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312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

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Agency/Board/Commission:	Board of Osteopathic Examination
Division:	
Contact Person:	Shiva K. Bozarth, Deputy General Counsel
Address:	Office of General Counsel 220 Athens Way, Suite 210 Nashville, Tennessee
Zip:	37243
Phone:	(615) 741-1611
Email:	Shiva.Bozarth@tn.gov

Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1050-02	General Rules and Regulations Governing the Practice of Osteopathy
Rule Number	Rule Title
1050-02-.21	Office Based Surgery

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Rulemaking Hearing Rules
Department of Health
Board of Osteopathic Examination
Division of Health Related Boards

Chapter 1050-02
General Rules and Regulations Governing the Practice of Osteopathy

Amendment

Rule 1050-02-.21 Office Based Surgery is amended by deleting the entire content of that rule in its entirety and substituting instead the following new content, so that as amended it shall read as follows:

1050-02-.21 Office Based Surgery. A license to practice osteopathic medicine issued pursuant to T.C.A. § 63-9-106 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 osteopathic 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 0720-10, 11 and 12.
- (3) Definitions
 - (a) Acceptable Plan of Correction. The Board of Osteopathic Examination approves an Office Based Surgical Suite's plan to correct deficiencies identified during an on-site survey conducted by the Division. The plan of correction shall be a written document and shall provide, but not be limited to, the following information:
 1. How the deficiency will be corrected.
 2. Who will be responsible for correcting the deficiency.
 3. The date the deficiency will be corrected.
 4. How the facility will prevent the same deficiency from re-occurring.
 - (b) 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.

- (c) ASA - American Society of Anesthesiologists.
- (d) ASTC - An ambulatory surgical treatment center licensed by the Department of Health Division of Health Care Facilities.
- (e) 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.
- (f) Board - The Tennessee Board of Osteopathic Examination.
- (g) 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.
- (h) 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.
- (i) 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.
- (j) 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.
- (k) Hospital - A hospital licensed by the Department of Health Division of Health Care Facilities.
- (l) Local Anesthetic - The administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.
- (m) 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.
- (n) Osteopathic Physician - A person licensed to practice osteopathic medicine and surgery pursuant to Tennessee Code Annotated Title 63, Chapter 9.

- (o) 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.
 - (p) Surgical Suite - The operating room and recovery room(s) located in a physician's office where surgery is to be performed.
- (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).
- (c) 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.
- (5) Level I Office Based Surgery
- (a) Level of Anesthesia - 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 I Surgical Procedures - Procedures authorized to be performed under Level I anesthesia include, but are not limited to, the following:
 1. Minor procedures including, but 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).
 - (c) Standards for Level I Office Based Surgery.
 1. Training required of personnel involved in Level I Surgical Procedures. 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 which shall be age and procedure appropriate.
 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.

- (d) 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.
- (6) Levels II and IIA Office Surgery
- (a) Level of Anesthesia - The following levels of anesthesia are authorized for use in performing Level II and IIA surgical procedures:
 - 1. Pre-operative medication and sedation introduced intravenously, intramuscularly, inhalation, orally, or rectally, thus making intra and postoperative monitoring necessary; and/or
 - 2. Local or peripheral major nerve block, including Bier Block; and/or
 - 3. Intravenous, oral, rectal or intramuscular sedation that preserve vital reflexes. However, the use of nitrous oxide in conjunction with other types of sedatives is not allowed for Level II or IIA surgical procedures; and/or
 - 4. Any level or type of anesthesia 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 and/or IIA surgeries.
 - (b) Level II Surgical Procedures - Procedures authorized to be performed under Level II anesthesia include, but are not limited to, the following:
 - 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 which usually require sedation.
 - (c) Level IIA Surgical Procedures - are those Level II office surgical procedures 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) Standards for Level II and IIA Office Based Surgery.
 - 1. 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.

2. Training required of personnel involved in Level II and IIA Surgical Procedures.
 - (i) 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 Osteopathic Association or the American Board of Medical Specialties or comparable background, training, or experience.
 - (ii) 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.
 - (iii) 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.
 - (iv) Individuals monitoring patients receiving these agents shall be able to recognize the associated complications.
 - (v) 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.
3. Equipment and Supplies: All of the following which shall be age and procedure appropriate are required:
 - (i) Suction devices, endotracheal tubes, laryngoscopes, etc.
 - (ii) Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
 - (iii) Double tourniquet for the Bier block procedure.
 - (iv) Monitors for blood pressure, EKG, Oxygen saturation, and temperature.
 - (v) Emergency intubation equipment.
 - (vi) Adequate operating room lighting.
 - (vii) Appropriate sterilization equipment.
 - (viii) IV solution and IV equipment.
 - (ix) Reversal or antagonist agents for medications used.
 - (x) A standard and emergency ACLS equipped cart and other such equipment as is necessary for the procedure being performed.
4. Assistance of Other Personnel Required.
 - (i) During the procedure
 - (I) Level II Surgical Procedures - 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.

(II) Level IIA Surgical Procedures - 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.

(ii) 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.

5. Pre, Intra, Postoperative Services In General.

(i) 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.

(ii) 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.

(iii) 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.

(iv) 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.

(v) 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.

(vi) 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.

- (vii) 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.
 - (viii) 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.
 - (ix) 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.
 - (x) If a 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.
6. Sufficient space in the room in which the surgical procedure is being performed 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.
7. 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.
8. 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.
- (e) ASA Risk Classifications - Level II and IIA surgeries are limited to patients who fall within ASA Class 1 and 2 risk classification criteria.
- (7) Level III Office Based Surgery
- (a) Levels of Anesthesia - Includes all levels of anesthesia which sedate a patient beyond the levels described in subparagraph (6)(a) of this rule which includes:
 - 1. Deep sedation as defined by subparagraph (3)(i) of this rule; and/or
 - 2. Major Conduction Anesthesia (epidural, spinal, caudal); and/or
 - 3. Major conduction anesthesia and pre-operative sedation; and/or
 - 4. General Anesthesia as defined in subparagraph (3)(j) of this rule; and/or
 - 5. The use of nitrous oxide in conjunction with other types of sedatives.
 - (b) Level III Surgical Procedures - Procedures authorized to be performed under Level III anesthesia are those contained on the Centers for Medicare & Medicaid Services (CMS) list of procedures published in Volume 71, Number 226 of the Federal Register dated November 24, 2006 as it may from time to time be amended that are authorized for

reimbursement at the Ambulatory Surgical Center (ASC) level and only those cosmetic surgical procedures that, based upon reasonable medical judgment, would require Level III sedation. The surgical procedures authorized pursuant to this subparagraph are limited to those that also have all the following characteristics:

1. Have a planned duration of less than four (4) hours. This includes multiple surgeries regardless of the level of surgery; the combined planned duration of all planned procedures shall be less than four (4) hours; and
2. Generally result in blood loss of less than ten percent (10%) of estimated blood volume in a patient with normal hemoglobin; and
3. Will not require major or prolonged intracranial or intrathoracic procedures; and
4. Will not require major or prolonged abdominal or major hip replacement procedures (this criteria does not apply to laparoscopic procedures); and
5. Will not be generally emergent or life threatening in nature.

