Nebraska

None

Nevada – Medical


§ 449.435. Definitions
As used in NRS 449.435 to 449.448, inclusive, unless the context otherwise requires, the words and terms defined in NRS 449.436 to 449.439, inclusive, have the meanings ascribed to them in those sections.

449.436. “Conscious sedation” defined
“Conscious sedation” means a minimally depressed level of consciousness, produced by a pharmacologic or nonpharmacologic method, or a combination thereof, in which the patient retains the ability independently and continuously to maintain an airway and to respond appropriately to physical stimulation and verbal commands.

449.437. “Deep sedation” defined
“Deep sedation” means a controlled state of depressed consciousness, produced by a pharmacologic or nonpharmacologic method, or a combination thereof, and accompanied by a partial loss of protective reflexes and the inability to respond purposefully to verbal commands.

449.438. “General anesthesia” defined
“General anesthesia” means a controlled state of unconsciousness, produced by a pharmacologic or nonpharmacologic method, or a combination thereof, and accompanied by partial or complete loss of protective reflexes and the inability independently to maintain an airway and respond purposefully to physical stimulation or verbal commands.

449.439. “Physician” defined
“Physician” means a person who is licensed to practice medicine pursuant to chapter 630 of NRS or osteopathic medicine pursuant to chapter 633 of NRS.

449.441. Exemption from provisions if physician’s office or facility only administers certain type of pain medication
The provisions of NRS 449.435 to 449.448, inclusive, do not apply to an office of a physician or a facility that provides health care, other than a medical facility, if the office of a physician or the facility only administers a medication to a patient to relieve the patient’s anxiety or pain and if the medication is not given
in a dosage that is sufficient to induce in a patient a controlled state of depressed consciousness or
unconsciousness similar to general anesthesia, deep sedation or conscious sedation.

449.442. Permit required for certain physicians’ offices and facilities to offer services; national accreditation
required; cessation of services for failure to maintain accreditation
1. An office of a physician or a facility that provides health care, other than a medical facility, must obtain a
permit pursuant to NRS 449.443 before offering to a patient a service of general anesthesia, conscious
sedation or deep sedation. An office of a physician or a facility that provides health care, other than a medical
facility, which operates at more than one location must obtain a permit for each location where a service of
general anesthesia, conscious sedation or deep sedation is offered.
2. To offer to a patient a service of general anesthesia, conscious sedation or deep sedation in this State, an
office of a physician or a facility that provides health care, other than a medical facility, must maintain current
accreditation by a nationally recognized organization approved by the Board. Upon receiving an initial
permit, the office or facility shall, within 6 months after obtaining the permit, submit proof to the Health
Division of accreditation by such an organization.
3. If an office of a physician or a facility that provides health care, other than a medical facility, fails to
maintain current accreditation or if the accreditation is revoked or is otherwise no longer valid, the office or
facility shall immediately cease offering to patients a service of general anesthesia, conscious sedation or deep
sedation.

449.443. Application for permit; fee; inspection by Health Division; term of permit
1. An office of a physician or a facility that provides health care, other than a medical facility, desiring a
permit pursuant to NRS 449.435 to 449.448, inclusive, must submit to the Health Division, on a form
prescribed by the Health Division and accompanied by the appropriate fee, an application for a permit.
2. Before issuing a permit, the Health Division shall conduct an on-site inspection pursuant to NRS
449.446 of each office of a physician or facility that applies for a permit.
3. Upon receipt of an application and the appropriate fee, the Health Division may, after conducting an
inspection pursuant to NRS 449.446, issue a permit.
4. A permit expires 1 year after the date of issuance and is renewable pursuant to NRS 449.444.

449.444. Application for renewal of permit; fee
1. The holder of a permit issued pursuant to NRS 449.443 may annually submit to the Health Division, on a
form prescribed by the Health Division and accompanied by the appropriate fee, an application for renewal
of the permit before the date on which the permit expires. The application must include proof satisfactory to
the Health Division that the office or facility maintains current accreditation by a nationally recognized
organization approved by the Board.
2. Upon receipt of an application for renewal and the accompanying fee, the Health Division may renew a
permit.

