RULE WITH TEXT ADOPTED ON 3/17/15 AND EFFECTIVE 4/6/15.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B8-9.009 Standard of Care for Office Surgery. NOTHING IN THIS RULE RELIEVES THE SURGEON OF THE RESPONSIBILITY FOR MAKING THE MEDICAL DETERMINATION THAT THE OFFICE IS AN APPROPRIATE FORUM FOR THE PARTICULAR PROCEDURE(S) TO BE PERFORMED ON THE PARTICULAR PATIENT.

(1) Definitions.

(a) Surgery. For the purpose of this rule, surgery is defined as any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(b) Surgeon. For the purpose of this rule, surgeon is defined as a licensed physician performing any procedure included within the definition of surgery.

(c) Equipment. For the purpose of this rule, implicit within the use of the term of equipment is the requirement that the specific item named must meet current performance standards according to manufacturer's guidelines.

(d) Office surgery. For the purpose of this rule office surgery is defined as surgery which is performed outside of any facility licensed under Chapter 390 or 395, F.S. Office surgical procedures shall not be of a type that generally result in blood loss of more than ten percent of estimated blood volume in a patient with a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; involve major blood vessels performed with direct visualization by open exposure of the major vessel, except for percutaneous endovascular intervention; or are generally emergent or life threatening in nature.

(e) Percutaneous endovascular intervention. For the purpose of this rule percutaneous endovascular intervention is defined as a procedure performed without open direct visualization of the target vessel, requires only needle puncture of an artery or vein followed by insertion of catheters, wires, or similar devices which 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 which include, but are not limited to, injection of contrast for imaging, treatment of vessels with angioplasty, atherectomy, covered or uncovered stenting, intentionally occluding vessels or organs (embolization), and delivering medications, radiation, or other energy such as laser, radiofrequency, or cryo.

(f) Major Blood Vessels. For the purpose of this rule major blood vessels are defined as 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.

(g) Pediatric patients are defined as those patients who are 13 years of age or under.

(2) General Requirements for Office Surgery.

(a) The surgeon must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. The surgeon may delegate the preoperative heart lung evaluation to a qualified anesthesia provider within the scope of the provider's practice and, if applicable, protocol. The surgeon must maintain complete records of each surgical procedure, as set forth in Rule 64B8-9.003, F.A.C., including anesthesia records, when applicable and the records shall contain written informed consent from the patient reflecting the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists, i.e., anesthesiologist, anesthesiologist assistant, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C.

(b) The requirement set forth in paragraph (2)(a) above for written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.

(c) The surgeon must maintain a log of all liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed, and Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, documentation of completion of the medical clearance as performed by the anesthesiologist or the operating physician, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, and the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, and any adverse incidents, as identified in Section 458.351, F.S. If not documented elsewhere in the patient record, the surgical log must note the type of post-operative care, duration

of recovery, disposition of the patient upon discharge, and list of medications used during surgery and recovery. The log and all surgical records shall be provided to investigators of the Department of Health upon request and must be maintained for six (6) years from the last patient contact.

(d) In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.

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

1. When combined with abdominoplasty, liposuction may not exceed 1000cc of supernatant fat;

2. When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000 cc of supernatant fat;

3. Major liposuction in excess of 1000cc supernatant fat may not be performed in a remote location from any other procedure.

(f) For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined must not exceed 8 hours. Except for elective cosmetic and plastic surgery, the surgeon shall not keep patients past midnight in a physician's office. For elective cosmetic and plastic surgical procedures, the patient must be discharged within 24 hours of presenting to the office for surgery; an overnight stay is permitted in the office provided the total time the patient is at the office does not exceed 23 hours and 59 minutes including the surgery time. An overnight stay in a physician's office for elective cosmetic and plastic surgery shall be strictly limited to the physician's office. If the patient has not recovered sufficiently to be safely discharged within the timeframes set forth, the patient must be transferred to a hospital for continued post-operative care.

(g) The Board of Medicine adopts the "Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring," approved by House Delegates on October 21, 1986, and last amended on October 20, 2010, as the standards for anesthetic monitoring by any qualified anesthesia provider.

1. These standards apply to general anesthetics, regional anesthetics, and monitored anesthesia care (Level II and III as defined by this rule) although, in emergency circumstances, appropriate life support measures take

precedence. These standards may be exceeded at any time based on the judgment of the responsible supervising physician or anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. This set of standards addresses only the issue of basic anesthesia monitoring, which is 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 untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. For purpose of this rule, "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time."