(c) Application for Certification and Renewal-

1. Application for Certification - A physician office which contains operating and recovery rooms wherein Level III office based surgeries are to be performed, which shall be referred to as "surgical suites" for purposes of this rule, must obtain certification from the Board before any Level III surgical procedures may be performed therein. The process for obtaining that certification is as follows:
 - (i) Obtain the Board's Level III Office Based Surgery Certification application (which shall also serve as the official request for a site survey) and provide all the information requested thereon which shall include the following:
 - (I) The name of a responsible physician in whose name the surgical suite certification shall be issued who shall also arrange to have provided, for each physician in the office who will be performing Level III procedures, the following information and/or documentation:
 - (II) A statement identifying all Level III procedures expected to be performed by each such physician; and
 - (III) A copy of what, if any, specialty board certification or board eligibility has been obtained by each such physician; and
 - (IV) Written verification of medical malpractice coverage from each physician's malpractice insurance carrier; and
 - (V) Written verification of hospital staff privileges from at least one hospital at which each of the physicians has been granted staff privileges that is within thirty (30) miles or thirty (30) minutes from the surgical suite.
 - (ii) Submit copies of both the office's by-laws and its documentation of the management system that will insure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time.

- (iii) Submit the Surgical Suite Certification fee in the amount of one thousand eighty dollars (\$1,080.00) and the state regulatory fee of five dollars (\$5.00).
 - (iv) Obtain a surgical suite site survey performed by the Board's authorized agents to determine compliance with the standards set forth in this rule. Those authorized agents shall have the authority to:
 - (I) Require plans of correction from the physician office for any deficiencies they may find in compliance with the standards set forth in this rule and to make a determination of the acceptability of the submitted plans of correction, and verify that the plans of correction have been implemented.
 - (II) Initiate subsequent, unannounced site surveys during regular business hours as long as the physician office continues to be used to perform Level III office-based surgeries but no more frequently than once every twelve (12) months.
 - (III) Respond to any complaints made by patients or the public against a physician who performs office based surgery or a physician's office at which Level III office-based surgery is being performed at the request of the Department's office of investigations.
 - (v) Receive approval from the Board on the result of the surgical suite site survey.
2. Renewal of Certification - A physician office which obtains Level III Office Based Surgery Certification for its surgical suites, must renew that certification every year by submitting to the Board the annual renewal fee in the amount of one thousand eighty dollars (\$1,080.00) and the state regulatory fee of five dollars (\$5.00), on or before its anniversary date.
 3. The information required to be included on and/or with the application form as itemized in subparagraph (c) 1 (i) and (ii) of this rule must be updated within thirty (30) days of the date on which any of the provided information or documentation has changed or additions need to be made.
 4. Transition Provisions -
 - (i) In order for a physician office at which Level III office-based surgeries have been performed prior to October 1, 2007, (pursuant to certifications/accreditations received pursuant to prior Board rules) to continue doing so, the office must submit an application and a request for a site survey and remit payment of the Surgical Suite Certification fee and the state regulatory fee to the board by October 1, 2007. If such office makes a timely filing in accordance with this provision, the physician's office may continue to be a site for office-based surgeries pending completion of a survey confirming compliance with board rules and subsequent issuance of a certification of the surgical suite(s).
 - (ii) A physician office at which office-based surgeries have not been performed as of October 1, 2007, (pursuant to certifications/accreditations received pursuant to prior Board rules) shall not perform any such procedures until an application form and payment of the Surgical Suite Certification fee and the state regulatory fee are submitted to the board and a site survey is completed and a certification of the surgical suite is issued by the board.

- (d) Level III Surgery Standards - All physician offices for which certification for performance of Level III surgeries is to be sought and obtained shall meet the following standards:
1. Infection Control
 - (i) The surgical suite(s) must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.
 - (ii) The physical environment of the surgical suite(s) shall be maintained in a safe, clean and sanitary manner.
 - (I) Any condition on the surgical suite(s) site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
 - (II) Cats, dogs or other animals shall not be allowed in any part of the surgical suite except for specially trained animals for the handicapped and except as addressed by physician office policy for pet therapy programs. The physician's office shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the surgical suite performed by medically trained personnel.
 - (III) A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.
 - (IV) Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.
 - (V) Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.
 - (VI) Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each use is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.
 - (iii) The physician office shall assure that an infection control committee including members of the medical, nursing and administrative staff develops guidelines and techniques for the prevention, surveillance, control and reporting of surgical suite infections. Duties of the committee shall include the establishment of:
 - (I) Written infection control policies;

- (II) Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;
 - (III) Written procedures governing the use of aseptic techniques and procedures in all areas of the facility;
 - (IV) Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 - (V) A log of incidents related to infectious and communicable diseases;
 - (VI) A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;
 - (VII) Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as hand washing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and
 - (VIII) Continuing education provided for all office personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.
- (iv) The physician office must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.
 - (v) The physician office shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that any person, employee or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.
 - (vi) The physician office and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.
 - (vii) The physician office shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome

2. Life Safety

- (i) All surgical suites shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities (if applicable), and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the

Standard Building Code shall prevail. All new and existing surgical suites are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.

- (ii) Any surgical suite(s) which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.
- (iii) A surgical suite(s) shall be provided fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the Board within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the facility may omit the name(s) of patient(s) and parties involved, however, should the department find the identities of such persons to be necessary to an investigation, the facility shall provide such information.
- (iv) The following alarms are required and shall be monitored twenty-four (24) hours per day:
 - (I) Fire alarms; and
 - (II) Generators (if applicable).
- (v) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms.
- (vi) The emergency power system shall:
 - (I) Use either propane, gasoline or diesel fuel. The generator shall be designed to meet the facility's HVAC and essential needs and shall have a minimum of twenty-four (24) hours of fuel designed to operate at its rated load. The fuel quantity shall be based on its expected or known connected load consumption during power interruptions.
 - (II) Automatically transfer within ten (10) seconds in surgical suites conducting invasive surgical procedures.
 - (III) Be inspected monthly and exercised at the actual load and operating temperature conditions and not on dual power for at least thirty (30) minutes each month, including automatic and manual transfer of equipment. A log shall be maintained for all inspections and tests and kept on file for a minimum of three (3) years. The facility shall have trained staff familiar with the generator's operation.
 - (IV) Emergency generators are not required if the surgical suite does not utilize anesthesia that renders the patient incapable of self preservation. However, the facility shall have an emergency

power source able to produce adequate power to run required equipment for a minimum of two (2) hours.