449.445. National accreditation required of surgical center for ambulatory patients; inspection by Health
Division; cessation of operation for failure to maintain accreditation
1. To operate in this State, a surgical center for ambulatory patients must maintain current accreditation by a
nationally recognized organization approved by the Board. Upon initial licensure, a surgical center for
ambulatory patients shall, within 6 months after obtaining its license, submit proof to the Health Division of
the accreditation of the surgical center by such an organization.
2. Before issuing a license to a surgical center for ambulatory patients, the Health Division shall conduct an
on-site inspection of the surgical center pursuant to NRS 449.446.
3. If a surgical center for ambulatory patients fails to maintain current accreditation or if the accreditation is
revoked or is otherwise no longer valid, the surgical center shall immediately cease to operate.
449.446. Annual inspections of holders of permits and surgical centers for ambulatory patients; correction of deficiencies identified in inspections; reporting of inspections to Legislature
1. The Health Division shall conduct annual and unannounced on-site inspections of each office of a physician or a facility that provides health care, other than a medical facility, which holds a permit issued pursuant to NRS 449.443 and each surgical center for ambulatory patients which holds a license issued pursuant to this chapter.
2. An inspection conducted pursuant to this section must focus on the infection control practices and policies of the surgical center for ambulatory patients, the office or the facility that is the subject of the inspection. The Health Division may, as it deems necessary, conduct a more comprehensive inspection of a surgical center, office or facility.
3. Upon completion of an inspection, the Health Division shall:
   (a) Compile a report of the inspection, including each deficiency discovered during the inspection, if any; and
   (b) Forward a copy of the report to the surgical center for ambulatory patients, the office of the physician or the facility where the inspection was conducted.
4. If a deficiency is indicated in the report, the surgical center for ambulatory patients, the office of the physician or the facility shall correct each deficiency indicated in the report in the manner prescribed by the Board pursuant to NRS 449.448.
5. The Health Division shall annually prepare and submit to the Legislative Committee on Health Care and the Legislative Commission a report which includes:
   (a) The number and frequency of inspections conducted pursuant to this section;
   (b) A summary of deficiencies or other significant problems discovered while conducting inspections pursuant to this section and the results of any follow-up inspections; and
   (c) Any other information relating to the inspections as deemed necessary by the Legislative Committee on Health Care or the Legislative Commission.

49.447. Violations; penalties; review of reports submitted pursuant to NRS 630.30665 and 633.524; reporting to professional licensing board of violations; administrative sanctions
1. If an office of a physician or a facility that provides health care, other than a medical facility, violates the provisions of NRS 449.435 to 449.448, inclusive, or the regulations adopted pursuant thereto, or fails to correct a deficiency indicated in a report pursuant to NRS 449.446, the Health Division, in accordance with the regulations adopted pursuant to NRS 449.448, may take any of the following actions:
   (a) Decline to issue or renew a permit;
   (b) Suspend or revoke a permit; or
   (c) Impose an administrative penalty of not more than $1,000 per day for each violation, together with interest thereon at a rate not to exceed 10 percent per annum.
2. The Health Division may review a report submitted pursuant to NRS 630.30665 or 633.524 to determine whether an office of a physician or a facility is in violation of the provisions of NRS 449.435 to 449.448, inclusive, or the regulations adopted pursuant thereto. If the Health Division determines that such a violation has occurred, the Health Division shall immediately notify the appropriate professional licensing board of the physician.
3. If a surgical center for ambulatory patients violates the provisions of NRS 449.435 to 449.448, inclusive, or the regulations adopted pursuant thereto, or fails to correct a deficiency indicated in a report pursuant to NRS 449.446, the Health Division may impose administrative sanctions pursuant to NRS 449.163.

449.448. Regulations
Currentness
1. The Board shall adopt regulations to carry out the provisions of NRS 449.435 to 449.448, inclusive, including, without limitation, regulations which:
   (a) Prescribe the amount of the fee required for applications for the issuance and renewal of a permit pursuant to NRS 449.443 and 449.444.
   (b) Prescribe the procedures and standards for the issuance and renewal of a permit.
(c) Identify the nationally recognized organizations approved by the Board for the purposes of the accreditation required for the issuance of a:
(1) License to operate a surgical center for ambulatory patients.
(2) Permit for an office of a physician or a facility that provides health care, other than a medical facility, to offer to a patient a service of general anesthesia, conscious sedation or deep sedation.
(d) Prescribe the procedures and scope of the inspections conducted by the Health Division pursuant to NRS 449.446.
(e) Prescribe the procedures and time frame for correcting each deficiency indicated in a report pursuant to NRS 449.446.
(f) Prescribe the criteria for the imposition of each sanction prescribed by NRS 449.447, including, without limitation:
(1) Setting forth the circumstances and manner in which a sanction applies;
(2) Minimizing the time between the identification of a violation and the imposition of a sanction; and
(3) Providing for the imposition of incrementally more severe sanctions for repeated or uncorrected violations.