3. Under extenuating circumstances, the responsible supervising physician or anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record. These standards are not intended for the application to the care of the obstetrical patient in labor or in the conduct of pain management.

a. Standard I.

(I) ~~I.~~ Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

(II) ~~II.~~ OBJECTIVE. Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., 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 anesthetic, the best judgment of the supervising physician or anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

b. Standard II.

(I) ~~I.~~ During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

(II) ~~II.~~ OXYGENATION.

(A) OBJECTIVE. To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

(B) METHODS.

I. ~~(I)~~ Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*

II. ~~(II)~~ Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as a pulse oximetry shall be employed.* When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm shall be audible to the qualifed anesthesia provider.* Adequate illumination and exposure of the patient are necessary to assess color.*

(III) ~~III.~~ VENTILATION.

(A) OBJECTIVE. To ensure adequate ventilation of the patient during all anesthetics.

(B) METHODS.

I. ~~(I)~~ Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*

II. ~~(II)~~ 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/supraglottic airway placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.* When capnography or capnometry is utilized, the end tidal carbon dioxide alarm shall be audible to the qualifed anesthesia provider.*

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

IV. ~~(IV)~~ During regional anesthesia (with no sedation) or local anesthesia (with no sedation), the adequacy of

ventilation shall be evaluated by continual observation of qualitative clinical signs. During moderate or deep sedation the adequacy of ventiliation shall be evaluated by continual observation of qualitative clinical signs. Monitoring for the presence of exhaled carbon dioxide is recommended.

(IV) ~~IV.~~ CIRCULATION.

(A) OBJECTIVE. To ensure the adequacy of the patient's circulatory function during all anesthetics.

(B) METHODS.

I. ~~(I)~~ Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*

II. ~~(II)~~ Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*

III. ~~(III)~~ Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

(V) ~~V.~~ BODY TEMPERATURE.

(A) OBJECTIVE. To aid in the maintenance of appropriate body temperature during all anesthetics.

(B) METHODS. Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

(h) The surgeon must assure that the post-operative care arrangements made for the patient are adequate to the procedure being performed as set forth in Rule 64B8-9.007, F.A.C. Management of post surgical care is the responsibility of the operating surgeon and may be delegated only as set forth in subsection 64B8-9.007(3), F.A.C. If there is an overnight stay at the office in relation to any surgical procedure:

1. The office must provide at least two (2) monitors, one of these monitors must be certified in Advanced Cardiac Life Support (ACLS), and maintain a monitor to patient ratio of at least 1 monitor to 2 patients. Once the surgeon 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. The full and current crash cart required below must be present in the office and immediately accessible for the monitors.

2. The surgeon must be reachable by telephone and readily available to return to the office if needed. For

purposes of this subsection, “readily available” means capable of returning to the office within 15 minutes of receiving a call.

(i) A policy and procedure manual must be maintained in the office, updated annually, and implemented. The policy and procedure manual must contain the following: duties and responsibilities of all personnel, quality assessment and improvement systems comparable to those required by Rule 59A-5.019, F.A.C.; cleaning, sterilization and infection control, and emergency procedures. This applies only to physician offices at which Level II and Level III procedures are performed.

(j) The surgeon shall establish a risk management program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,

2. The identification of trends or patterns of incidents,

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

4. The documentation of these functions and periodic review no less than quarterly of such information by the surgeon.

(k) The surgeon shall report to the Department of Health any adverse incidents that occur within the office surgical setting. This report shall be made within 15 days after the occurrence of an incident as required by Section 458.351, F.S.

(l) A sign must be prominently posted in the office which states that the office is a doctor’s office regulated pursuant to the rules of the Board of Medicine as set forth in Rule Chapter 64B8, F.A.C. This notice must also appear prominently within the required patient informed consent.

(m) All physicians performing office surgery must be qualified by education, training, and experience to perform any procedure the physician performs in the office surgery setting.

(3) 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, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient. The patient’s level of sedation is that of minimal sedation and anxiolysis. Minimal sedation and anxiolysis is a drug-induced state

during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.

2. Liposuction involving the removal of less than 4000cc supernatant fat is permitted.

3. Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).

4. Pre-operative medications not required or used other than minimal pre-operative tranquilization of the patient; anesthesia is local, topical, or none. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted in level I Office Surgery.

5. Chances of complication requiring hospitalization are remote.

(b) Standards for Level I Office Surgery.

1. Training Required. Surgeon's continuing medical education should include: proper dosages; management of toxicity or hypersensitivity to regional anesthetic drugs. One assistant must hold current certification in an American Heart Association or American Safety and Health Institute approved Basic Life Support course, and the surgeon must hold current certification in an American Heart Association or American Safety and Health Institute approved Advanced Cardiac Life Support course.

