 years before the date of the office's most recent annual inspection under s. 458.328. A transfer agreement must affirmatively disclose an effective date and a termination date.

2. The physician performing the surgery must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office surgery setting or must be able to document satisfactory completion of

training, such as board certification or board eligibility by a board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or Board of Osteopathic Medicine, as applicable, or must be able to establish comparable background, training, and experience. Such board certification or comparable background, training, and experience must also be directly related to and include the procedures being performed by the physician in the office surgery facility.

3. One assistant must be currently certified in basic life support.

4. The physician performing the surgery must be currently certified in advanced cardiac life support.

5. A complete and current crash cart must be available at all times at the location where the anesthesia is being administered. The designated physician of an office surgery is responsible for ensuring that the crash cart is replenished after each use, the expiration dates for the crash cart's medications are checked weekly, and crash cart events are documented in the cart's logs. Medicines must be stored per the manufacturer's recommendations, and multidose vials must be dated once opened and checked daily for expiration. The crash cart must, at a minimum, include the following intravenous or inhaled medications:

a. Adenosine, 18 mg.

b. Albuterol, 2.5 mg with a small volume nebulizer.

c. Amiodarone, 300 mg.

d. Atropine, 3 mg.

e. Calcium chloride, 1 gram.

f. Dextrose, 50 percent; 50 ml.

g. Diphenhydramine, 50 mg.

h. Dopamine, 200 mg, minimum.

i. Epinephrine, 1 mg, in 10 ml.

j. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

k. Flumazenil, 1 mg.

l. Furosemide, 40 mg.

m. Hydrocortisone, 100 mg.

n. Lidocaine appropriate for cardiac administration, 100 mg.

o. Magnesium sulfate, 2 grams.

p. Naloxone, 1.2 mg.

q. A beta blocker class drug.

r. Sodium bicarbonate, 50 mEq/50 ml.

s. Paralytic agent that is appropriate for use in rapid sequence intubation.

t. A calcium channel blocker class drug.

u. If nonneuraxial regional blocks are performed, Intralipid, 20 percent, 500 ml solution.

v. Any additional medication the board determines by rule is warranted for patient safety and by the evolution of technology and medical practice.

6. In the event of a drug shortage, the designated physician is authorized to substitute a therapeutically equivalent drug that meets the prevailing practice standards.

7. The designated physician is responsible for ensuring that the office maintains documentation of its unsuccessful efforts to obtain the required drug.

8. The designated physician is responsible for ensuring

that the following are present in the office surgery:

a. A benzodiazepine.

b. A positive pressure ventilation device, such as Ambu, plus oxygen supply.

c. An end-tidal carbon dioxide detection device.

d. Monitors for blood pressure, electrocardiography, and oxygen saturation.

e. Emergency intubation equipment that must, at a minimum, include suction devices, endotracheal tubes, working laryngoscopes, oropharyngeal airways, nasopharyngeal airways, and bag valve mask apparatus that are sized appropriately for the specific patient.

f. A working defibrillator with defibrillator pads or defibrillator gel, or an automated external defibrillator unit.

g. Sufficient backup power to allow the physician performing the surgery to safely terminate the procedure and to allow the patient to emerge from the anesthetic, all without compromising the sterility of the procedure or the environment of care.

h. Working sterilization equipment cultured weekly.

i. Sufficient intravenous solutions and equipment for a minimum of a week’s worth of surgical cases.

j. Any other equipment required by board rule, as warranted by the evolution of technology and medical practice.

9. The physician performing the surgery must be assisted by a qualified anesthesia provider, which may include any of the following types of providers:

a. An anesthesiologist.

b. A certified registered nurse anesthetist.

c. A registered nurse, if the physician performing the surgery is certified in advanced cardiac life support and the registered nurse assists only with local anesthesia or conscious sedation.

An anesthesiologist assistant may assist the anesthesiologist as provided by board rule. An assisting anesthesia provider may not function in any other capacity during the procedure.

10. If additional anesthesia assistance is required by the specific procedure or patient circumstances, such assistance must be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician.

11. The designated physician is responsible for ensuring that each patient is monitored in the recovery room until the patient is fully recovered from anesthesia. Such monitoring must be provided by a licensed physician, physician assistant, registered nurse with postanesthesia care unit experience, or the equivalent who is currently certified in advanced cardiac life support, or, in the case of pediatric patients, currently certified in pediatric advanced life support.

(6) LEVEL II-A OFFICE SURGERY.—

(a) *Scope.*—Level II-A office surgeries are those Level II office surgeries that have a maximum planned duration of 5 minutes or less and in which the chances of complications requiring hospitalization are remote.

(b) *Standards of practice.*—

1. All practice standards for Level II office surgery set forth in paragraph (5)(b) must be met for Level II-A office

surgery except for the requirements set forth in subparagraph (5)(b)9. regarding assistance by a qualified anesthesia provider.

2. During the surgical procedure, the physician performing the surgery must be assisted by a licensed physician, physician assistant, registered nurse, or licensed practical nurse.

3. Additional assistance may be required by specific procedure or patient circumstances.

4. Following the procedure, a licensed physician, physician assistant, or registered nurse must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitoring provider must be currently certified in advanced cardiac life support, or, in the case of pediatric patients, currently certified in pediatric advanced life support.

(7) LEVEL III OFFICE SURGERY.—

(a) *Scope.*—

1. Level III office surgery includes those types of surgery during which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. As used in this subparagraph, the term:

a. "Deep sedation and analgesia" means a drug-induced depression of consciousness during which:

(I) Patients cannot be easily aroused but respond purposefully following repeated or painful stimulation;

(II) The ability to independently maintain ventilatory function may be impaired;

(III) Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and

(IV) Cardiovascular function is usually maintained.

For purposes of this sub-subparagraph, reflex withdrawal from a painful stimulus is not considered a purposeful response.

b. "General anesthesia" means a drug-induced loss of consciousness during which:

(I) Patients are not arousable, even by painful stimulation;

(II) The ability to independently maintain ventilatory function is often impaired;

(III) 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; and

(IV) Cardiovascular function may be impaired.

2. The use of spinal or epidural anesthesia for a procedure requires that the procedure be considered a Level III office surgery.

3. Only patients classified under the American Society of Anesthesiologists' (ASA) risk classification criteria as Class I or Class II are appropriate candidates for a Level III office surgery.

a. All Level III office surgeries on patients classified as ASA III or higher must be performed only in a hospital or ambulatory surgical center.

b. For all ASA II patients above the age of 50, the physician performing the surgery must obtain a complete workup performed before the performance of a Level III office surgery in the office surgery setting.

c. If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative electrocardiogram and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.

