Notice of Rulemaking Hearing

Board of Osteopathic Examination

There will be a hearing before the Tennessee Board of Osteopathic Examination to consider the promulgation of an amendment to a rule pursuant to T.C.A. §§ 4-5-202, 4-5-204, 63-9-101, and Public Chapter 373 of the Public Acts of 2007. The hearing will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204 and will take place in the Department of Health Conference Center's Iris Room on the First Floor of the Heritage Place Building located at 227 French Landing, Nashville, TN at 10:30 a.m. (CST) on the 21st day of May, 2008.

Any individuals with disabilities who wish to participate in these proceedings (review these filings) should contact the Department of Health, Division of Health Related Boards to discuss any auxiliary aids or services needed to facilitate such participation or review. Such initial contact may be made no less than ten (10) days prior to the scheduled meeting date (the date such party intends to review such filings), to allow time for the Division to determine how it may reasonably provide such aid or service. Initial contact may be made with the ADA Coordinator at the Division of Health Related Boards, 227 French Landing, Suite 300, Heritage Place, MetroCenter, Nashville, TN 37243, (615) 532-4397.

For a copy of the entire text of this notice of rulemaking hearing contact:

Schean G. Belton, Assistant General Counsel, Office of General Counsel, 220 Athens Way, Suite 210, Plaza I, MetroCenter, Nashville, TN 37243, (615) 741-1611.

Substance of Proposed Rule

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

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 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 Examiners approves an Office Based Surgery Suite's plan to correct deficiencies identified during an on-site survey conducted by the Department. The plan of correction shall be a written document and shall provide, but not be limited to, the following information:

i. How the deficiency will be corrected?

ii. Who will be responsible for correcting the deficiency?

iii. The date the deficiency will be corrected.

iv. 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 Examiners.

(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's 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's 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's 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, Chapters 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 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, or the patient suffers cardiac or respiratory arrest during the procedure, the patient must be transferred to a hospital or acute care facility for continued operative/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, or the patient suffers cardiac or respiratory arrest during the procedure, the patient must be transferred to a hospital or acute care facility for continued operative/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's 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; and

(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 the patient has not recovered sufficiently to be safely discharged within twelve (12) hours after the initial administration of anesthesia, or the patient suffers cardiac or respiratory arrest during the procedure, the patient must be transferred to a hospital or acute care facility for continued operative/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)(h) 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)(i) 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 Department before any Level III surgical procedures may be performed therein. The process for obtaining that certification is as follows:

(i) Obtain the Department’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. Such

physician shall in turn, also arrange to provide the following information and/or documentation, for each physician in the office who will be performing Level III procedures; and

(II) A statement identifying all Level III procedures expected to be performed by each physician; and

(III) A copy of what, if any, specialty board certification or board eligibility has been obtained by each physician; and

(IV) Written verification of medical malpractice coverage from each physicians' malpractice insurance carrier; and

(V) Written verification of hospital staff privileges from at least one (1) hospital at which each of the physicians listed has been granted staff privileges that are 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 Department to determine compliance with the standards set forth in this rule. The Department 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 Department 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 and 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 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 (1) 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. If individual equipment for each use is provided then the equipment must be sterilized or disinfected between patients 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 facility 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 the Center for Disease Control (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 facilities 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 facilities are subject to the requirements of the Americans with Disabilities Act (ADA). 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:

(a) Fire alarms; and

(b) 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:

(a) Utilize 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.

(b) Automatically transfer within ten (10) seconds to the surgical suit conducting invasive surgical procedures.

(c) 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.

(d) Emergency generators are not required if the facility 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; and

(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 leak proof, 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; and

(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; and

(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; and

(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 others except essential personnel;

(II) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of subpart (vi) of this part;

(III) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure 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 (1) 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 such device 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 subparagraph. 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

(VIII) 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.

(v) Properly executed informed consent forms must be in the patient's chart before surgery, except in emergencies.

(vi) The facility 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.

(vii) The physician office shall report to the Department of Health each case of communicable disease detected in the surgical suite. Repeated failure to report communicable diseases shall be cause for revocation of a surgical suite's license.

(viii) Any claim required to be reported under Tenn Code Ann. § 56-54-101 (Reports on Medical Malpractice Cliams) 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.

(ix) Unusual events shall be reported by the facility 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.

(a) 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:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. 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;

7. burns of a second or third degree;

8. 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;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

   (i) procedure related injury requiring repair or removal of an organ;

   (ii) hemorrhage;

   (iii) displacement, migration or breakage of an implant, device, graft or drain;

   (iv) post operative wound infection following clean or clean/contaminated case;

   (v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) 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;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) 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 physician office 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 facility shall maintain or have immediate access to thirty-six (36) ampules of dantrolene and its diluent for injection. If dantrolene is administered, appropriate monitoring must be provided postoperatively.

(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.

(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, or the patient suffers cardiac or respiratory arrest during the procedure, the patient must be transferred to a hospital or acute care facility for continued operative/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 surgical suite is found by the Department to have committed a violation of this chapter, the Department will issue to the physician office a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the physician office must return a policy of correction indicating the following:

(i) How the deficiency will be corrected?

(ii) The date upon which each deficiency will be corrected;

(iii) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur? and

(iv) How the corrective action will be monitored to ensure that the deficient practice does not recur?

(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 the surgical suite's certificaion to possible disciplinary action.

Authority: T.C.A. §§ 63-9-101, 63-9-106, 63-9-111, and Public Chapter 373 of the Public Acts of 2007.

The notice of rulemaking set out herein was properly filed in the Department of State on the 11th day of March, 2008. (FS 03-04-08; DBID 834)