

RULES OF TENNESSEE BOARD OF MEDICAL EXAMINERS

CHAPTER 0880-2

GENERAL RULES AND REGULATIONS GOVERNING THE PRACTICE OF MEDICINE

0880-2-.21 OFFICE BASED SURGERY. A license to practice medicine issued pursuant to T.C.A. § 63-6-204 authorizes the holder to perform surgery. To the extent that any licensee performs surgery in his or her office rather than a hospital, abortion clinic, or ASTC, that licensee, or the governing body of the entity lawfully authorized to practice medicine wherein the surgery is to be performed, shall comply with these rules.

(1) General Statement and Precaution - The Board will always judge the decision to perform surgery in the office setting based upon what was in the patient's best interest and through strict application of these rules.

(2) Intent and Application

(a) Intent – It is not the intent of these rules to circumvent the law and rules and regulations governing ambulatory surgical treatment centers. The intent of these rules is to provide physicians, who perform Level I, II, IIA, and III surgeries as part of a medical practice whose focus is on provision of medical services and procedures that are not related to surgery (and procedures and services incidental thereto), an option to provide on-site surgical and surgical related services that are within the scope of the physician's specialty and training and in the best interest of the patient.

(b) Application – These rules do not apply to physicians or the governing body of entities lawfully authorized to practice medicine whose practice location(s) has as its primary purpose the provision of Level I, II, IIA and III surgical or surgical preparatory services and/or procedures. Those types of practice locations must comply with all laws, rules and regulations applicable to ambulatory surgical treatment centers including rules 0720-3-.01 through .07.

(3) Definitions

(a) AAAASF - American Association for the Accreditation of Ambulatory Surgical Facilities.

(b) AAAHC - Accreditation Association for Ambulatory Healthcare.

(c) ACLS (Advanced cardiac life support) - A certification that means a person has successfully completed an advanced cardiac life support course offered by a recognized accrediting organization in accordance with American Heart Association (AHA) guidelines.

(d) ASA - American Society of Anesthesiologists.

(e) ASTC - An ambulatory surgical treatment center licensed by the Department of Health Division of Health Care Facilities.

(f) Block -

1. Digital Block - The injection of a local anesthetic to stop or prevent painful sensation in a digit (i.e., finger or toe).
2. Minor Regional Block or Minor Regional Anesthesia - The administration of local anesthetics to interrupt nerve impulses in an extremity, or other minor region of the body, including but not limited to upper and lower extremity plexus blocks.
3. Major Regional Block or Major Regional Anesthesia - The administration of local anesthetic agents to interrupt nerve impulses in a major region of the body, including but not limited to spinal blocks, epidural blocks, caudal blocks, and intravenous regional anesthetic.

(g) Board - The Tennessee Board of Medical Examiners.

(h) BCLS (Basic Cardiac Life Support) - A certification that means a person has successfully completed a basic cardiac life support course offered by a recognized accrediting organization in accordance with AHA guidelines.

(i) Conscious Sedation/Moderate Sedation/Sedation-Analgesia - 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 usually required to maintain a patient airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.

(j) Deep Sedation - 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 often require assistance in maintaining a patient airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(k) General Anesthesia - 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 patient 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.

(l) Hospital - A hospital licensed by the Department of Health Division of Health Care Facilities.

(m) JCAHO - Joint Commission on Accreditation of Healthcare Organizations.

(n) Local Anesthetic - The administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

(o) PALS (Pediatric Advanced Life Support) - A certification that means a person has successfully completed a pediatric advanced life support course offered by a recognized accrediting organization in accordance with AHA guidelines.

(p) Physician - A person licensed to practice medicine and surgery pursuant to Tennessee Code Annotated Title 63, Chapters 6 and 9.