(b) *Standards of practice.*—Practice standards for Level III office surgery include all Level II office surgery standards and all of the following requirements:

1. The physician performing the surgery must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office surgery 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 Board of Osteopathic Medicine, as applicable, 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 being performed by the physician performing the surgery in the office surgery setting. In addition, the physician performing the surgery must have knowledge of the principles of general anesthesia.

2. The physician performing the surgery must be currently certified in advanced cardiac life support.

3. At least one operating assistant must be currently certified in basic life support.

4. An emergency policy and procedures manual related to serious anesthesia complications must be available in the office surgery and reviewed biannually by the designated physician, practiced with staff, updated, and posted in a conspicuous location in the office. Topics to be covered in the manual must include all of the following:

a. Airway blockage and foreign body obstruction.

b. Allergic reactions.

c. Bradycardia.

d. Bronchospasm.

e. Cardiac arrest.

f. Chest pain.

g. Hypoglycemia.

h. Hypotension.

i. Hypoventilation.

j. Laryngospasm.

k. Local anesthetic toxicity reaction.

l. Malignant hyperthermia.

m. Any other topics the board determines by rule are warranted for patient safety and by the evolution of technology and medical practice.

5. An office surgery performing Level III office surgeries must maintain all of the equipment and medications required for Level II office surgeries and comply with all of the following additional requirements:

a. Maintain at least 720 mg of dantrolene on site if halogenated anesthetics or succinylcholine are used.

b. Equipment and medication for monitored postanesthesia recovery must be available in the office.

6. Anesthetic safety regulations must be developed, posted in a conspicuous location in the office, and enforced by the designated physician. Such regulations must include all of the following requirements:

a. All operating room electrical and anesthesia equipment must be inspected at least semiannually, and a written record of the results and corrective actions must be maintained.

b. Flammable anesthetic agents may not be employed in office surgery facilities.

c. Electrical equipment in anesthetizing areas must be on an audiovisual line isolation monitor, with the exception of radiologic equipment and fixed lighting more than 5 feet above the floor.

d. Each anesthesia gas machine must have a pin index safety system or equivalent safety system and a minimum oxygen flow safety device.

e. All reusable anesthesia equipment in direct contact with a patient must be cleaned or sterilized as appropriate after each use.

f. The following monitors must be applied to all patients receiving conduction or general anesthesia:

(I) Blood pressure cuff.

(II) A continuous temperature device, readily available to measure the patient’s temperature.

(III) Pulse oximeter.

(IV) Electrocardiogram.

(V) An inspired oxygen concentration monitor and a capnograph, for patients receiving general anesthesia.

g. Emergency intubation equipment must be available in all

office surgery suites.

h. Surgical tables must be capable of Trendelenburg and other positions necessary to facilitate surgical procedures.

i. An anesthesiologist, a certified registered nurse anesthetist, an anesthesiologist assistant, or a physician assistant qualified as set forth in board rule must administer the general or regional anesthesia.

j. A physician, a registered nurse, a licensed practical nurse, a physician assistant, or an operating room technician must assist with the surgery. The anesthesia provider may not function in any other capacity during the procedure.

k. The patient must be monitored in the recovery room until he or she has fully recovered from anesthesia. The monitoring must be provided by a physician, a physician assistant, a certified registered nurse anesthetist, an anesthesiologist assistant, or a registered nurse with postanesthesia care unit experience or the equivalent who is currently certified in advanced cardiac life support, or, in the case of pediatric patients, currently certified in pediatric advanced life support.

(8) EXEMPTION.—This section does not apply to a physician who is dually licensed as a dentist under chapter 466 when he or she is performing dental procedures that fall within the scope of practice of dentistry and are regulated under chapter 466.

(9) RULEMAKING.—The board may adopt by rule additional standards of practice for physicians who perform office surgeries or procedures under this section as warranted for patient safety and by the evolution of technology and medical practice.

Section 3. Section 459.0138, Florida Statutes, is amended to read:

459.0138 Office surgeries.—

(1) REGISTRATION.—

(a)~~1.~~ An office in which a physician performs or intends to perform a liposuction procedure in which more than 1,000 cubic centimeters of supernatant fat is temporarily or permanently removed, a liposuction procedure during which the patient is rotated between the supine, lateral, and prone positions, a Level II office surgery, or a Level III office surgery must register with the department. ~~unless the office is licensed as~~ A facility licensed under chapter 390 or chapter 395 may not be registered under this section.

(b)~~2.~~ The department must complete an inspection of any office seeking registration under this section before the office may be registered.

1. The inspection of the office seeking registration under this section must include inspection for compliance with the standards of practice set out in this section and s. 458.3281 and any applicable board rules for the levels of office surgery and procedures listed on the application which any physician practicing at the office performs or intends to perform. The application must be updated within 10 calendar days before any additional surgical procedures or levels of office surgery are to be performed at the office. Failure to timely update the application for any such additional surgical procedures or levels of office surgery is a violation of this section and subject to discipline under ss. 456.072 and 459.015.

2. The department must immediately suspend the registration

process of an office that refuses an inspection under subparagraph 1., and the applicant must be required to reapply for registration.

3. If the department determines that an office seeking registration under this section is one in which a physician may perform, or intends to perform, liposuction procedures that include a patient being rotated between the supine, lateral, and prone positions during the procedure, or in which a physician may perform, or intends to perform, gluteal fat grafting procedures, the office must provide proof to the department that it has met the applicable requirements of s. 469 of the Florida Building Code, relating to office surgery suites, and s. 458.3281 and the applicable rules adopted thereunder, and the department must inspect the office to ensure that all of the following are present or in place:

a. Equipment and a procedure for measuring and documenting in a log the amount of supernatant fat removed, both temporarily and permanently, from a particular patient, including tissue disposal procedures.

b. A procedure for measuring and documenting the amount of lidocaine injected for tumescent liposuction, if used.

c. Working ultrasound guidance equipment or other guidance technology authorized under board rule which equals or exceeds the quality of ultrasound guidance.

d. The office procedure for obtaining blood products.

e. Documentation on file at the office demonstrating that any physician performing these procedures has privileges to perform such procedures in a hospital no more than 30 minutes away.

f. Procedures for emergency resuscitation and transport to a hospital.

g. Procedures for anesthesia and surgical recordkeeping.

h. Any additional inspection requirements, as set by board rule.

