

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.

(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; directly involve major blood vessels; or are generally emergent or life threatening in nature.

(e) 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 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, 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 Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, the name of the physician who provided medical clearances, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, the type of post-operative care, duration of recovery, disposition of the patient upon discharge, list of medications used during surgery and recovery, and any adverse incidents, as identified in Section 458.351, F.S. The log and all surgical records shall be provided to investigators of the Department of Health upon request.

(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 21, 1998, 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 address 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. Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

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

II. OXYGENATION.

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

(B) METHODS.

(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) Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as a pulse oximetry shall be employed.* Adequate illumination and exposure of the patient are necessary to assess color.*

III. VENTILATION.

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

(B) METHODS.

(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) When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask 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.*

(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) During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs.

IV. CIRCULATION.

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

(B) METHODS.

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

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

(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. 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 197, Chapter 99-397, Laws of Florida.

(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.
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. Basic Life Support Certification is recommended but not required.
2. Equipment and Supplies Required. Oxygen, positive pressure ventilation device, Epinephrine (or other vasopressor), Corticoids, Antihistamine and Atropine if any anesthesia is used.
3. 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 is that in which peri-operative medication and sedation are used by any means altering the level of consciousness, thus making intra and post-operative monitoring necessary. Such procedures shall include, but not be limited to: hemorrhoidectomy, hernia repair, reduction of simple fractures, large joint dislocations, breast biopsies, colonoscopy, and liposuction involving the removal of up to 4000cc supernatant fat.
2. Level II Office surgery includes any surgery in which the patient is placed in a state which allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by this definition.

(b) Standards for Level II Office Surgery.

1. Transfer Agreement Required. The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician 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 Basic Life Support and the surgeon must be currently certified in Advanced Cardiac Life Support.

3. Equipment and Supplies Required.

a. Full and current crash cart at the location the anesthetizing is being carried out. The crash cart must include, at a minimum, the following resuscitative medications:

- I. Adenosine 6 mg/2 ml x 3
- II. Albuterol Inhaler
- III. Amiodarone 150 mg x 2

- IV. Atropine 0.4 mg/ml; 3 ml
- V. Calcium chloride 10%; 10 ml
- VI. Dextrose 50%; 50 ml
- VII. Diphenhydramine 50 mg
- VIII. Dopamine 200 mg minimum
- IX. Epinephrine 1:10,000 dilution; 10 ml
- X. Epinephrine 1:1000 dilution; 1 ml x 3
- XI. Flumazenil 0.1 mg/ml; 5 ml x 2
- XII. Furosemide 40 mg
- XIII. Hydrocortisone or Methylprednisolone or Dexamethasone
- XIV. Lidocaine 100 mg
- XV. Magnesium sulfate 1 gm x 2
- XVI. Naloxone 0.4 mg/ml; 3 ml
- XVII. Propranolol 1 mg x 1
- XVIII. Sodium bicarbonate 50 mEq/50 ml
- XIX. Succinylcholine 1 vial
- XX. Vasopressin 20 units x 2
- XXI. Verapamil 5 mg x 2

- b. A Benzodiazepine must be stocked, but not on the crash cart.
- c. Suction devices, endotracheal tubes, laryngoscopes, etc.
- d. Positive pressure ventilation device (e.g. Ambu) plus oxygen supply.
- e. Double tourniquet for the Bier block procedure.
- f. Monitors for blood pressure/EKG/Oxygen saturation.
- g. Emergency intubation equipment.
- h. Defibrillator or an Automated External Defibrillator unit (AED).
- i. Adequate operating room lighting.
- j. Emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours.
- k. Appropriate sterilization equipment.
- l. 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 Anesthetist, 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 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 in Advanced Cardiac Life Support or, in the case of pediatric patients, Pediatric Advanced Life Support, 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 in Advanced Cardiac

Life Support, or, in the case of pediatric patients, Pediatric Advanced Life Support.

(6) Level III Office Surgery.

(a) Scope.

1. Level III Office Surgery is that surgery which involves, or reasonably should require, the use of a general anesthesia or major conduction anesthesia and pre-operative sedation. This includes the use of:

- a. Intravenous sedation beyond that defined for Level II office surgery;
- b. General Anesthesia: loss of consciousness and loss of vital reflexes with probable requirement of external support of pulmonary or cardiac functions; or
- c. Major conduction anesthesia.

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 an independent medical clearance. 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 in Basic Life Support and the surgeon must be currently certified in Advanced Cardiac Life Support.

2. Emergency procedures related to serious anesthesia complications should be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location.

3. Equipment and Supplies Required.

a. Equipment, medication, including at least 36 ampules of dantrolene on site, 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 CO₂ monitor; pulse oximeter, precordial or esophageal stethoscope, emergency intubation equipment and a temperature monitoring device.

d. Defibrillator or an Automated External Defibrillator Unit (AED).

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

f. IV solutions and IV equipment.

4. Assistance of Other Personnel Required. An Anesthesiologist, Certified Registered Nurse Anesthetist, 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 physician assistant, or a licensed registered nurse with post-anesthesia care unit experience or the equivalent, and credentialed in Advanced Cardiac Life Support, or in the case of pediatric patients, Pediatric Advanced Life Support, 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)(g), (t), (v), (w), 458.351 FS. History—New 2-1-94, Amended 5-17-94, Formerly 61F6-27.009, Amended 9-8-94, 11-15-94, Formerly 59R-9.009, Amended 2-17-00, 12-7-00, 2-27-01, 8-1-01, 8-12-01, 3-25-02, 3-22-05, 4-19-05, 10-23-05, 10-10-06, 4-18-07, 9-3-07, 3-25-10.