(q) Surgery - The excision or resection, partial or complete, destruction, incision or other structural alteration of human tissue by any means (including through the use of lasers) performed upon the body of a living human for purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering, or for aesthetic, reconstructive or cosmetic purposes, to include, but not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed or an open reduction of a fracture; extraction of tissue, including premature extraction of products of conception from the uterus; and insertion of natural or artificial implants. For the purpose of this rule, certain diagnostic and therapeutic procedures requiring medication to immobilize the patient are contained within the definition of surgery.

(4) Surgery on Infants and Children

(a) Infants - Infants shall include only those persons in the neonatal age group. For such infants, only those procedures that can be reasonably performed under local anesthetic, such as neonatal circumcisions, may be performed in a physician's office.

(b) Children –

1. Level I surgeries may be performed in a physician's office on a patient under the age of fourteen (14).

2. No Level II, Level IIA or Level III surgeries or any surgery requiring any level of sedation may be performed on patients under the age of (2) years in a physician's office.

3. Most Level II and IIA surgeries are not allowed to be performed in a physician's office on any patient under the age of fourteen (14) years. Provided however, it is recognized that in the pediatric population, certain types of surgeries may be performed under mild sedation in a physician's office. Those Level II and IIA surgeries are limited to the following conditions and circumstances all of which must be met before the surgery is allowed:

(i) The child is at least two (2) years of age but younger than fourteen (14) years of age and is healthy according to ASA risk classification criteria; and

(ii) The surgery is anticipated to be brief and superficial and is of such a nature that it is more safely performed while the patient is not agitated; and

(iii) Sedative or anxiolytic medications are not to be administered at home as part of a pre-procedural sedating plan; and

(iv) Only minimal sedation is to be used which shall include only one (1) sedating drug that is administered only one (1) time, in a low dose in addition to a local anesthetic or appropriate block such that at all times the child is awake and interactive. An antagonist to the sedating drug used must be immediately available; and

(v) A pediatric equipped emergency cart is available and a person who has a current certification in PALS is assigned with the task of staying in close proximity to the child at all times to observe the child throughout the pre-operative and surgical procedures and until such time as the child is declared fit to be released from the office.

4. No Level III surgeries may be performed in a physician's office on a patient under the age of fourteen (14).

(5) Levels of Surgery Defined

(a) Level I Office Surgery is the type of surgery in which pre-operative medications are not required or used other than minimal pre-operative tranquilization/anxiolysis of the patient. There is no anesthesia or it is a local, topical, or appropriate block. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted and the chances of complication requiring hospitalization are remote.

(b) Level II Office Surgery includes the following:

1. Those in which pre-operative medication and sedation are used intravenously, intramuscularly, inhalation, orally, or rectally, thus making intra and postoperative monitoring necessary; and
2. Those in which local or peripheral major nerve block, including Bier Block are used; and
3. Those in which intravenous, oral, rectal or intramuscular sedation that preserve vital reflexes are used. However, the use of nitrous oxide in conjunction with other types of sedatives qualifies as Level III surgery.
4. Any surgery in which the patient is placed in a state that allows the patient to tolerate unpleasant procedures while maintaining adequate cardio respiratory function and the ability to respond purposefully to verbal command and/or light tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than is authorized for Level II surgeries.

(c) Level IIA office procedures are those Level II office surgeries with a maximum planned duration of thirty (30) minutes or less and in which chances of complications requiring hospitalization are remote. This category includes procedures requiring sedation for diagnostic purposes including, but not limited to, endoscopic procedures and radiologic procedures.

(d) Level III office surgeries are those which involve, or reasonably should require, the use of a general anesthesia, deep sedation, or major conduction anesthesia and pre-operative sedation. This includes the use of:

1. A level of sedation beyond that defined for Level II office surgery; and/or
2. General Anesthesia: loss of consciousness and loss of vital reflexes with probable requirement of external support of pulmonary or cardiac functions; and/or
3. Major Conduction Anesthesia (epidural, spinal, caudal); and/or
4. The use of nitrous oxide in conjunction with other types of sedatives.