4. If an applicant is required under subparagraph 3. to provide proof to the department that the office is in compliance with the applicable requirements of s. 469 of the Florida Building Code, relating to office surgery suites, or s. 458.3281 and the applicable rules adopted thereunder, but is unable to provide such proof, the department must notify the Agency for Health Care Administration and request the agency to inspect the office and consult with the office about the process to apply for ambulatory surgical center licensure under chapter 395 and how the office may seek qualification for such licensure, notwithstanding the office's failure to meet all requirements associated with such licensure at the time of inspection and notwithstanding any pertinent exceptions provided under s. 395.002(3).

(c) ~~(b)~~ To be ~~By January 1, 2020, each office~~ registered under this section or s. 458.328, an office must, at the time of application, list a designated ~~designate a~~ physician who is responsible for the office's compliance with the office health and safety requirements of this section and rules adopted hereunder. A designated physician must have a full, active, and unencumbered license under this chapter or chapter 458 and shall practice at the office for which he or she has assumed responsibility. Within 10 calendar days after the termination of a designated physician relationship, the office must notify the

department of the designation of another physician to serve as the designated physician. The department may not register an office if the office fails to comply with this requirement at the time of application and must seek an emergency suspension of the ~~suspend a~~ registration of ~~for~~ an office pursuant to s. 456.074(6) if the office fails to timely notify the department of its new designated physician within 10 calendar days after the termination of the previous designated physician relationship ~~comply with the requirements of this paragraph~~.

(d) As a condition of registration, each office must, at the time of application, list all medical personnel who will be practicing at the office, including all of the following:

1. Physicians who intend to practice surgery or assist in surgery at the office seeking registration, including their respective license numbers and practice addresses.

2. Anesthesia providers, including their license numbers.

3. Nursing personnel licensed under chapter 464, including their license numbers unless already provided under subparagraph 2.

4. Physician assistants, including their respective license numbers and supervising physicians.

The office must notify the department of the addition or termination of any of the types of medical personnel specified under this paragraph within 10 calendar days before such addition or after such termination. Failure to timely notify the department of such addition or termination is a violation of this section and subject to discipline under ss. 456.072 and 459.015.

(e)~~(c)~~ As a condition of registration, each office must establish financial responsibility by demonstrating that it has met and continues to maintain, at a minimum, the same requirements applicable to physicians in ss. 458.320 and 459.0085. Each physician practicing at an office registered under this section or s. 458.328 must meet the financial responsibility requirements under s. 458.320 or s. 459.0085, as applicable.

(f)~~(d)~~ Each physician practicing or intending to practice at an office registered under this section or s. 458.328 must ~~shall~~ advise the board, in writing, within 10 calendar days before ~~after~~ beginning or after ending his or her practice at a ~~the~~ registered office, as applicable.

(g)~~(e)1.~~ The department shall inspect a registered office at least annually, including a review of patient records, anesthesia logs, surgery logs, and liposuction logs, to ensure that the office is in compliance with this section and rules adopted hereunder unless the office is accredited in office-based surgery by the Joint Commission or other ~~a~~ nationally recognized accrediting agency approved by the board. The inspection may be unannounced, except for the inspection of an office that meets the description of a clinic specified in s. 459.0137(1)(a)3.h., and those wholly owned and operated physician offices described in s. 459.0137(1)(a)3.g. which perform procedures referenced in s. 459.0137(1)(a)3.h., which must be announced.

(h)~~2.~~ The department must immediately suspend the registration of a registered office that refuses an inspection under paragraph (g) ~~subparagraph 1~~. The office must close during

such suspension. The suspension must remain in effect for at least 14 consecutive days and may not terminate until the department issues a written declaration that the office may reopen following the department's completion of an inspection of the office.

(i) ~~(f)~~ The department may suspend or revoke the registration of an office in which a procedure or surgery identified in paragraph (a) is performed for failure of any of its physicians, owners, or operators to comply with this section and rules adopted hereunder or s. 458.328 and rules adopted thereunder. If an office's registration is revoked for any reason, the department may deny any person named in the registration documents of the office, including the persons who own or operate the office, individually or as part of a group, from registering an office to perform procedures or office surgeries pursuant to this section or s. 458.328 for 5 years after the revocation date.

(j) ~~(g)~~ The department may impose any penalty set forth in s. 456.072(2) against the designated physician for failure of the office to operate in compliance with the office health and safety requirements of this section and rules adopted hereunder or s. 458.328 and rules adopted thereunder.

~~(h) A physician may only perform a procedure or surgery identified in paragraph (a) in an office that is registered with the department. The board shall impose a fine of $5,000 per day on a physician who performs a procedure or surgery in an office that is not registered with the department.~~

(k) ~~(i)~~ The actual costs of registration and inspection or accreditation must ~~shall~~ be paid by the person seeking to

register and operate the office in which a procedure or surgery identified in paragraph (a) will be performed.

(2) REGISTRATION UPDATE.—

(a) An office that registered under this section before July 1, 2024, in which a physician performs liposuction procedures that include a patient being rotated between the supine, lateral, and prone positions during the procedure or in which a physician performs gluteal fat grafting procedures must provide a registration update to the department consistent with the requirements of the initial registration under subsection (1) no later than 30 days before the office surgery's next annual inspection.

(b) Registration update inspections required under subsection (1) must be performed by the department on the date of the office surgery's next annual inspection.

(c) During the registration update process, the office surgery may continue to operate under the original registration.

(d) In order to provide an office surgery time to update to the requirements of subsection (1) and s. 459.0139, effective July 1, 2024, and the applicable provisions of s. 469 of the Florida Building Code, relating to office surgery suites, any office surgery registered under this section before July 1, 2024, whose annual inspection is due in July or August 2024, may request from the department, in writing, a 60-day postponement of the required annual inspection, which postponement must be granted.

(e) All other requests to the department for a postponement of the registration update inspection required under this registration update process must be in writing and be approved

by the chair of the Board of Medicine for good cause shown, and such postponement may not exceed 30 days.

(3) STANDARDS OF PRACTICE.—

(a) A physician performing a procedure or surgery in an office registered under this section must comply with the applicable provisions of s. 469 of the Florida Building Code, relating to office surgery suites, and the standards of practice for office surgery set forth in this section and s. 459.0139 and any applicable rules adopted thereunder.

(b) A physician may not perform any surgery or procedure identified in paragraph (1)(a) in a setting other than an office registered under this section or a facility licensed under chapter 390 or chapter 395, as applicable. The board shall impose a fine of $5,000 per incident on a physician who violates this paragraph ~~performing a gluteal fat grafting procedure in an office surgery setting shall adhere to standards of practice pursuant to this subsection and rules adopted by the board~~.