2. The regulations adopted pursuant to this section must require that the practices and policies of each holder of a permit to offer to a patient a service of general anesthesia, conscious sedation or deep sedation and each holder of a license to operate a surgical center for ambulatory patients provide adequately for the protection of the health, safety and well-being of patients.

Nevada – Osteopathic

N.R.S. 633.524 Osteopathic physician required to report certain information concerning surgeries and sentinel events; effect of failure to report; duties of Board; confidentiality of report; applicability

1. The Board shall require each holder of a license to practice osteopathic medicine issued pursuant to this chapter to submit to the Board, on a form provided by the Board, and in the format required by the Board by regulation, a report stating the number and type of surgeries requiring conscious sedation, deep sedation or general anesthesia performed by the holder of the license at his or her office or any other facility, excluding any surgical care performed:
(1) At a medical facility as that term is defined in NRS 449.0151; or
(2) Outside of this State.

2. In addition to the report required pursuant to subsection 1, the Board shall require each holder of a license to practice osteopathic medicine to submit a report to the Board concerning the occurrence of any sentinel event arising from any surgery described in subsection 1. The report must be submitted in the manner prescribed by the Board which must be substantially similar to the manner prescribed by the State Board of Health for reporting information pursuant to NRS 439.835.

3. Each holder of a license to practice osteopathic medicine shall submit the reports required pursuant to subsections 1 and 2:
(a) At the time the holder of the license renews his or her license; and
(b) Whether or not the holder of the license performed any surgery described in subsection 1. Failure to submit a report or knowingly filing false information in a report constitutes grounds for initiating disciplinary action pursuant to NRS 633.511.

4. In addition to the reports required pursuant to subsections 1 and 2, the Board shall require each holder of a license to practice osteopathic medicine to submit a report to the Board concerning the occurrence of any sentinel event arising from any surgery described in subsection 1 within 14 days after the occurrence of the sentinel event. The report must be submitted in the manner prescribed by the Board.

5. The Board shall:
(a) Collect and maintain reports received pursuant to subsections 1, 2 and 4;
(b) Ensure that the reports, and any additional documents created from the reports, are protected adequately from fire, theft, loss, destruction and other hazards, and from unauthorized access; and
(c) Submit to the Health Division a copy of the report submitted pursuant to subsection 1. The Health Division shall maintain the confidentiality of such reports in accordance with subsection 6.

6. Except as otherwise provided in NRS 239.0115, a report received pursuant to subsection 1, 2 or 4 is confidential, not subject to subpoena or discovery, and not subject to inspection by the general public.

7. The provisions of this section do not apply to surgical care requiring only the administration of oral medication to a patient to relieve the patient's anxiety or pain, if the medication is not given in a dosage that is sufficient to induce in a patient a controlled state of depressed consciousness or unconsciousness similar to general anesthesia, deep sedation or conscious sedation.

8. In addition to any other remedy or penalty, if a holder of a license to practice osteopathic medicine fails to submit a report or knowingly files false information in a report submitted pursuant to this section, the Board may, after providing the holder of a license to practice osteopathic medicine with notice and opportunity for a hearing, impose against the holder of a license an administrative penalty for each such violation. The Board shall establish by regulation a sliding scale based on the severity of the violation to determine the amount of the administrative penalty to be imposed against the holder of the license to practice osteopathic medicine. The regulations must include standards for determining the severity of the violation and may provide for a more severe penalty for multiple violations.