2. Equipment and Supplies Required. Intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device shall be available in the office, along with the following medications, stored per manufacturer's recommendations:

a. ~~(a)~~ Atropine 3 mg;

b. ~~(b)~~ Diphenhydramine 50 mg;

c. ~~(c)~~ Epinephrine 1 mg in 10 ml;

d. ~~(d)~~ Epinephrine 1 mg in 1 ml vial, 3 vials total; and

e. ~~(e)~~ Hydrocortisone 100 mg.

3. When performing minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas, and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia, physicans are exempt from subsections (3)(b) 1. and 2., above. Current Basic Life Support certification is recommended but not required.

4. Assistance of Other Personnel Required. No other assistance is required, unless the specific surgical procedure being performed requires an assistant.

(4) Level II Office Surgery.

(a) Scope.

1. Level II Office Surgery shall include, but not be limited to: hemorrhoidectomy, hernia repair, large joint dislocations, colonoscopy, and liposuction involving the removal of up to 4000cc supernatant fat.

2. Level II Office surgery includes any surgery in which the patient's level of sedation is that of moderate sedation and analgesia or conscious sedation. Moderate sedation and analgesia or conscious sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained. Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(b) Standards for Level II Office Surgery.

1. Transfer Agreement Required. The physician, or the facility where the procedure is being performed, must have a transfer agreement with a licensed hospital within reasonable proximity if the physician performing the procedure does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity. “Reasonable proximity” is defined as not to exceed thirty (30) minutes transport time to the hospital.

2. Training Required.

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

b. One (1) assistant must be currently certified in and by an American Heart Associaton or American Safety and Health Institute approved Basic Life Support course and the surgeon must be currently certified in and by an American Heart Associaton or American Safety and Health Institute approved Advanced Cardiac Life Support

course.

3. Equipment and Supplies Required.

a. Full and current crash cart at the location the anesthetizing is being carried out. Medicines shall be stored per the manufacturer's recommendations and multi-dose vials shall be dated once opened. The crash cart must include, at a minimum, the following intravenous or inhaled medications:

(I) ~~I.~~ Adenosine 18 mg

(II) ~~II.~~ Albuterol 2.5 mg with small volume nebulizer

(III) ~~III.~~ Amiodarone 300 mg

(IV) ~~IV.~~ Atropine 3 mg

(V) ~~V.~~ Calcium chloride 1 gram

(VI) ~~VI.~~ Dextrose 50%; 50 ml

(VII) ~~VII.~~ Diphenhydramine 50 mg

(VIII) ~~VIII.~~ Dopamine 200 mg minimum

(IX) ~~IX.~~ Epinephrine 1 mg in 10 ml

(X) ~~X.~~ Epinephrine 1 mg in 1 ml vial, 3 vials total

(XI) ~~XI.~~ Flumazenil 1 mg

(XII) ~~XII.~~ Furosemide 40 mg

(XIII) ~~XIII.~~ Hydrocortisone 100 mg

(XIV) ~~XIV.~~ Lidocaine appropriate for cardiac administration 100 mg

(XV) ~~XV.~~ Magnesium sulfate 2 grams

(XVI) ~~XVI.~~ Naloxone 1.2 mg

(XVII) ~~XVII.~~ A beta blocker class drug

(XVIII) ~~XVIII.~~ Sodium bicarbonate 50 mEq/50 ml

(XIX) ~~XIX.~~ Paralytic agent that is appropriate for use in rapid sequence intubation

(XX) ~~XX.~~ Vasopressin 40 units

(XXI) ~~XXI.~~ A calcium channel blocker class drug

(XXII) ~~XXII.~~ Intralipid 20% 500 ml solution (only if non-neuraxial regional blocks are performed)

In the event of a drug shortage, the physician is allowed to substitute a therapeutically equivalent drug that

meets the prevailing standard of care. The office must maintain documentation of its unsuccessful efforts to obtain the required drug.

b. A Benzodiazepine must be present in the office.

c. Positive pressure ventilation device (e.g. Ambu) plus oxygen supply.

d. End tidal CO2 detection device.

e. Monitors for blood pressure/EKG/Oxygen saturation.

f. Emergency intubation equipment, which shall at a minimum include suction devices, endotracheal tubes, laryngoscopes, oropharyngeal airways, nasopharyngeal airways and bag valve mask apparatus that are patient-size specific.

g. Defibrillator with defibrillator pads or defibrillator gel, or an Automated External Defibrillator unit (AED).

h. Sufficient back up power is required to allow the physician 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.

i. Sterilization equipment.

j. IV solution and IV equipment.