(c) ~~(b)~~ Office surgeries may not:

1. Be a type of surgery that generally results in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin level;

2. Require major or prolonged intracranial, intrathoracic, abdominal, or joint replacement procedures, except for laparoscopic procedures;

3. Involve major blood vessels and be performed with direct visualization by open exposure of the major blood vessel, except for percutaneous endovascular intervention; or

4. Be emergent or life threatening.

(d) ~~(c)~~ A physician performing a gluteal fat grafting

procedure in an office surgery setting must comply with the applicable provisions of s. 469 of the Florida Building Code, relating to office surgery suites, and the standards of practice under this subsection and s. 459.0139 and applicable rules adopted thereunder, including, but not limited to, all of the following standards of practice:

1. The ~~A~~ physician performing the ~~a~~ gluteal fat grafting procedure must conduct an in-person examination of the patient while physically present in the same room as the patient no later than the day before the procedure.

2. Before a physician may delegate any duties during a gluteal fat grafting procedure, the patient must provide written, informed consent for such delegation. Any duty delegated by a physician during a gluteal fat grafting procedure must be performed under the direct supervision of the physician performing such procedure. Fat extraction and gluteal fat injections must be performed by the physician and may not be delegated.

3. Fat may only be injected into the subcutaneous space of the patient and may not cross the fascia overlying the gluteal muscle. Intramuscular or submuscular fat injections are prohibited.

4. When the physician performing a gluteal fat grafting procedure injects fat into the subcutaneous space of the patient, the physician must use ultrasound guidance, or guidance with other technology authorized under board rule which equals or exceeds the quality of ultrasound, during the placement and navigation of the cannula to ensure that the fat is injected into the subcutaneous space of the patient above the fascia

overlying the gluteal muscle. Such guidance with the use of ultrasound or other technology is not required for other portions of such procedure.

5. An office in which a physician performs gluteal fat grafting procedures shall at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.

(e) ~~(d)~~ If a procedure in an office surgery setting results in hospitalization, the incident must be reported as an adverse incident pursuant to s. 458.351.

~~(c) An office in which a physician performs gluteal fat grafting procedures must at all times maintain a ratio of one physician to one patient during all phases of the procedure, beginning with the administration of anesthesia to the patient and concluding with the extubation of the patient. After a physician has commenced, and while he or she is engaged in, a gluteal fat grafting procedure, the physician may not commence or engage in another gluteal fat grafting procedure or any other procedure with another patient at the same time.~~

(4) ~~(3)~~ RULEMAKING.—

(a) The board may ~~shall~~ adopt by rule additional standards of practice for physicians who perform office procedures or ~~office~~ surgeries under ~~pursuant to~~ this section, as warranted for patient safety and by the evolution of technology and

medical practice.

(b) The board may adopt rules to administer the registration, registration update, inspection, and safety of offices in which a physician performs office procedures or ~~office~~ surgeries under ~~pursuant to~~ this section.

Section 4. Section 459.0139, Florida Statutes, is created to read:

459.0139 Standard of practice for office surgery.—

(1) CONSTRUCTION.—This section does not relieve a physician performing a procedure or surgery from the responsibility of making the medical determination of whether an office is an appropriate setting in which to perform that particular procedure or surgery, taking into consideration the particular patient on which the procedure or surgery is to be performed.

(2) DEFINITIONS.—As used in this section, the term:

(a) "Certified in advanced cardiac life support" means a person holds a current certification in an advanced cardiac life support course with didactic and skills components, approved by the American Heart Association, the American Safety and Health Institute, the American Red Cross, Pacific Medical Training, or the Advanced Cardiovascular Life Support (ACLS) Certification Institute.

(b) "Certified in basic life support" means a person holds a current certification in a basic life support course with didactic and skills components, approved by the American Heart Association, the American Safety and Health Institute, the American Red Cross, Pacific Medical Training, or the ACLS Certification Institute.

(c) "Certified in pediatric advanced life support" means a

person holds a current certification in a pediatric advanced life support course with didactic and skills components approved by the American Heart Association, the American Safety and Health Institute, or Pacific Medical Training.

(d) "Continual monitoring" means monitoring that is repeated regularly and frequently in steady, rapid succession.

(e) "Continuous" means monitoring that is prolonged without any interruption at any time.

(f) "Equipment" means a medical device, instrument, or tool used to perform specific actions or take certain measurements during, or while a patient is recovering from, a procedure or surgery which must meet current performance standards according to its manufacturer's guidelines for the specific device, instrument, or tool, as applicable.

(g) "Major blood vessels" means a group of critical arteries and veins, including the aorta, coronary arteries, pulmonary arteries, superior and inferior vena cava, pulmonary veins, and any intra-cerebral artery or vein.

(h) "Office surgery" means a physician's office in which surgical procedures are performed by a physician for the practice of medicine as authorized by this section and board rule. The office must be an office at which a physician regularly performs consultations with surgical patients, preoperative examinations, and postoperative care, as necessitated by the standard of care related to the surgeries performed at the physician's office, and at which patient records are readily maintained and available. The types of procedures or surgeries performed in an office surgery are those which need not be performed in a facility licensed under chapter

390 or chapter 395, and are not of the type that:

1. Generally result in blood loss of more than 10 percent of estimated blood volume in a patient with a normal hemoglobin count;

2. Require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures;

3. Involve major blood vessels and are performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or

4. Are generally emergent or life threatening in nature.

(i) "Pediatric patient" means a patient who is 13 years of age or younger.

(j) "Percutaneous endovascular intervention" means a procedure performed without open direct visualization of the target vessel and which requires only needle puncture of an artery or vein followed by insertion of catheters, wires, or similar devices that are then advanced through the blood vessels using imaging guidance. Once the catheter reaches the intended location, various maneuvers to address the diseased area may be performed, including, but not limited to, injection of contrast medium for imaging; treatment of vessels with angioplasty; atherectomy; covered or uncovered stenting; embolization or intentionally occluding vessels or organs; and delivering medications or radiation or other energy, such as laser, radiofrequency, or cryo.

(k) "Reasonable proximity" means a distance that does not exceed 30 minutes of transport time to the hospital.

(l) "Surgery" means any manual or operative procedure

performed upon the body of a living human being, including, but not limited to, those performed with the use of lasers, for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting a deformity or defect, prolonging life, or relieving suffering, or any elective procedure for aesthetic, reconstructive, or cosmetic purposes. The term includes, but is not limited to, incision or curettage of tissue or an organ; suture or other repair of tissue or an 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.

(3) GENERAL REQUIREMENTS FOR OFFICE SURGERY.—

(a) The physician performing the surgery must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. The physician performing the surgery 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.