9. As used in this section:
(a) “Conscious sedation” has the meaning ascribed to it in NRS 449.436.
(b) “Deep sedation” has the meaning ascribed to it in NRS 449.437.
(c) “General anesthesia” has the meaning ascribed to it in NRS 449.438.
(d) “Health Division” has the meaning ascribed to it in NRS 449.009.
(e) “Sentinel event” means an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof, including, without limitation, any process variation for which a recurrence would carry a significant chance of serious adverse outcome. The term includes loss of limb or function.

New Hampshire

None

New Jersey

Subchapter 4a. Surgery, Special Procedures and Anesthesia Services Performed in an Office Setting

13:35-4A.1 Purpose
These rules are designed to promote the health, safety and welfare of the members of the general public who undergo surgery (other than minor surgery), special procedures and receive anesthesia services in an office setting.

13:35-4A.2 Scope
(a) This subchapter establishes policies and procedures and staffing and equipment requirements for practitioners and physicians who perform surgery (other than minor surgery), special procedures and administer anesthesia services in an office setting.
(b) For purposes of this subchapter, the standards set forth at N.J.A.C. 13:35-4A.6 do not apply to those performing non-invasive special procedures, such as non-invasive radiologic procedures. However, the standards set forth at N.J.A.C. 13:35-4A.7, including the privileging standards set forth at (a) above, do apply to the anesthesia services provided in connection with all special procedures, whether invasive or non-invasive.
13:35-4A.3 Definitions
The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Advanced cardiac life support trained” means that a licensee has successfully completed an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (APLS) is appropriate.

“Anesthesia services” means administration of any anesthetic agent with the purpose of creating conscious sedation, regional anesthesia or general anesthesia. For the purposes of this subchapter, the administration of topical or local anesthesia, minor conduction blocks, pain management or pain medication shall not be deemed to be anesthesia services.

“Anesthesiologist” means a physician who has successfully completed a residency program in anesthesiology approved by the Accreditation Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who currently is a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

“Anesthetic agent” means any drug or combination of drugs administered with the purpose of creating conscious sedation, regional anesthesia or general anesthesia.

“Anesthetizing location” means any location in an office where anesthetic agents are administered to a patient.

“Board” means the New Jersey State Board of Medical Examiners.

“Certified registered nurse anesthetist” (CRNA) means a registered professional nurse who is licensed in this State and who holds current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA), and who meets the conditions for practice as a nurse anesthetist as set forth at N.J.A.C. 13:37-13.1.

“Complications” means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia services which was performed in an office setting including, but not limited to, any of the following events: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, wound infections requiring intravenous antibiotic treatment or hospitalization, unintended return to an operating room or hospitalization, death or temporary or permanent loss of function not considered to be a likely or usual outcome of the procedure.

“Conscious sedation” means the administration of a drug or drugs in order to induce that state of consciousness in a patient which allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function and the ability to respond purposefully to verbal command or to tactile stimulation if verbal response is not possible as, for example, in the case of a small child or deaf person. For the purposes of this subchapter, conscious sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. Within the context of this subchapter, “conscious sedation” shall be synonymous with the term “sedation/analgesia” as used by the American Society of Anesthesiologists.

“General anesthesia” means the administration of a drug or drugs which cause loss of consciousness as the result of which the patient is unable to make meaningful responses but may still display reflex withdrawal from a painful stimulus.

“Health care personnel” means any office staff member who is licensed by a professional or health care occupational licensing board such as a professional registered nurse, licensed practical nurse or physician assistant.

“Hospital” means a hospital licensed by the state in which it is situated.
“Local anesthesia” means an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

“Minor conduction block” means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, local infiltration or local nerve block), or the block of a nerve by direct pressure or refrigeration. Minor conduction blocks include, but are not limited to, retrobulbar blocks, peribulbar blocks, pudendal blocks, digital blocks, metacarpal blocks and ankle blocks. “Minor conduction block” does not include regional anesthesia that affects larger areas of the body, such as brachial plexus anesthesia or spinal anesthesia.

“Minor surgery” means surgery which can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intra-operative tranquilization and where the likelihood of complications requiring hospitalization is remote. Minor surgery specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor surgery also specifically excludes procedures which may be performed under local anesthesia, but which involve extensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor surgery includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other surgery limited to the skin and subcutaneous tissue. Additional examples of minor surgery include closed reduction of a fracture, the incision and drainage of abscesses, certain simple ophthalmologic surgical procedures, such as treatment of chalazions and non-invasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses and paracenteses. Minor surgery shall not include any procedure identified as “major surgery” within the meaning of N.J.A.C. 13:35-4.1.