- (vii) Emergency electrical power connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. (It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source.)

3. Patient Rights

- (i) Each patient has at least the following rights:
 - (I) To privacy in treatment and personal care;
 - (II) To be free from mental and physical abuse. Should this right be violated, the physician office must notify the department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately as required by T.C.A. §§ 71-6-101 et seq;
 - (III) To refuse treatment. The patient must be informed of the consequences of that decision; the refusal and its reason must be reported to the physician and documented in the medical record;
 - (IV) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;
 - (V) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The physician office must have policies to govern access and duplication of the patient's record;
 - (VI) To have appropriate assessment and management of pain; and
 - (VII) To be involved in the decision making of all aspects of their care.
- (ii) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

4. Hazardous Waste

- (i) Each physician office must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.
- (ii) The following waste shall be considered to be infectious waste:

- (I) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals;"
 - (II) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;
 - (III) Waste human blood and blood products such as serum, plasma, and other blood components;
 - (IV) Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;
 - (V) All discarded sharps (including but not limited to, hypodermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;
 - (VI) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals;
 - (VII) Other waste determined to be infectious by the physician office in its written policy.
- (iii) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the physician office.
 - (iv) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.
 - (I) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;
 - (II) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;
 - (III) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste;

- (IV) Opaque packaging must be used for pathological waste.
- (v) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.
 - (I) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal;
 - (II) Plastic bags of infectious waste must be transported by hand.
- (vi) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons.
 - (I) Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.
 - (II) Pathological waste must be promptly treated, disposed of, or placed into refrigerated storage.
- (vii) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the physician office must ensure that proper actions are immediately taken to:
 - (I) Isolate the area from the public and all except essential personnel;
 - (II) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of subpart (iv) of this part;
 - (III) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedures must specify how this will be done; and
 - (IV) Complete incident report and maintain copy on file.
- (viii) Except as provided otherwise in this section a physician office must treat or dispose of infectious waste by one or more of the methods specified in this part.
 - (I) A physician office may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious wastes treated in such a device are rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records

kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (nonhazardous) solid waste under current rules of the Department of Environment and Conservation.

- (II) The physician may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §§ 69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.
- (III) Any physician office accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.
- (ix) The physician office may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the physician office must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the physician office must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable Federal and State requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.
- (x) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subpart. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.
- (xi) All garbage, trash and other non-infectious wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.

5. Equipment and Supplies

- (i) Adequate equipment and supplies must be available to the operating room suites and to the postoperative care area which, when applicable shall be age and procedure appropriate and shall include but not be limited to the following:
 - (I) Call-in system (OR)

- (II) Cardiac monitor
 - (III) Pulse Oximeter
 - (IV) Resuscitator
 - (V) Defibrillator
 - (VI) Aspirator
 - (VII) Tracheotomy set
- (ii) A crash cart must be available and include at a minimum all the medication and supplies recommended by the current ACLS guidelines of the American Heart Association and:
- (I) Dantrolene

6. Administration

- (i) Physician offices that perform office-based surgery must adopt bylaws that put in place a management system and documentation that will insure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time.
- (ii) Except for emergencies, a surgical suite certified for office based surgery may be utilized only by physician employees of the practice in which the surgical suite is located. Surgical suites may not be shared with other practices or other physicians.
- (iii) When licensure is applicable for a particular job within the surgery suite, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience, and personnel background of the employee.
- (iv) The surgical suite shall have available a plan for emergency transportation to a licensed local hospital.
- (v) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.
- (vi) There must be a complete history and physical work-up in the chart of every patient prior to surgery. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.
- (vii) Properly executed informed consent forms must be in the patient's chart before surgery, except in emergencies.
- (viii) The physician office shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

- (ix) The physician office shall report to the Department of Health each case of communicable disease detected in the office. Repeated failure to report communicable diseases shall be cause for revocation of a surgical suite's certification.
- (x) Any claim required to be reported under T.C.A. §56-54-101 (Reports on Medical Malpractice Claims) shall be reported to the Department of Health in a format designed by the Department within seven (7) business days of the date of the payment of the claim.
- (xi) Unusual events shall be reported by the physician office to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.
 - (l) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:
 - I. medication errors;
 - II. aspiration in a non-intubated patient related to conscious/moderate sedation;
 - III. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;
 - IV. volume overload leading to pulmonary edema;
 - V. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;
 - VI. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;
 - VII. burns of a second or third degree;
 - VIII. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;
 - IX. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:
 - A. procedure related injury requiring repair or removal of an organ;
 - B. hemorrhage;

- C. displacement, migration or breakage of an implant, device, graft or drain;
- D. post operative wound infection following clean or clean/contaminated case;
- E. any unexpected operation or reoperation related to the primary procedure;
- F. hysterectomy in a pregnant woman;
- G. ruptured uterus;
- H. circumcision;
- I. incorrect procedure or incorrect treatment that is invasive;
- J. wrong patient/wrong site surgical procedure;
- K. unintentionally retained foreign body;
- L. loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;
- M. criminal acts;
- N. suicide or attempted suicide;
- O. elopement from the facility;
- P. infant abduction, or infant discharged to the wrong family;
- Q. adult abduction;
- R. rape;
- S. patient altercation;
- T. patient abuse, patient neglect, or misappropriation of resident/patient funds;
- U. restraint related incidents; or
- V. poisoning occurring within the facility.

- 7. 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.
- 8. Training Required – The physician performing the surgery must have documentation of training to perform the particular surgical procedures and must have knowledge of the principles of general anesthesia. The physician performing the surgery and at least one (1) assistant must be currently certified in ACLS.
- 9. Assistance of Other Personnel Required.