(b) The physician performing the surgery shall maintain complete patient records of each surgical procedure performed, which must include all of the following:

1. The patient's name, patient number, preoperative diagnosis, postoperative diagnosis, surgical procedure, anesthetic, anesthesia records, recovery records, and complications, if any.

2. The name of each member of the surgical team, including

the surgeon, first assistant, anesthesiologist, nurse anesthetist, anesthesiologist assistant, circulating nurse, and operating room technician, as applicable.

(c) Each office surgery's designated physician shall ensure that the office surgery has procedures in place to verify that all of the following have occurred before any surgery is performed:

1. The patient has signed the informed consent form for the procedure reflecting the patient's knowledge of identified risks of the procedure, consent to the procedure, the type of anesthesia and anesthesia provider to be used during the procedure, and the fact that the patient may choose the type of anesthesia provider for the procedure, such as an anesthesiologist, a certified registered nurse anesthetist, a physician assistant, an anesthesiologist assistant, or another appropriately trained physician as provided by board rule.

2. The patient's identity has been verified.

3. The operative site has been verified.

4. The operative procedure to be performed has been verified with the patient.

5. All of the information and actions required to be verified under this paragraph are documented in the patient's medical record.

(d) With respect to the requirements set forth in paragraph (c), written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.

(e) The physician performing the surgery shall maintain a log of all liposuction procedures performed at the office surgery where more than 1,000 cubic centimeters of supernatant

fat is temporarily or permanently removed and where Level II and Level III surgical procedures are performed. The log must, at a minimum, include all of the following:

1. A confidential patient identifier.

2. Time of arrival in the operating suite.

3. The name of the physician performing the procedure.

4. The patient's diagnosis, CPT codes used for the procedure, the patient's classification for risk with anesthesia according to the American Society of Anesthesiologists' physical status classification system, and the type of procedure and level of surgery performed.

5. Documentation of completion of the medical clearance performed by the anesthesiologist or the physician performing the surgery.

6. The name and provider type of the anesthesia provider and the type of anesthesia used.

7. The duration of the procedure.

8. Any adverse incidents as identified in s. 458.351.

9. The type of postoperative care, duration of recovery, disposition of the patient upon discharge, including the address of where the patient is being discharged, discharge instructions, and list of medications used during surgery and recovery.

All surgical and anesthesia logs must be kept at the office surgery and maintained for 6 years after the date of last patient contact and must be provided to department investigators upon request.

(f) For any liposuction procedure, the physician performing

the surgery is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4,000 cubic centimeters of supernatant fat may be removed by liposuction in the office surgery setting. A maximum of 50mg/kg of lidocaine may be injected for tumescent liposuction in the office surgery setting.

(g)1. Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III surgical procedure only in the following circumstances:

a. When combined with an abdominoplasty, liposuction may not exceed 1,000 cubic centimeters of supernatant fat.

b. When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1,000 cubic centimeters of supernatant fat.

2. Major liposuction in excess of 1,000 cubic centimeters of supernatant fat may not be performed on a patient's body in a location that is remote from the site of another procedure being performed on that patient.

(h) For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined may not exceed 8 hours. Except for elective cosmetic and plastic surgery, the physician performing the surgery may 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 after presenting to the office for surgery. However, an overnight stay is allowed in the office if 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 must 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 postoperative care.

(i) The American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring are hereby adopted and incorporated by reference as the standards for anesthetic monitoring by any qualified anesthesia provider under this section.

1. These standards apply to general anesthetics, regional anesthetics, and monitored Level II and III anesthesia care. However, in emergency circumstances, appropriate life support measures take priority. These standards may be exceeded at any time based on the judgment of the responsible supervising physician or anesthesiologist. While these standards are intended to encourage quality patient care, observing them does not guarantee any specific patient outcome. This set of standards addresses only the issue of basic anesthesia monitoring, which is only one component of anesthesia care.

2. In certain rare or unusual circumstances, some of these methods of monitoring may be clinically impractical, and appropriate use of the described monitoring methods may fail to detect adverse clinical developments. In such cases, a brief interruption of continual monitoring may be unavoidable and does not by itself constitute a violation of the standards of practice of this section.

3. Under extenuating circumstances, the physician performing the surgery or the anesthesiologist may waive the

following requirements:

a. The use of an oxygen analyzer with a low oxygen concentration limit alarm, or other technology authorized under board rule which equals or exceeds the quality of the oxygen analyzer, during the administration of general anesthesia with an anesthesia machine.

b. The use of pulse oximetry with a variable pitch pulse tone and an audible low threshold alarm, or other technology authorized under board rule which equals or exceeds the quality of a pulse oximeter, and the use of adequate illumination and exposure of the patient to assess color.

c. The use of capnography, capnometry, or mass spectroscopy, or other technology authorized under board rule which equals or exceeds the quality of capnography, capnometry, or mass spectroscopy, as a quantitative method of analyzing the end-tidal carbon dioxide for continual monitoring for the presence of expired carbon dioxide during ventilation, from the time of the endotracheal tube or supraglottic airway placement until extubation or removal or initiating transfer of the patient to a postoperative care location.

d. The use of continuous electrocardiogram display, or other technology authorized under board rule which equals or exceeds the quality of electrocardiogram display, from the beginning of anesthesia until preparing to leave the anesthetizing location.

e. The measuring of arterial blood pressure and heart rate evaluated at least every 5 minutes during anesthesia.

When any of the monitoring is waived for extenuating

circumstances under this subparagraph, it must be documented in a note in the patient's medical record, including the reasons for the need to waive the requirement. These standards are not intended for the application to the care of an obstetrical patient in labor or in the conduct of pain management.

(j)1. Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel must be continuously present in the room to provide anesthesia care for the entire duration of all general anesthetics, regional anesthetics, and monitored anesthesia care conducted on the patient. In the event that there is a direct known hazard, such as radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthesia, the best judgment of the supervising physician or anesthesiologist shall be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthesia during the temporary absence.