“Monitoring” means continuous visual observation of a patient and continuous observation of the patient using instruments to measure, display and record the values of certain physiologic variables, such as pulse, oxygen saturation, blood pressure, end-tidal carbon dioxide and respiration.

“Office” means a location at which medical, surgical or podiatric services are rendered and which contains only one operating room and which is not subject to the jurisdiction and licensure requirements of the New Jersey State Department of Health and Senior Services.

“Operating room” means that location in the office dedicated to the performance of surgery or special procedures.

“Pain management” means the administration to a patient, by any route, of pharmacologic agents or drugs which are not intended to result in a loss of consciousness, awareness or defensive reflexes, but which are intended to alleviate pain. It includes the use or application of other modalities and medical devices such as, but not limited to, heat or cold, massage, transepidermal nerve stimulation (TENS), and neurolytic techniques such as radiofrequency coagulation and cryotherapy.

“Pain medication” means, for the purpose of this subchapter, the administration to a patient, by any route, of pharmacologic agents or drugs which are not intended to result in a loss of consciousness, awareness or defensive reflexes, but which are intended to alleviate pain occurring in the absence of an invasive, operative or manipulative procedure.

“Physical status classification” means a description of a patient used in determining if an office surgery or procedure is appropriate. The American Society of Anesthesiologists enumerates classifications: I--Normal healthy patient; II--A patient with mild systemic disease; III--A patient with severe systemic disease limiting activity but not incapacitating; IV--A patient with incapacitating systemic disease that is a constant threat to life; and V--Moribund patients not expected to live 24 hours with or without operation.

“Physician” means an individual holding an M.D. or D.O. degree licensed pursuant to N.J.S.A. 45:9-1 et seq.

“Podiatrist” means an individual holding a D.P.M. degree licensed pursuant to N.J.S.A. 45:5-1 et seq.

“Practitioner” means a physician or a podiatrist.

“Privileges” means the authorization granted to a practitioner or physician by a hospital licensed in the jurisdiction in which it is located to provide specified services or alternatively by the Board pursuant to
N.J.A.C. 13:35-4A.12, such as surgery or the administration or the supervision of administration of one or more types of anesthetic agents or procedures.

“Recovery area” means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

“Regional anesthesia” means the administration of anesthetic agents to a patient to interrupt nerve impulses without loss of consciousness and includes epidural, caudal, spinal and brachial plexus anesthesia. Regional anesthesia does not include minor conduction blocks as defined in this section.

“Special procedure” means patient care which requires anesthesia services because it involves entering the body with instruments in a potentially painful manner, or requires the patient to be immobile, for a diagnostic or therapeutic procedure. Examples of special procedures include diagnostic or therapeutic endoscopy or bronchoscopy performed utilizing conscious sedation or general anesthesia; invasive radiologic procedures performed utilizing conscious sedation; pediatric magnetic resonance imaging performed utilizing conscious sedation; or manipulation under anesthesia (MUA). The term special procedure does not include a procedure which only requires medication to reduce anxiety such as oral benzodiazepine unless the dose given is intended to provide conscious sedation.

“Supervision” means responsibility by a credentialed physician who is immediately available to oversee the administration and monitoring of anesthesia by health care personnel authorized by this rule to render anesthesia services in an office.

“Surgery” means a manual or operative procedure, including the use of lasers, performed upon the body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering. Surgery includes, but is not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; a closed or open reduction of a fracture or extraction of tissue from the uterus.