(6) Level I Surgeries - Description and Standards

(a) Level I surgeries include, but are not limited to, the following:

1. Minor procedures performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal oral preoperative tranquilization/anxiolysis of the patient and include, but are not limited to, the following:
 - (i) Excision of skin lesions, moles, warts, cysts, lipomas; and
 - (ii) Repair of lacerations or surgery limited to the skin and subcutaneous tissue,
2. Liposuction involving the removal of less than 250 cc supernatant fat,
3. Incision and drainage of superficial abscesses,
4. Limited endoscopies such as proctoscopies,
5. Skin biopsies, arthrocentesis, thoracentesis, paracentesis, endometrial biopsy,
6. IUD's, colposcopy,

7. Dilation of urethra, cysto-scopic procedures, and
8. Closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).

(b) Standards for Level I Office Surgery.

1. Training Required – The physician's continuing medical education should include instruction in proper dosages of regional anesthetic drugs and management of toxicity or hypersensitivity to those drugs. It is required that either the physician or someone in the operating room at the time of the surgery has a current BCLS certification.
2. Equipment and Supplies Required - Basic medications and equipment to manage toxic or hypersensitivity reactions.
3. Assistance of Other Personnel Required - No assistance from other personnel is required unless the specific surgical procedure being performed should reasonably involve an assistant.

(7) Level II Surgeries - Description and Standards

(a) Level II Surgeries include, but are not limited to, the following depending upon the level of anesthetic identified:

1. Hemorrhoidectomy,
2. Hernia repair,
3. Reduction of closed, uncomplicated fractures,
4. Large joint dislocations,
5. Breast biopsies,
6. Colonoscopy and other endoscopic procedures,
7. Diagnostic radiologic procedures requiring sedation,
8. Liposuction involving the removal of up to 4000 cc supernatant fat, and
9. Diagnostic cardiac procedures requiring sedation.

(b) Transfers – The physician performing the surgery must have staff privileges at a licensed hospital within reasonable proximity or a written transfer protocol to a licensed hospital within reasonable proximity.

(c) Training Required.

1. The physician 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 comparable background, training, or experience.
2. The physician or one (1) assistant must have current certification in ACLS or there must be a qualified anesthetic provider practicing within the scope of the provider's license present to manage the anesthetic.
3. Individuals responsible for patients receiving sedation/analgesia should understand the pharmacology of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines.
4. Individuals monitoring patients receiving these agents shall be able to recognize the associated complications.
5. At least one (1) individual with current ACLS certification who is capable of establishing a patient airway and positive pressure ventilation shall be continuously present whenever sedation/analgesia are administered. There must also be a means immediately available for summoning additional assistance.

(d) Equipment and Supplies (age and procedure appropriate) Required:

1. Suction devices, endotracheal tubes, laryngoscopes, etc.

2. Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
3. Double tourniquet for the Bier block procedure.
4. Monitors for blood pressure, EKG, Oxygen saturation, and temperature.
5. Emergency intubation equipment.
6. Adequate operating room lighting.
7. Appropriate sterilization equipment.
8. IV solution and IV equipment.
9. Reversal or antagonist agents for medications used.
10. A standard and emergency ACLS equipped cart and other such equipment as is necessary for the procedure being performed.

(e) Assistance of Other Personnel Required.

1. During the Procedure - The physician must be assisted by a professional licensed pursuant to Tennessee Code Annotated Title 63, Chapters 6, 7, 9, or 19 and practicing within the lawful scope of their licensure functioning as an assisting anesthesia provider who cannot function in any other capacity during the procedure.

2. Following the procedure –

(i) There must be a person with current ACLS certification present at all times with the patient while in the recovery area; and

(ii) An additional professional who has post-anesthesia care unit experience or its equivalent and a current ACLS certification and who is licensed pursuant to either Tennessee Code Annotated, Title 63 Chapter 6, 9 or 19 or a registered or advanced practice nurse licensed pursuant to Tennessee Code Annotated, Title 63 Chapter 7 must also be immediately available on the premises to assist in monitoring the patient in the recovery room until the patient has recovered from anesthesia.