2. During all anesthesia, the patient's oxygenation, ventilation, circulation, and temperature must be continually evaluated to ensure adequate oxygen concentration in the inspired gas and the blood.

a. During all general anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system must be measured by an oxygen analyzer with a low oxygen concentration limit alarm used to measure blood oxygenation.

b. During all anesthesia, a quantitative method of

assessing oxygenation, such as pulse oximetry, must be employed. When a pulse oximeter is used, the variable pitch pulse tone and the low threshold alarm must be audible to the qualified anesthesia provider. Adequate illumination and exposure of the patient are necessary to assess color.

c. During all anesthesia, every patient must have the adequacy of his or her ventilation continually evaluated, including, but not limited to, the evaluation of qualitative clinical signs, such as chest excursion, observation of the reservoir breathing bag, and auscultation of breath sounds. Continual monitoring for the presence of expired carbon dioxide must be performed unless invalidated by the nature of the patient's condition, the procedure, or the equipment. Quantitative monitoring of the volume of expired gas must also be performed.

d. When an endotracheal tube or supraglottic airway is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end-tidal carbon dioxide analysis, in use from the time of endotracheal tube or supraglottic airway placement until extubation or removal or initiating transfer of the patient to a postoperative care location, must be performed using a quantitative method, such as capnography, capnometry, or mass spectroscopy, or other technology authorized under board rule which equals or exceeds the quality of capnography, capnometry, or mass spectroscopy. When capnography or capnometry is used, the end-tidal carbon dioxide alarm must be audible to the qualified anesthesia provider.

e. When ventilation is controlled by a mechanical

ventilator, there must be in continuous use a device capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.

f. During regional anesthesia without sedation or local anesthesia with no sedation, the adequacy of ventilation must be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation, the adequacy of ventilation must be evaluated by continual observation of qualitative clinical signs. Monitoring for the presence of exhaled carbon dioxide is recommended.

g. Every patient receiving anesthesia must have the electrocardiogram or other technology authorized under board rule which equals or exceeds the quality of electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.

h. Every patient receiving anesthesia must have arterial blood pressure and heart rate determined and evaluated at least every 5 minutes.

i. Every patient receiving general anesthesia must have circulatory function continually evaluated by at least one of the following methods:

(I) Palpation of a pulse.

(II) Auscultation of heart sounds.

(III) Monitoring of a tracing of intra-arterial pressure.

(IV) Ultrasound peripheral pulse monitoring.

(V) Pulse plethysmography or oximetry.

(VI) Other technology authorized under board rule which equals or exceeds the quality of any of the methods listed in

sub-sub-subparagraphs (I)-(V).

j. Every patient receiving anesthesia must have his or her temperature monitored when clinically significant changes in body temperature are intended, anticipated, or suspected.

(k)1. The physician performing the surgery shall ensure that the postoperative care arrangements made for the patient are adequate for the procedure being performed, as required by board rule.

2. Management of postoperative care is the responsibility of the physician performing the surgery and may be delegated as determined by board rule. If the physician performing the surgery is unavailable to provide postoperative care, the physician performing the surgery must notify the patient of his or her unavailability for postoperative care before the procedure.

3. If there is an overnight stay at the office in relation to any surgical procedure:

a. The office must provide at least two persons to act as monitors, one of whom must be certified in advanced cardiac life support, and maintain a monitor-to-patient ratio of at least one monitor to two patients.

b. Once the physician performing the surgery has signed a timed and dated discharge order, the office may provide only one monitor to monitor the patient. The monitor must be qualified by licensure and training to administer all of the medications required on the crash cart and must be certified in advanced cardiac life support.

c. A complete and current crash cart must be present in the office surgery and immediately accessible for the monitors.

4. The physician performing the surgery must be reachable by telephone and readily available to return to the office if needed.

5. A policy and procedures manual must be maintained in the office at which Level II and Level III procedures are performed. The manual must be updated and implemented annually. The policy and procedures manual must provide for all of the following:

a. Duties and responsibilities of all personnel.

b. A quality assessment and improvement system designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and opportunities to improve performance.

c. Cleaning procedures and protocols.

d. Sterilization procedures.

e. Infection control procedures and personnel responsibilities.

f. Emergency procedures.

6. The designated physician shall establish a risk management program that includes all of the following components:

a. The identification, investigation, and analysis of the frequency and causes of adverse incidents.

b. The identification of trends or patterns of adverse incidents.

c. The development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents.

d. The documentation of such functions and periodic review of such information at least quarterly by the designated physician.

7. The designated physician shall report to the department any adverse incidents that occur within the scope of office surgeries. This report must be made within 15 days after the occurrence of an incident as required by s. 458.351.

8. The designated physician is responsible for prominently posting a sign in the office which states that the office is a doctor's office regulated under this section and ss. 458.328, 458.3281, and 459.0138 and the applicable rules of the Board of Medicine and the Board of Osteopathic Medicine as set forth in rules 64B8 and 64B15, Florida Administrative Code. This notice must also appear prominently within the required patient informed consent form.

9. All physicians performing surgery at the office surgery must be qualified by education, training, and experience to perform any procedure the physician performs in the office surgery.

10. When Level II, Level II-A, or Level III procedures are performed in an office surgery setting, the physician performing the surgery is responsible for providing the patient, in writing, before the procedure, with the name and location of the hospital where the physician performing the surgery has privileges to perform the same procedure as the one being performed in the office surgery setting or the name and location of the hospital with which the physician performing the surgery has a transfer agreement in the event of an emergency.

(4) LEVEL I OFFICE SURGERY.—

(a) *Scope.*—Level I office surgery includes the following:

1. Minor procedures such as excision of skin lesions, moles, warts, cysts, or lipomas and repair of lacerations or

surgery limited to the skin and subcutaneous tissue which are performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient.

2. Liposuction involving the removal of less than 4,000 cubic centimeters of supernatant fat.

3. Incision and drainage of superficial abscesses; limited endoscopies, such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of the urethra, cystoscopic procedures, and closed reduction of simple fractures; or small joint dislocations, such as in the finger or toe joints.

4. Procedures in which anesthesia is limited to minimal sedation. The patient's level of sedation must be that of minimal sedation and anxiolysis, and the chances of complications requiring hospitalization must be remote. As used in this sub-subparagraph, the term "minimal sedation and anxiolysis" means a drug-induced state during which patients respond normally to verbal commands, and although cognitive function and physical coordination may be impaired, airway reflexes and ventilatory and cardiovascular functions remain unaffected. Controlled substances, as defined in ss. 893.02 and 893.03, must be limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.

5. Procedures for which chances of complications requiring hospitalization are remote as specified in board rule.

(b) *Standards of practice.*—Standards of practice for Level I office surgery include all of the following:

1. The medical education, training, and experience of the physician performing the surgery must include training on proper dosages and management of toxicity or hypersensitivity to regional anesthetic drugs, and the physician must be certified in advanced cardiac life support.