- (i) 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.
 - (ii) When general anesthesia using volatile anesthetic gases, succinylcholine or other agents known to trigger malignant hyperthermia are administered, the surgical suite shall maintain or have immediate access to thirty-six (36) ampoules of dantrolene and its diluent for injection. If dantrolene is administered, appropriate monitoring must be provided postoperatively.
 - (iii) 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.
 - (III) 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.
10. Level III surgical suites shall be used exclusively for surgery and recovery, respectively and for no other purpose.
11. Physicians performing Level III surgery in an office setting shall obtain written informed consent prior to the procedure from the patient or the patient's representative which shall be documented in the patient's health record. The consent shall explain to the patient the risks and benefits of the procedure; the alternative treatments to the surgical procedure; the type of anesthesia to be used and its risks; and the qualifications of the professional who is expected to administer the anesthesia during the procedure.
12. A physician performing Level III surgery in an office setting must inform the patient, in writing, that the medical office is not a licensed facility and that the patient may elect to have the surgery performed at a licensed ASTC or hospital. The patient or the patient's representative must consent in writing to have the surgery performed in a medical office.
- (e) ASA Risk Classifications - Only patients classified under the ASA risk classification criteria as Class 1 or 2 are appropriate candidates for Level III office based surgical procedures.
 - (f) The Board shall post on its web site a list, including the names and locations of physician offices that have qualified as sites for Level III surgeries and have been issued certification by the Board. Information on the list shall be updated at least quarterly.

(8) Procedure Specific Restrictions

(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.

(9) 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.

(10) Any violation of these rules shall be grounds for disciplinary actions before the board pursuant to T.C.A. § 63-9-111(b) (1), (2) or (4) or Public Chapter 373 of the Public Acts of 2007.

(a) When a physician office is found by the department to have committed a violation of this chapter, the department will issue a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the physician office must return a plan of correction indicating the following:

1. How the deficiency will be corrected.
2. Who will be responsible for correcting the deficiency.
3. The date the deficiency will be corrected.
4. How the facility will prevent the same deficiency from re-occurring.

(b) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject a surgical suite's certification to possible disciplinary action.

Authority: T.C.A. §§ 63-6-221, 63-9-101, 63-9-106, and 63-9-111.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Karen R. Shepherd, D.O.	X				
Rafael M. Sanchez, D.O.				X	
Paul G. Smith, Jr., D.O.	X				
Jill Robinson, D.O.	X				
Donald H. Polk, D.O.	X				
Janice E. Hinton				X	

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Osteopathic Examination on 05/21/2008, and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 03/11/08

Rulemaking Hearing(s) Conducted on: (add more dates). 05/21/08

Date: 4/22/10

Signature: [Signature]

Name of Officer: Shiva K. Bozarth

Deputy General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: 4/22/10

Notary Public Signature: Theodora P. Wildna

My Commission Expires on: 11/7/2011



All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

[Signature]
 Robert E. Cooper, Jr.
 Attorney General and Reporter
4-29-10
 Date

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 PUBLICATIONS

Filed with the Department of State on: 4/30/10

Effective on: 7/29/10

[Signature]
 Tre Hargett
 Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Rulemaking Comments

The rulemaking hearing was conducted during a regular meeting of the Tennessee Board of Osteopathic Examination on May 21, 2008. The meeting was held at the Bureau of Health Licensure and Regulation, 227 French Landing Drive, 1st Floor, Poplar Conference Room, Heritage Place Metro Center, Nashville, Tennessee 37243. Schean G. Belton, Assistant General Counsel, Tennessee Department of Health, presided over the meeting. No members of the public attended and there were no comments received.

Regulatory Flexibility Addendum

Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

REGULATORY FLEXIBILITY ANALYSIS

Pursuant to the Regulatory Flexibility Act of 2007, 2007 Pub. Acts, c. 464, § 4, eff. June 21, 2007, the Department of Health submits the following regulatory flexibility analysis:

- (1) The proposed rule amendment does not overlap, duplicate, or conflict with other federal, state, and local governmental rules.
- (2) The proposed rule amendment exhibits clarity, conciseness, and lacks ambiguity.
- (3) The proposed rule amendment clarifies rules for Office Based Surgery by clarifying particular levels of surgeries that are acceptable for office based procedures and limits the surgical procedures to those listed in the Centers for Medicare and Medicaid Services. The amendment also clarifies appropriate candidates for surgery as well as the appropriate levels of anesthesia for each level of surgery performed. The proposed rules require physicians to utilize surgical suites when performing more complicated procedures. The proposed rules does allow for flexible compliance or reporting requirements for osteopathic physicians applying for licensure in Tennessee and as it establishes procedures for compliance with the Board and the Department of Health. The Department of Health and the Board of Osteopathic Examination believe that this is necessary to protect the health and safety of the citizens of the state who choose the option of office based surgery.
- (4) The proposed rule amendment does not affect any schedules or deadlines for compliance and/or reporting requirements for small businesses as currently there are no osteopathic physicians conducting level III office based surgeries.
- (5) The proposed rule amendment does affect compliance or reporting requirements for small businesses. The rule amendment requires that those osteopathic physicians that wish to perform Level III office based surgeries designate a particular part of the office where such surgeries are to take place. This area, a surgical suite, must be certified by the Board and is regulated by the Department of Health, Division of Health Care Facilities. The surgical suite must meet building and fire safety requirements and is required to report any unplanned or unexpected incidents to the Board within seven business days of the event.
- (6) The proposed rule amendment does establish performance standards for small businesses in that the physicians are limited to performing only those surgical procedures that they could otherwise perform in a hospital.
- (7) This amendment may create entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs, however, the requirements are necessary to ensure that the citizens of the state receive an adequate level of care from health care professionals during surgical procedures performed in a physician's office.

Economic Impact Statement

- (1) Type or types of small business subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:

Osteopathic physicians and osteopathic practices that perform surgeries in their offices.

- (2) Identification and estimate of the number of small businesses subject to the proposed rule:

As of December 31, 2006, Tennessee had 18,776 licensed medical doctors and 762 licensed osteopathic doctors who were eligible for licensure renewal.

Two (2) of the three (3) Board-approved accrediting agencies designated in the current rules have informed the Board of Medical Examiners and Board of Osteopathic Examination that twelve (12) physician's offices have been accredited for Level III surgeries. When the third accrediting agency reports, the Board will have knowledge of approximately twenty (20) accredited physician's offices, none of which are osteopathic physicians.

- (3) Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:

The proposed amendments which have economic impact on small businesses will have minimal increases or new reporting, recordkeeping and other administrative costs that are required for compliance. This will occur primarily because of the new site inspection process which incorporates proving adherence to written infection control and hazardous waste policies that must be developed. This includes the keeping of a log of incidents related to infectious and communicable diseases. No new professional skills are needed.