(f) Level II surgeries are limited to patients who fall within ASA Class 1, 2, and 3 risk classification criteria.

(8) Level IIA Office Surgery – Description and Standards

(a) All the standards set forth in subparagraphs (7) (a) through (e) for Level II Surgeries must be met for Level IIA surgeries but the following substitute for part (7) (e) 1. shall apply to all Level IIA surgeries.

(b) During the procedure - A certified nurse practitioner, physician assistant, registered nurse, advanced practice nurse or licensed practical nurse must assist the physician. Additional assistance may be required by specific procedure or patient circumstances and if so, it must be provided by a person licensed pursuant to either Tennessee Code Annotated, Title 63, Chapters 6, 7, 9 or 19, or a nationally certified operating room technician.

(9) Level III Office Surgery – Description and Standards

(a) Except to the extent that any provision of these rules provide a stricter standard in which case these rules shall govern, the Board adopts as its own the standards established, and as they may be from time to time amended, by all of the following

1. The AAAASF;
2. The AAAHC;
3. The JCAHO.

(b) Even though the Board adopts the standards of all the above listed agencies, a practice location at which Level III surgeries are to be performed must meet the standards of and have a current accreditation from only one (1) of those listed accrediting agencies (AAAASF, AAAHC or JCAHO). The choice of which accrediting agency to seek accreditation from is entirely up to the physician.

1. Practices covered by these rules in existence on the effective date of these rules will have one (1) year from the effective date of these rules to obtain or be scheduled to obtain such accreditation.
2. The physician shall cause the accrediting organization to notify the Board of practice locations that have applied for accreditation and have subsequently been denied accreditation.

(c) Only patients classified under the ASA risk classification criteria as Class 1 or 2 are appropriate candidates for Level III office surgery.

(d) Hospital Staff Privileges required - The physician performing the surgery must have staff privileges to perform the same procedure as that being performed in the office setting at a licensed hospital within reasonable proximity.

(e) Training Required – The physician must have documentation of training to perform the particular surgical procedures and must have knowledge of the principles of general anesthesia. The physician and at least one (1) assistant must be currently certified in ACLS.

(f) Assistance of Other Personnel Required.

1. An anesthesiologist or certified registered nurse anesthetist licensed pursuant to Tennessee Code Annotated, Title 63, Chapter 7 and practicing within the lawful scope of that license, must administer the general or regional anesthesia. The anesthesia provider cannot function in any other capacity during the procedure and shall be physically present with the patient at all times during the intra-operative period.

2. When general anesthesia using volatile anesthetic gases, succinylcholine or other agents known to trigger malignant hyperthermia are administered, the facility shall maintain or have immediate access to thirty-six (36) ampules of dantrolene and its diluent for injection. If dantrolene is administered, appropriate monitoring must be provided postoperatively.

3. Following the procedure –

- (i) There must be a person with current ACLS certification present at all times with the patient while in the recovery area; and

- (ii) An additional professional who has post-anesthesia care unit experience or its equivalent and a current ACLS certification and who is licensed pursuant to either Tennessee Code Annotated, Title 63 Chapter 6, 9 or 19 or a registered or advanced practice nurse licensed pursuant to Tennessee Code Annotated, Title 63 Chapter 7 must also be immediately available on the premises to assist in monitoring the patient in the recovery room until the patient has recovered from anesthesia.

(10) Requirements Applicable to Level II and II A Surgeries Performed in Office Locations not Accredited by the AAAASF, the AAAHC or the JCAHO.

(a) Pre, Intra, Postoperative Services In General.