2. At least one operating assistant must be certified in basic life support.

3. Intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device must be available in the office surgery, along with the following medications, stored per the manufacturer's recommendation:

a. Atropine, 3 mg.

b. Diphenhydramine, 50 mg.

c. Epinephrine, 1 mg in 10 ml.

d. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

e. Hydrocortisone, 100 mg.

f. If a benzodiazepine is administered, flumazenil, 0.5 mg in 5 ml vial, 2 vials total.

g. If an opiate is administered, naloxone, 0.4 mg in 1 ml vial, 2 vials total.

4. When performing minor procedures, such as excision of skin lesions, moles, warts, cysts, or lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia in an office surgery setting, physicians performing the procedure are exempt from subparagraphs 1.-3. Current certification in basic life support is recommended but not required.

5. A physician performing the surgery need not have an assistant during the procedure unless the specific procedure

being performed requires an assistant.

(5) LEVEL II OFFICE SURGERY.—

(a) *Scope.*—Level II office surgery includes, but is not limited to, all of the following procedures:

1. Hemorrhoidectomy.

2. Hernia repair.

3. Large joint dislocations.

4. Colonoscopy.

5. Liposuction involving the removal of up to 4,000 cubic centimeters of supernatant fat.

6. Any other procedure the board designates by rule as a Level II office surgery.

7. Surgeries in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. As used in this subparagraph, the term "moderate sedation and analgesia or conscious sedation" is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation; interventions are not required to maintain a patent airway; spontaneous ventilation is adequate; and cardiovascular function is maintained. For purposes of this term, reflex withdrawal from a painful stimulus is not considered a purposeful response.

(b) *Standards of practice.*—Standards of practice for Level II office surgery include, but are not limited to, the following:

1. The physician performing the surgery, or the office 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 office surgery setting at a licensed hospital within reasonable proximity. The transfer agreement required by this section must be current and have been entered into no more than 5 years before the date of the office's most recent annual inspection under s. 459.0138. A transfer agreement must affirmatively disclose an effective date and a termination date.

2. The physician performing the surgery must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office surgery setting or must be able to document satisfactory completion of training, such as board certification or board eligibility by a board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or Board of Osteopathic Medicine, as applicable, or must be able to establish comparable background, training, and experience. Such board certification or comparable background, training, and experience must also be directly related to and include the procedures being performed by the physician in the office surgery facility.

3. One assistant must be currently certified in basic life support.

4. The physician performing the surgery must be currently certified in advanced cardiac life support.

5. A complete and current crash cart must be available at all times at the location where the anesthesia is being administered. The designated physician of an office surgery is responsible for ensuring that the crash cart is replenished

after each use, the expiration dates for the crash cart's medications are checked weekly, and crash cart events are documented in the cart's logs. Medicines must be stored per the manufacturer's recommendations, and multidose vials must be dated once opened and checked daily for expiration. The crash cart must, at a minimum, include the following intravenous or inhaled medications:

a. Adenosine, 18 mg.

b. Albuterol, 2.5 mg with a small volume nebulizer.

c. Amiodarone, 300 mg.

d. Atropine, 3 mg.

e. Calcium chloride, 1 gram.

f. Dextrose, 50 percent; 50 ml.

g. Diphenhydramine, 50 mg.

h. Dopamine, 200 mg, minimum.

i. Epinephrine, 1 mg, in 10 ml.

j. Epinephrine, 1 mg in 1 ml vial, 3 vials total.

k. Flumazenil, 1 mg.

l. Furosemide, 40 mg.

m. Hydrocortisone, 100 mg.

n. Lidocaine appropriate for cardiac administration, 100 mg.

o. Magnesium sulfate, 2 grams.

p. Naloxone, 1.2 mg.

q. A beta blocker class drug.

r. Sodium bicarbonate, 50 mEq/50 ml.

s. Paralytic agent that is appropriate for use in rapid sequence intubation.

t. A calcium channel blocker class drug.

u. If nonneuraxial regional blocks are performed, Intralipid, 20 percent, 500 ml solution.

v. Any additional medication the board determines by rule is warranted for patient safety and by the evolution of technology and medical practice.

6. In the event of a drug shortage, the designated physician is authorized to substitute a therapeutically equivalent drug that meets the prevailing practice standards.

7. The designated physician is responsible for ensuring that the office maintains documentation of its unsuccessful efforts to obtain the required drug.

8. The designated physician is responsible for ensuring that the following are present in the office surgery:

a. A benzodiazepine.

b. A positive pressure ventilation device, such as Ambu, plus oxygen supply.

c. An end-tidal carbon dioxide detection device.

d. Monitors for blood pressure, electrocardiography, and oxygen saturation.

e. Emergency intubation equipment that must, at a minimum, include suction devices, endotracheal tubes, working laryngoscopes, oropharyngeal airways, nasopharyngeal airways, and bag valve mask apparatus that are sized appropriately for the specific patient.

f. A working defibrillator with defibrillator pads or defibrillator gel, or an automated external defibrillator unit.

g. Sufficient backup power to allow the physician performing the surgery to safely terminate the procedure and to allow the patient to emerge from the anesthetic, all without

compromising the sterility of the procedure or the environment of care.

h. Working sterilization equipment cultured weekly.

i. Sufficient intravenous solutions and equipment for a minimum of a week's worth of surgical cases.

j. Any other equipment required by board rule, as warranted by the evolution of technology and medical practice.

9. The physician performing the surgery must be assisted by a qualified anesthesia provider, which may include any of the following types of providers:

a. An anesthesiologist.

b. A certified registered nurse anesthetist.

c. A registered nurse, if the physician performing the surgery is certified in advanced cardiac life support and the registered nurse assists only with local anesthesia or conscious sedation.

An anesthesiologist assistant may assist the anesthesiologist as provided by board rule. An assisting anesthesia provider may not function in any other capacity during the procedure.

10. If additional anesthesia assistance is required by the specific procedure or patient circumstances, such assistance must be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician.

11. The designated physician is responsible for ensuring that each patient is monitored in the recovery room until the patient is fully recovered from anesthesia. Such monitoring must be provided by a licensed physician, physician assistant,

registered nurse with postanesthesia care unit experience, or the equivalent who is currently certified in advanced cardiac life support, or, in the case of pediatric patients, currently certified in pediatric advanced life support.

(6) LEVEL II-A OFFICE SURGERY.—

(a) *Scope*.—Level II-A office surgeries are those Level II office surgeries that have a maximum planned duration of 5 minutes or less and in which the chances of complications requiring hospitalization are remote.

(b) *Standards of practice.*—

1. All practice standards for Level II office surgery set forth in paragraph (5)(b) must be met for Level II-A office surgery except for the requirements set forth in subparagraph (5)(b)9. regarding assistance by a qualified anesthesia provider.