- (4) Statement of the probable effect on impacted small businesses and consumers:

Implementation of these rules, when compared to the current office based surgery rules, brings no certainty that there will be any benefits or increases in costs to small businesses, but if there are such benefits or increases in costs, it will be the osteopathic physicians and osteopathic practices that perform surgeries in their offices that are impacted.

If state certification is easier to obtain than the presently required national accreditation (even though the standards are virtually the same), this may encourage more osteopathic physicians and osteopathic practices to perform office based surgery. It would be logical to assume that they would see an increase in patients, and that would be economically beneficial. This may, in turn, reduce revenues to the hospitals and ambulatory surgical treatment centers which are the traditional surgical settings

If the fees for state certification are more than the fees for the presently required national accreditation, this will come directly from the "bottom line" profits of osteopathic physicians and osteopathic practices.

Over time, it is anticipated that this rule amendment may benefit consumers as the cost of surgical procedures to consumers is reduced (or at least the rate of cost increase is slowed).

- (5) Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:

The Board does not believe there are less burdensome alternatives because Public Chapter 373 of the Public Acts of 2007 requires the promulgation of this rule.

- (6) Comparison of the proposed rule with any federal or state counterparts:

Federal The Board is not aware of any federal counterparts. Osteopathic physicians are not licensed by the federal government.

State The Board's office surgery rule is fairly unique amongst the health-related licensing boards in that it contains standards, requirements and limitations to a degree not typically found in other profession's rules. However, in many ways the rules resemble the Board of Medical Examiner's office based surgery rules.

- (7) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

It is not possible to exempt the impacted small businesses from all or any part of the requirements contained in the proposed rule because the impacted small businesses are the Board's licensees. If there were to be an exemption, the proposed rule amendments would have no actual effect.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

1050-02-.21 Office Based Surgery – the current rule requires physician's offices where Level III surgical procedures are performed to be accredited by any one (1) of three (3) national accrediting agencies. Public Chapter 373 of the Public Acts of 2007 required the Tennessee Board of Osteopathic Examination to promulgate more restrictive rules for office based surgery. In response, the new rule governs Level I, Level II, Level IIA, and Level III office based surgery and sets guidelines on when each type of surgery may be performed in an office setting. The rules require physician's offices where Level III surgical procedures are performed to be certified by the Board based upon standards similar to Tennessee's requirements for Ambulatory Surgical Treatment Centers.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The amendments to the Tennessee Board of Osteopathic Examination rules are made pursuant to T.C.A. §63-9-101 *et seq.*, and from Public Chapter 373 of the Public Acts of 2007.

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The amendments affect physicians who conduct any office based surgery in their practices. The Tennessee Board of Osteopathic Examination is aware of only twelve (12) Level III surgery suites in the state.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

There are no known opinions of the attorney general or any judicial ruling which relate to these rules.

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

These rules are expected to require additional resources in the form of inspection of Level III office based surgery suites by inspectors from Health Care Facilities and the creation of a new licensing program within the Tennessee Board of Osteopathic Examination. The financial impact to the department is expected to be offset the \$1080.00 fee to be paid by each office based surgery suite.

- (F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Rosemarie Otto, Executive Director of the Tennessee Board of Osteopathic Examination and Shiva Bozarth, Deputy General Counsel, possess substantial knowledge and understanding of these rules.

- (G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Rosemarie Otto, Executive Director of the Tennessee Board of Osteopathic Examination and Shiva Bozarth, Deputy General Counsel, will explain the rule at a scheduled meeting of the committees.

- (H)** Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Rosemarie Otto, Executive Director, Board of Osteopathic Examination, Suite 300, 227 French Landing Dr., Nashville, Tennessee 37243, 615-741-4540, Rosemarie.Otto@tn.gov, and Shiva Bozarth, Deputy General Counsel, Tennessee Department of Health, 220 Athens Way, Suite 210, Nashville, Tennessee 37243, 615-741-1611, Shiva.Bozarth@tn.gov.

- (I)** Any additional information relevant to the rule proposed for continuation that the committee requests.

None

(Rule 1050-02-.20, continued)

be submission of originals of those documents or sets of documents by the issuing institution(s).

- (4) Application review and licensure decisions for these types of osteopathic licensure or organization registration shall be governed by rule 1050-02-.05.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 63-1-201, 63-6-701 through 63-6-707, 63-9-101, and 63-9-115.
Administrative History: Original rule filed October 6, 2005; effective December 20, 2005.

~~**1050-02-.21 OFFICE BASED SURGERY.** Osteopathic physicians who perform Level III surgical procedures in the office based setting, pursuant to Public Chapter 373 of the Public Acts of 2007, shall perform only the Level III surgical procedures contained on the Centers for Medicare & Medicaid Services (CMS) list of procedures published in Volume 71, Number 226 of the Federal Register dated November 24, 2006, as it may from time to time be amended that are authorized for reimbursement at the Ambulatory Surgical Center (ASC) level and only those cosmetic surgical procedures that, based upon reasonable medical judgment, would require Level III sedation which is defined as follows:~~

- ~~(1) The use of a general anesthesia, deep sedation, or major conduction anesthesia and pre-operative sedation. This includes the use of:
 - ~~(a) General Anesthesia: loss of consciousness and loss of vital reflexes with probable requirement of external support of pulmonary or cardiac functions; and/or~~
 - ~~(b) Major Conduction Anesthesia (epidural, spinal, caudal); and/or~~
 - ~~(c) The use of nitrous oxide in conjunction with other types of sedatives.~~~~

1050-02-.21 Office Based Surgery. A license to practice osteopathic medicine issued pursuant to T.C.A. § 63-9-106 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 osteopathic 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 0720-10, 11 and 12.

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(3) Definitions

- (a) Acceptable Plan of Correction. The Board of Osteopathic Examination approves an Office Based Surgical Suite's plan to correct deficiencies identified during an on-site survey conducted by the Division. The plan of correction shall be a written document and shall provide, but not be limited to, the following information:
 - 1. How the deficiency will be corrected.
 - 2. Who will be responsible for correcting the deficiency.
 - 3. The date the deficiency will be corrected.
 - 4. How the facility will prevent the same deficiency from re-occurring.
- (b) 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.
- (c) ASA - American Society of Anesthesiologists.
- (d) ASTC - An ambulatory surgical treatment center licensed by the Department of Health Division of Health Care Facilities.
- (e) 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.
- (f) Board - The Tennessee Board of Osteopathic Examination.
- (g) 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.
- (h) 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.