1. An operative/procedure note shall be created for each surgery describing the procedure performed, the techniques used, participating personnel and their titles, postoperative diagnosis, type of anesthesia, and complications. Where similar procedures are performed at an office routinely, partially pre-printed forms may be utilized as a guide, provided that original data and conclusions applicable to the specific patient are contemporaneously entered to create a complete report.
2. A post-procedure note shall be created for each surgery and completed prior to discharge of a patient from the office, which shall include such post-procedure data as the patient's general condition, vital signs, treatments ordered, and all drugs prescribed, administered or dispensed including dosages and quantities.
3. All patients, except those who receive minor regional blocks and/or local anesthetic only, shall receive appropriate postoperative management. A patient may be excused from a stay in the recovery area only by a specific order of the anesthesia personnel or the operating physician.
4. The patient shall be transported to the recovery area accompanied by a member of the anesthesia care team who is knowledgeable about the patient's condition. The patient shall be continually evaluated and treated during transport appropriate to the patient's condition.
5. An oral report on the patient's condition shall be given to the health care personnel responsible for the patient in the recovery area who were not present in the anesthetizing location.
6. The patient's recovery area condition shall be evaluated and recorded in the medical record. The blood pressure, pulse rate, respiratory rate, blood oxygen saturation, level of consciousness, and when appropriate temperature shall be assessed at least every fifteen (15) minutes (five [5] minutes for pediatric patients) until they are stable and returned to pre-operative baseline values and/or normal values consistent with the patient's age and medical condition.
7. Objective criteria (for example a scoring system such as PARR or Aldrete Score) shall be established to determine when a patient is medically ready or "fit" to be discharged.
8. Before discharge, the patient shall be given written and verbal instructions for follow-up care and advice concerning complications. Emergency phone number shall be provided to the patient.
9. If sedation or regional blocks have been used, a responsible adult must be available to accompany the patient and be instructed with regard to the patient care and follow-up.
 - (b) Sufficient space shall be available to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient and all resuscitation and monitoring equipment.
 - (c) Pharmaceutical Services - The office shall maintain and provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet

which shall be kept locked at all times and a log of all such drugs and biologicals dispensed shall be maintained.

(d) Ancillary Services - All ancillary or supportive health medical services, including but not limited to, radiological, pharmaceutical, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.

(11) Miscellaneous

(a) Liposuction - Liposuction procedures performed pursuant to these rules shall be performed only by physicians with appropriate training following prescribed national professional guidelines. These procedures shall be within the scope of practices of the physician and capabilities of the office. Provided however, no such procedures may be performed if the anticipated supernatant fat removal is to be greater than 4000 cc. In addition the following shall also apply:

1. When combined with other surgical procedures, liposuction may not exceed 2000 cc of supernatant fat.
2. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting. A maximum of 35mg/kg of Lidocaine can be injected for non-tumescent liposuction in the office setting.

(b) Laser surgery - Laser surgeries performed pursuant to these rules require written policies and procedures that include, but are not limited to, laser safety, education, training, and the supervision of other licensed health care practitioners who are performing laser treatments. A safe environment shall be maintained for laser surgery.

(c) Time Limits and Additional Requirements –

1. For all Level III surgery procedures performed pursuant to these rules, the maximum planned duration of all surgical procedures combined must not exceed six (6) hours.
2. If the patient has not recovered sufficiently to be safely discharged within twelve (12) hours after the initial administration of anesthesia, the patient must be transferred to a hospital for continued postoperative care. (12) The Board shall appoint a standing Office Based Surgery Committee comprised of three (3) members of the Board who shall meet twice a year to review and make whatever recommendations for revision of these rules as circumstances require. All comments and suggestions for revision and improvement of these rules should be addressed to that committee and sent to the Board's Administrative Office.

(13) Any violation of these rules shall be grounds for disciplinary actions before the board pursuant to T.C.A. § 63-6-214 (b) (1), (2) or (4).

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-6-101, 63-6-204 and 63-6-214.
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