2. During the surgical procedure, the physician performing the surgery must be assisted by a licensed physician, physician assistant, registered nurse, or licensed practical nurse.

3. Additional assistance may be required by specific procedure or patient circumstances.

4. Following the procedure, a licensed physician, physician assistant, or registered nurse must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitoring provider must be currently certified in advanced cardiac life support, or, in the case of pediatric patients, currently certified in pediatric advanced life support.

(7) LEVEL III OFFICE SURGERY.—

(a) *Scope.*—

1. Level III office surgery includes those types of surgery during which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia. As used in this subparagraph, the term:

a. "Deep sedation and analgesia" means a drug-induced depression of consciousness during which:

(I) Patients cannot be easily aroused but respond purposefully following repeated or painful stimulation;

(II) The ability to independently maintain ventilatory function may be impaired;

(III) Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and

(IV) Cardiovascular function is usually maintained.

For purposes of this sub-subparagraph, reflex withdrawal from a painful stimulus is not considered a purposeful response.

b. "General anesthesia" means a drug-induced loss of consciousness during which:

(I) Patients are not arousable, even by painful stimulation;

(II) The ability to independently maintain ventilatory function is often impaired;

(III) 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; and

(IV) Cardiovascular function may be impaired.

2. The use of spinal or epidural anesthesia for a procedure requires that the procedure be considered a Level III office

surgery.

3. Only patients classified under the American Society of Anesthesiologists' (ASA) risk classification criteria as Class I or Class II are appropriate candidates for a Level III office surgery.

a. All Level III office surgeries on patients classified as ASA III or higher must be performed only in a hospital or ambulatory surgical center.

b. For all ASA II patients above the age of 50, the physician performing the surgery must obtain a complete workup performed before the performance of a Level III office surgery in the office surgery setting.

c. If the patient has a cardiac history or is deemed to be a complicated medical patient, the patient must have a preoperative electrocardiogram and be referred to an appropriate consultant for medical optimization. The referral to a consultant may be waived after evaluation by the patient's anesthesiologist.

(b) *Standards of practice.*—Practice standards for Level III office surgery include all Level II office surgery standards and all of the following requirements:

1. The physician performing the surgery must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office surgery 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 Board of Osteopathic Medicine, as applicable, 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 being performed by the physician performing the surgery in the office surgery setting. In addition, the physician performing the surgery must have knowledge of the principles of general anesthesia.

2. The physician performing the surgery must be currently certified in advanced cardiac life support.

3. At least one operating assistant must be currently certified in basic life support.

4. An emergency policy and procedures manual related to serious anesthesia complications must be available in the office surgery and reviewed biannually by the designated physician, practiced with staff, updated, and posted in a conspicuous location in the office. Topics to be covered in the manual must include all of the following:

a. Airway blockage and foreign body obstruction.

b. Allergic reactions.

c. Bradycardia.

d. Bronchospasm.

e. Cardiac arrest.

f. Chest pain.

g. Hypoglycemia.

h. Hypotension.

i. Hypoventilation.

j. Laryngospasm.

k. Local anesthetic toxicity reaction.

l. Malignant hyperthermia.

m. Any other topics the board determines by rule are warranted for patient safety and by the evolution of technology and medical practice.

5. An office surgery performing Level III office surgeries must maintain all of the equipment and medications required for Level II office surgeries and comply with all of the following additional requirements:

a. Maintain at least 720 mg of dantrolene on site if halogenated anesthetics or succinylcholine are used.

b. Equipment and medication for monitored postanesthesia recovery must be available in the office.

6. Anesthetic safety regulations must be developed, posted in a conspicuous location in the office, and enforced by the designated physician. Such regulations must include all of the following requirements:

a. All operating room electrical and anesthesia equipment must be inspected at least semiannually, and a written record of the results and corrective actions must be maintained.

b. Flammable anesthetic agents may not be employed in office surgery facilities.

c. Electrical equipment in anesthetizing areas must be on an audiovisual line isolation monitor, with the exception of radiologic equipment and fixed lighting more than 5 feet above the floor.

d. Each anesthesia gas machine must have a pin index safety system or equivalent safety system and a minimum oxygen flow safety device.

e. All reusable anesthesia equipment in direct contact with

a patient must be cleaned or sterilized as appropriate after each use.

f. The following monitors must be applied to all patients receiving conduction or general anesthesia:

(I) Blood pressure cuff.

(II) A continuous temperature device, readily available to measure the patient's temperature.

(III) Pulse oximeter.

(IV) Electrocardiogram.

(V) An inspired oxygen concentration monitor and a capnograph, for patients receiving general anesthesia.

g. Emergency intubation equipment must be available in all office surgery suites.

h. Surgical tables must be capable of Trendelenburg and other positions necessary to facilitate surgical procedures.

i. An anesthesiologist, a certified registered nurse anesthetist, an anesthesiologist assistant, or a physician assistant qualified as set forth in board rule must administer the general or regional anesthesia.

j. A physician, a registered nurse, a licensed practical nurse, a physician assistant, or an operating room technician must assist with the surgery. The anesthesia provider may not function in any other capacity during the procedure.

k. The patient must be monitored in the recovery room until he or she has fully recovered from anesthesia. The monitoring must be provided by a physician, a physician assistant, a certified registered nurse anesthetist, an anesthesiologist assistant, or a registered nurse with postanesthesia care unit experience or the equivalent who is currently certified in

advanced cardiac life support, or, in the case of pediatric patients, currently certified in pediatric advanced life support.

(8) EXEMPTION.—This section does not apply to a physician who is dually licensed as a dentist under chapter 466 when he or she is performing dental procedures that fall within the scope of practice of dentistry and are regulated under chapter 466.

(9) RULEMAKING.—The board may adopt by rule additional standards of practice for physicians who perform office surgeries or procedures under this section as warranted for patient safety and by the evolution of technology and medical practice.

Section 5. Subsection (6) of section 456.074, Florida Statutes, is amended to read

456.074 Certain health care practitioners; immediate suspension of license.—

(6) The department must issue an emergency order suspending or restricting the registration of an office registered under s. 458.328 or s. 459.0138 ~~s. 459.0139~~ upon a finding of probable cause that the office or a physician practicing in the office is not in compliance with the standards of practice for office surgery adopted by the boards pursuant to s. 458.328 or s. 459.0138, as applicable, or is in violation of s. 458.331(1)(v) or s. 459.015(1)(z), and that such noncompliance or violation constitutes an immediate danger to the public.

Section 6. This act shall take effect upon becoming a law.