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- (i) 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.
 - (j) 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.
 - (k) Hospital - A hospital licensed by the Department of Health Division of Health Care Facilities.
 - (l) Local Anesthetic - The administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.
 - (m) 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.
 - (n) Osteopathic Physician - A person licensed to practice osteopathic medicine and surgery pursuant to Tennessee Code Annotated Title 63, Chapter 9.
 - (o) 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.
 - (p) Surgical Suite - The operating room and recovery room(s) located in a physician's office where surgery is to be performed.
- (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).

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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).
 - (c) 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.
- (5) Level I Office Based Surgery
 - (a) Level of Anesthesia - 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 I Surgical Procedures - Procedures authorized to be performed under Level I anesthesia include, but are not limited to, the following:

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1. Minor procedures including, but 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).
- (c) Standards for Level I Office Based Surgery.
1. Training required of personnel involved in Level I Surgical Procedures. 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 which shall be age and procedure appropriate.
 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.
- (d) 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.
- (6) Levels II and IIA Office Surgery
- (a) Level of Anesthesia - The following levels of anesthesia are authorized for use in performing Level II and IIA surgical procedures:
1. Pre-operative medication and sedation introduced intravenously, intramuscularly, inhalation, orally, or rectally, thus making intra and postoperative monitoring necessary; and/or
 2. Local or peripheral major nerve block, including Bier Block; and/or

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3. Intravenous, oral, rectal or intramuscular sedation that preserve vital reflexes. However, the use of nitrous oxide in conjunction with other types of sedatives is not allowed for Level II or IIA surgical procedures; and/or
 4. Any level or type of anesthesia 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 and/or IIA surgeries.
- (b) Level II Surgical Procedures - Procedures authorized to be performed under Level II anesthesia include, but are not limited to, the following:
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 which usually require sedation.
- (c) Level IIA Surgical Procedures - are those Level II office surgical procedures 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) Standards for Level II and IIA Office Based Surgery.
1. 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.
 2. Training required of personnel involved in Level II and IIA Surgical Procedures.
 - (i) 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 Osteopathic Association or the American Board of Medical Specialties or comparable background, training, or experience.

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- (ii) 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.
 - (iii) 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.
 - (iv) Individuals monitoring patients receiving these agents shall be able to recognize the associated complications.
 - (v) 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.
3. Equipment and Supplies: All of the following which shall be age and procedure appropriate are required:
- (i) Suction devices, endotracheal tubes, laryngoscopes, etc.
 - (ii) Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
 - (iii) Double tourniquet for the Bier block procedure.
 - (iv) Monitors for blood pressure, EKG, Oxygen saturation, and temperature.
 - (v) Emergency intubation equipment.
 - (vi) Adequate operating room lighting.
 - (vii) Appropriate sterilization equipment.
 - (viii) IV solution and IV equipment.
 - (ix) Reversal or antagonist agents for medications used.
 - (x) A standard and emergency ACLS equipped cart and other such equipment as is necessary for the procedure being performed.
4. Assistance of Other Personnel Required.
- (i) During the procedure
 - (I) Level II Surgical Procedures - 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

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licensure functioning as an assisting anesthesia provider who cannot function in any other capacity during the procedure.

(II) Level IIA Surgical Procedures - 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.

(ii) 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.

5. Pre, Intra, Postoperative Services In General.

(i) 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.

(ii) 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.

(iii) 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.

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- (iv) 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.
 - (v) 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.
 - (vi) 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.
 - (vii) 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.
 - (viii) 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.
 - (ix) 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.
 - (x) If a 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.
6. Sufficient space in the room in which the surgical procedure is being performed 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.
7. 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.
8. 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.

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- (e) ASA Risk Classifications - Level II and IIA surgeries are limited to patients who fall within ASA Class 1 and 2 risk classification criteria.

(7) Level III Office Based Surgery

- (a) Levels of Anesthesia - Includes all levels of anesthesia which sedate a patient beyond the levels described in subparagraph (6)(a) of this rule which includes:

1. Deep sedation as defined by subparagraph (3)(i) of this rule; and/or
2. Major Conduction Anesthesia (epidural, spinal, caudal); and/or
3. Major conduction anesthesia and pre-operative sedation; and/or
4. General Anesthesia as defined in subparagraph (3)(j) of this rule; and/or
5. The use of nitrous oxide in conjunction with other types of sedatives.

- (b) Level III Surgical Procedures - Procedures authorized to be performed under Level III anesthesia are those contained on the Centers for Medicare & Medicaid Services (CMS) list of procedures published in Volume 71, Number 226 of the Federal Register dated November 24, 2006 as it may from time to time be amended that are authorized for reimbursement at the Ambulatory Surgical Center (ASC) level and only those cosmetic surgical procedures that, based upon reasonable medical judgment, would require Level III sedation. The surgical procedures authorized pursuant to this subparagraph are limited to those that also have all the following characteristics:

1. Have a planned duration of less than four (4) hours. This includes multiple surgeries regardless of the level of surgery; the combined planned duration of all planned procedures shall be less than four (4) hours; and
2. Generally result in blood loss of less than ten percent (10%) of estimated blood volume in a patient with normal hemoglobin; and
3. Will not require major or prolonged intracranial or intrathoracic procedures; and
4. Will not require major or prolonged abdominal or major hip replacement procedures (this criteria does not apply to laparoscopic procedures); and
5. Will not be generally emergent or life threatening in nature.

- (c) Application for Certification and Renewal-

1. Application for Certification - A physician office which contains operating and recovery rooms wherein Level III office based surgeries are to be performed, which shall be referred to as "surgical suites" for purposes of this rule, must obtain certification from the Board before any Level III surgical procedures may be performed therein. The process for obtaining that certification is as follows:

- (i) Obtain the Board's Level III Office Based Surgery Certification application (which shall also serve as the official request for a

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site survey) and provide all the information requested thereon which shall include the following:

- (I) The name of a responsible physician in whose name the surgical suite certification shall be issued who shall also arrange to have provided, for each physician in the office who will be performing Level III procedures, the following information and/or documentation:
 - (II) A statement identifying all Level III procedures expected to be performed by each such physician; and
 - (III) A copy of what, if any, specialty board certification or board eligibility has been obtained by each such physician; and
 - (IV) Written verification of medical malpractice coverage from each physician's malpractice insurance carrier; and
 - (V) Written verification of hospital staff privileges from at least one hospital at which each of the physicians has been granted staff privileges that is within thirty (30) miles or thirty (30) minutes from the surgical suite.
- (ii) Submit copies of both the office's by-laws and its documentation of the management system that will insure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time.
 - (iii) Submit the Surgical Suite Certification fee in the amount of one thousand eighty dollars (\$1,080.00) and the state regulatory fee of five dollars (\$5.00).
 - (iv) Obtain a surgical suite site survey performed by the Board's authorized agents to determine compliance with the standards set forth in this rule. Those authorized agents shall have the authority to:
 - (I) Require plans of correction from the physician office for any deficiencies they may find in compliance with the standards set forth in this rule and to make a determination of the acceptability of the submitted plans of correction, and verify that the plans of correction have been implemented.
 - (II) Initiate subsequent, unannounced site surveys during regular business hours as long as the physician office continues to be used to perform Level III office-based surgeries but no more frequently than once every twelve (12) months.
 - (III) Respond to any complaints made by patients or the public against a physician who performs office based surgery or a physician's office at which Level III office-

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based surgery is being performed at the request of the Department's office of investigations.