4. Assistance of Other Personnel Required. The surgeon must be assisted by a qualified anesthesia provider as follows: An Anesthesiologist, Certified Registered Nurse Anesthesist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C., or a registered nurse may be utilized to assist with the anesthesia, if the surgeon is ACLS certified. An anesthesiologist assistant may assist the anesthesiologist as set forth in Rule 64B8-31.005, F.A.C. An assisting anesthesia provider cannot function in any other capacity during the procedure. If additional 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. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, a licensed registered nurse with post-anesthesia care unit experience or the equivalent, credentialed by an American Heart Association or American Safety and Health Institute approved Advanced Cardiac Life Support course or, in the case of pediatric patients, by an American Heart Association or American Safety and Health Institute approved Pediatric Advanced Life Support course and, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.

(5) Level IIA Office Surgery.

(a) Scope. Level IIA office surgeries are those Level II office surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote.

(b) Standards for Level IIA Office Surgery.

1. The standards set forth in subsection 64B8-9.009(4), F.A.C., must be met except for the requirements set forth in subparagraph 64B8-9.009(4)(b)4., F.A.C., regarding assistance of other personnel.

2. Assistance of Other Personnel Required. During the procedure, the surgeon must be assisted by a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or by a licensed registered nurse or a licensed practical nurse. Additional assistance may be required by specific procedure or patient circumstances. Following the procedure, a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or a licensed registered nurse must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitor must be certified by an American Heart Association or American Safety and Health Institute approved Advanced Cardiac Life Support course, or, in the case of pediatric patients, by an American Heart Association or American Safety and Health Institute approved Pediatric Advanced Life Support course.

(6) Level III Office Surgery.

(a) Scope.

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

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

a. All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center.

b. For all ASA II patients above the age of 40, the surgeon must obtain, at a minimum, an EKG and a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient is deemed to be a complicated medical patient, the patient must be referred to an appropriate consultant for medical optimization. This requirement may be waived after evaluation by the patient's anesthesiologist.

(b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:

1. Training Required.

a. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. Such Board certification or comparable background, training and experience must also be directly related to and include the procedure(s) being performed by the physician in the office surgery facility. In addition, the surgeon must have knowledge of the principles of general anesthesia.

b. One assistant must be currently certified by an American Heart Association or American Safety and Health Institute approved Basic Life Support course and the surgeon must be currently certified by an American Heart Association or American Safety and Health Institute approved Advanced Cardiac Life Support course.

2. Emergency policies and procedures related to serious anesthesia complications shall be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location. Topics to be covered shall include the following:

a. Airway Blockage (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; and

l. Malignant Hyperthermia.

3. Equipment and Supplies Required.

a. Equipment and medication, including at least 720 mg of dantrolene on site (if halogenated anesthetics or succinylcholine are utilized), and monitored post-anesthesia recovery must be available in the office.

b. The office, in terms of general preparation, equipment, and supplies, must be comparable to a free standing ambulatory surgical center, including, but not limited to, recovery capability, and must have provisions for proper recordkeeping.

c. Blood pressure monitoring equipment; EKG; end tidal CO_2 monitor; pulse oximeter, emergency intubation equipment and a temperature monitoring device.

d. Table capable of trendelenburg and other positions necessary to facilitate the surgical procedure.

4. Assistance of Other Personnel Required. An Anesthesiologist, Certified Registered Nurse Anesthetist, Anesthesiologist Assistant, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(c)6., F.A.C., must administer the general or regional anesthesia and an M.D., D.O., Registered Nurse, Licensed Practical Nurse, Physician Assistant, or Operating Room Technician must assist with the surgery. The anesthesia provider cannot function in any other capacity during the procedure. A physician licensed under Chapter 458 or 459, F.S., a licensed anesthesiologist assistant, a licensed physician assistant, or a licensed registered nurse with post-anesthesia care unit experience or the equivalent, and credentialed by an American Heart Association or American Safety and Health Institute approved Advanced Cardiac Life Support course, or in the case of pediatric patients, by an American Heart Association or American Safety and Health Institute approved Pediatric Advanced Life Support course, must be available to monitor the patient in the recovery room until the patient has recovered from anesthesia.

Rulemaking Authority 458.309(1), 458.331(1)(v) FS.

Law Implemented 458.331(1)(v), 458.351 FS.

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