- (v) Receive approval from the Board on the result of the surgical suite site survey.
- 2. Renewal of Certification - A physician office which obtains Level III Office Based Surgery Certification for its surgical suites, must renew that certification every year by submitting to the Board the annual renewal fee in the amount of one thousand eighty dollars (\$1,080.00) and the state regulatory fee of five dollars (\$5.00), on or before its anniversary date.
- 3. The information required to be included on and/or with the application form as itemized in subparagraph (c) 1 (i) and (ii) of this rule must be updated within thirty (30) days of the date on which any of the provided information or documentation has changed or additions need to be made.
- 4. Transition Provisions -
 - (i) In order for a physician office at which Level III office-based surgeries have been performed prior to October 1, 2007, (pursuant to certifications/accreditations received pursuant to prior Board rules) to continue doing so, the office must submit an application and a request for a site survey and remit payment of the Surgical Suite Certification fee and the state regulatory fee to the Board by October 1, 2007. If such office makes a timely filing in accordance with this provision, the physician's office may continue to be a site for office-based surgeries pending completion of a survey confirming compliance with board rules and subsequent issuance of a certification of the surgical suite(s).
 - (ii) A physician office at which office-based surgeries have not been performed as of October 1, 2007, (pursuant to certifications/accreditations received pursuant to prior Board rules) shall not perform any such procedures until an application form and payment of the Surgical Suite Certification fee and the state regulatory fee are submitted to the board and a site survey is completed and a certification of the surgical suite is issued by the board.
- (d) Level III Surgery Standards - All physician offices for which certification for performance of Level III surgeries is to be sought and obtained shall meet the following standards:
 - 1. Infection Control
 - (i) The surgical suite(s) must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.

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- (ii) The physical environment of the surgical suite(s) shall be maintained in a safe, clean and sanitary manner.
 - (I) Any condition on the surgical suite(s) site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.
 - (II) Cats, dogs or other animals shall not be allowed in any part of the surgical suite except for specially trained animals for the handicapped and except as addressed by physician office policy for pet therapy programs. The physician's office shall designate in its policies and procedures those areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the surgical suite performed by medically trained personnel.
 - (III) A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.
 - (IV) Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.
 - (V) Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.
 - (VI) Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each use is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.
- (iii) The physician office shall assure that an infection control committee including members of the medical, nursing and administrative staff develops guidelines and techniques for the prevention, surveillance, control and reporting of surgical suite infections. Duties of the committee shall include the establishment of:
 - (I) Written infection control policies;

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- (II) Techniques and systems for identifying, reporting, investigating and controlling infections in the facility;
 - (III) Written procedures governing the use of aseptic techniques and procedures in all areas of the facility;
 - (IV) Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;
 - (V) A log of incidents related to infectious and communicable diseases;
 - (VI) A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;
 - (VII) Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as hand washing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and
 - (VIII) Continuing education provided for all office personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.
- (iv) The physician office must ensure that the facility-wide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.
 - (v) The physician office shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that any person, employee or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.
 - (vi) The physician office and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases.
 - (vii) The physician office shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome

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2. Life Safety

- (i) All surgical suites shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities (if applicable), and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing surgical suites are subject to the requirements of the Americans with Disabilities Act (A.D.A.). Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.
- (ii) Any surgical suite(s) which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.
- (iii) A surgical suite(s) shall be provided fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the Board within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the facility may omit the name(s) of patient(s) and parties involved, however, should the department find the identities of such persons to be necessary to an investigation, the facility shall provide such information.
- (iv) The following alarms are required and shall be monitored twenty-four (24) hours per day:
 - (I) Fire alarms; and
 - (II) Generators (if applicable).
- (v) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms.
- (vi) The emergency power system shall:
 - (I) Use either propane, gasoline or diesel fuel. The generator shall be designed to meet the facility's HVAC and essential needs and shall have a minimum of twenty-four (24) hours of fuel designed to operate at its rated load. The fuel quantity shall be based on its

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release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The physician office must have policies to govern access and duplication of the patient's record;

(VI) To have appropriate assessment and management of pain; and

(VII) To be involved in the decision making of all aspects of their care.

(ii) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

4. Hazardous Waste

(i) Each physician office must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.

(ii) The following waste shall be considered to be infectious waste:

(I) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals;"

(II) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures;

(III) Waste human blood and blood products such as serum, plasma, and other blood components;

(IV) Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;

(V) All discarded sharps (including but not limited to, hypodermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;

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- (VI) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals;
 - (VII) Other waste determined to be infectious by the physician office in its written policy.
- (iii) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the physician office.
- (iv) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.
- (I) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;
 - (II) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;
 - (III) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste;
 - (IV) Opaque packaging must be used for pathological waste.
- (v) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.
- (I) Waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal;
 - (II) Plastic bags of infectious waste must be transported by hand.
- (vi) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction,

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- and minimizes the potential of exposure or access by unknowing persons.
- (I) Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.
 - (II) Pathological waste must be promptly treated, disposed of, or placed into refrigerated storage.
- (vii) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the physician office must ensure that proper actions are immediately taken to:
- (I) Isolate the area from the public and all except essential personnel;
 - (II) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of subpart (iv) of this part;
 - (III) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedures must specify how this will be done; and
 - (IV) Complete incident report and maintain copy on file.
- (viii) Except as provided otherwise in this section a physician office must treat or dispose of infectious waste by one or more of the methods specified in this part.
- (I) A physician office may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious wastes treated in such a device are rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management

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requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (nonhazardous) solid waste under current rules of the Department of Environment and Conservation.

- (II) The physician may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §§ 69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.
- (III) Any physician office accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.
- (ix) The physician office may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the physician office must ensure that it has all necessary State and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the physician office must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable Federal and State requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.
- (x) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subpart. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.
- (xi) All garbage, trash and other non-infectious wastes shall be stored and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, be constructed of easily cleanable material and be kept on elevated platforms.

5. Equipment and Supplies

- (i) Adequate equipment and supplies must be available to the operating room suites and to the postoperative care area which, when applicable shall be age and procedure appropriate and shall include but not be limited to the following;

- (I) Call-in system (OR)

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- (II) Cardiac monitor
- (III) Pulse Oximeter
- (IV) Resuscitator
- (V) Defibrillator
- (VI) Aspirator
- (VII) Tracheotomy set

(ii) A crash cart must be available and include at a minimum all the medication and supplies recommended by the current ACLS guidelines of the American Heart Association and:

- (I) Dantrolene

6. Administration

- (i) Physician offices that perform office-based surgery must adopt bylaws that put in place a management system and documentation that will insure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time.
- (ii) Except for emergencies, a surgical suite certified for office based surgery may be utilized only by physician employees of the practice in which the surgical suite is located. Surgical suites may not be shared with other practices or other physicians.
- (iii) When licensure is applicable for a particular job within the surgery suite, a copy of the current license must be included as a part of the personnel file. Each personnel file shall contain accurate information as to the education, training, experience, and personnel background of the employee.
- (iv) The surgical suite shall have available a plan for emergency transportation to a licensed local hospital.
- (v) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.
- (vi) There must be a complete history and physical work-up in the chart of every patient prior to surgery. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.
- (vii) Properly executed informed consent forms must be in the patient's chart before surgery, except in emergencies.

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- (viii) The physician office shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.
- (ix) The physician office shall report to the Department of Health each case of communicable disease detected in the office. Repeated failure to report communicable diseases shall be cause for revocation of a surgical suite's certification.
- (x) Any claim required to be reported under T.C.A. §56-54-101 (Reports on Medical Malpractice Claims) shall be reported to the Department of Health in a format designed by the Department within seven (7) business days of the date of the payment of the claim.
- (xi) Unusual events shall be reported by the physician office to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.
 - (l) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:
 - I. medication errors;
 - II. aspiration in a non-intubated patient related to conscious/moderate sedation;
 - III. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;
 - IV. volume overload leading to pulmonary edema;
 - V. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;
 - VI. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;
 - VII. burns of a second or third degree;

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- VIII. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;
- IX. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:
 - A. procedure related injury requiring repair or removal of an organ;
 - B. hemorrhage;
 - C. displacement, migration or breakage of an implant, device, graft or drain;
 - D. post operative wound infection following clean or clean/contaminated case;
 - E. any unexpected operation or reoperation related to the primary procedure;
 - F. hysterectomy in a pregnant woman;
 - G. ruptured uterus;
 - H. circumcision;
 - I. incorrect procedure or incorrect treatment that is invasive;
 - J. wrong patient/wrong site surgical procedure;
 - K. unintentionally retained foreign body;
 - L. loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;
 - M. criminal acts;
 - N. suicide or attempted suicide;
 - O. elopement from the facility;
 - P. infant abduction, or infant discharged to the wrong family;

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- Q. adult abduction;
 - R. rape;
 - S. patient altercation;
 - T. patient abuse, patient neglect, or misappropriation of resident/patient funds;
 - U. restraint related incidents; or
 - V. poisoning occurring within the facility.
7. 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.
8. Training Required – The physician performing the surgery must have documentation of training to perform the particular surgical procedures and must have knowledge of the principles of general anesthesia. The physician performing the surgery and at least one (1) assistant must be currently certified in ACLS.
9. Assistance of Other Personnel Required.
- (i) 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.
 - (ii) When general anesthesia using volatile anesthetic gases, succinylcholine or other agents known to trigger malignant hyperthermia are administered, the surgical suite shall maintain or have immediate access to thirty-six (36) ampoules of dantrolene and its diluent for injection. If dantrolene is administered, appropriate monitoring must be provided postoperatively.
 - (iii) 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

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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.

- (III) 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.
- 10. Level III surgical suites shall be used exclusively for surgery and recovery, respectively and for no other purpose.
- 11. Physicians performing Level III surgery in an office setting shall obtain written informed consent prior to the procedure from the patient or the patient's representative which shall be documented in the patient's health record. The consent shall explain to the patient the risks and benefits of the procedure; the alternative treatments to the surgical procedure; the type of anesthesia to be used and its risks; and the qualifications of the professional who is expected to administer the anesthesia during the procedure.
- 12. A physician performing Level III surgery in an office setting must inform the patient, in writing, that the medical office is not a licensed facility and that the patient may elect to have the surgery performed at a licensed ASTC or hospital. The patient or the patient's representative must consent in writing to have the surgery performed in a medical office.
- (e) ASA Risk Classifications - Only patients classified under the ASA risk classification criteria as Class 1 or 2 are appropriate candidates for Level III office based surgical procedures.
- (f) The Board shall post on its web site a list, including the names and locations of physician offices that have qualified as sites for Level III surgeries and have been issued certification by the Board. Information on the list shall be updated at least quarterly.
- (8) Procedure Specific Restrictions
 - (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.

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- (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.
- (9) 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.
- (10) Any violation of these rules shall be grounds for disciplinary actions before the board pursuant to T.C.A. § 63-9-111(b) (1), (2) or (4) or Public Chapter 373 of the Public Acts of 2007.
 - (a) When a physician office is found by the department to have committed a violation of this chapter, the department will issue a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the physician office must return a plan of correction indicating the following:
 1. How the deficiency will be corrected.
 2. Who will be responsible for correcting the deficiency.
 3. The date the deficiency will be corrected.
 4. How the facility will prevent the same deficiency from re-occurring.
 - (b) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject a surgical suite's certification to possible disciplinary action.

Authority: T.C.A. § 63-6-221, 63-9-101, 63-9-106, 63-9-111, and 63-9-117. **Administrative History:** Public necessity new rule filed October 5, 2007; expired March 18, 2008. Public necessity rule filed October 5, 2007 expired effective March 19, 2007, and reverted to its previous status. Original rule filed January 25, 2008; effective April 8, 2008.

1050-02-.22 TAMPER-RESISTANT PRESCRIPTIONS.

- (1) Purpose.

This rule is designed to implement the law requiring that licensed osteopathic physicians have all written, typed, or computer-generated prescriptions issued on tamper-resistant prescription paper.

- (2) Definitions.

The following definitions are applicable to this rule:

- (a) "Drug" shall have the same meaning as set forth in T.C.A. § 63-10-204(16).