“Topical anesthesia” means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

13:35-4A.4 Policies and procedures requirements
(a) Practitioners who perform surgery (other than minor surgery) or special procedures and physicians who administer or supervise the administration or monitoring of anesthesia services in an office shall establish written policies and procedures concerning the following:
1. The specific surgical or special procedures which may be performed in the office;
2. The specific anesthesia services which may be performed in the office;
3. The responsibilities of the health care personnel providing services to patients in the office;
4. The infection control practices to be followed, including lawful disposal of hazardous waste;
5. The procedures to be followed in the event that a patient experiences a complication;
6. The procedures to be followed if the patient requires transport for emergency services, including the identity and telephone numbers of the ambulance service if one is to be utilized and the hospital to which the patient is to be transported, and the functions to be undertaken by health care personnel until a transfer of the patient is completed;
7. The procedures to be followed in the event that a surgery or special procedure needs to be terminated because of an equipment malfunction or other complication;
8. The procedures to be followed while a patient is recovering in the office;
9. The objective criteria for discharging patients; and
10. The procedures to be followed to review records, and to ensure follow-up on complications and outcomes.
(b) The written policies and procedures shall also contain the identity of the specific practitioners within the office who are responsible for ensuring that:
1. All healthcare personnel providing services to patients possess the qualifications required by this subchapter and are currently licensed, registered or certified, as applicable;
2. All equipment and instruments utilized in the performance of surgery are maintained in proper working order and in accordance with such sterilization techniques as are required for safe medical practice;
3. All equipment and safety systems utilized in the administration and monitoring of anesthesia as required by N.J.A.C. 13:35-4A.14 are maintained in proper working order;
4. All emergency equipment and supplies as required by N.J.A.C. 13:35-4A.13 are available and are not outdated; and
5. All medical records are audited on at least an annual basis to assess quality of care and complications.
   (c) The written policies and procedures are to be reviewed annually and revised as needed with the person conducting the review or making the revision recording the date thereof.
   (d) Written policies and procedures shall be presented to the Board upon request.

3:35-4A.5 Duty to report incidents related to surgery, special procedures or anesthesia in an office
Any incident related to surgery, special procedures or the administration of anesthesia within the office which results in a patient death, transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, or a complication or untoward event as defined in N.J.A.C. 13:35-4A.3, shall be reported to the Executive Director of the Board within seven days, in writing and on such forms as shall be required by the Board. Such reports shall be investigated by the Board and will be deemed confidential pursuant to N.J.S.A. 45:9-19.3.

13:35-4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery and discharge
(a) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall be privileged to perform that surgery or special procedure by a hospital. If a practitioner is not privileged but wishes to perform surgery or special procedures in an office, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.
(b) Before any practitioner may perform surgery (other than minor surgery), or special procedures, the practitioner shall have:
   1. A written transfer agreement with a licensed hospital with acute care capabilities which can be reached within 20 minutes during all hours in which surgery or special procedures are performed in the office, if the hospital where the practitioner is privileged is not reachable within 20 minutes or if the practitioner is privileged by the Board; and
   2. A written policy for handling emergency transport to a hospital at which the practitioner is privileged through 9-1-1 call or a written transfer agreement with a licensed ambulance service which assures immediate transport of patients experiencing complications to the hospital which the practitioner has established a transfer agreement. The written transfer agreement shall be posted in the office and all health care personnel in the office shall specifically be informed of the procedure to be followed.
   (c) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall provide pre-procedure counseling and preparation as follows:
      1. The practitioner shall appropriately assess, or review a referring physician's assessment of, the physical condition of the patient on whom surgery or a special procedure is to be performed. The practitioner shall refer a patient who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility for the performance of the surgery or the special procedure.
      Only patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.
      2. A history and physical examination shall be performed within the 14 days preceding the proposed surgery either by the practitioner performing the surgery or procedure (as appropriate to that practitioner's scope of practice) or by another physician or physician assistant under the supervision of a physician. Necessary
laboratory tests, as guided by the patient's underlying medical condition, shall be conducted within seven days preceding the proposed surgery;
3. The risks and benefits of the surgery or special procedure and alternative methods or treatments shall be fully explained by the practitioner or other health care personnel, and written informed consent for the specific surgery or special procedure contemplated shall be obtained from the patient, guardian or authorized representative;
4. An appropriate fasting protocol shall be explained and provided to the patient;
5. If the history and physical are not done on the same day as the procedure, an interim assessment shall be performed by the practitioner or a physician assistant under the supervision of a physician immediately prior to the procedure, which assessment shall be documented and dated; and
6. Prior to surgery, the practitioner shall ensure that the patient removes all cosmetics, jewelry, contact lenses, dental appliances and prosthetic devices which might reasonably jeopardize patient safety.
(d) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall ensure the following during recovery and prior to discharge:
1. Immediately after the surgery or special procedure, the patient shall be evaluated by either the practitioner who performed the surgery or the physician or CRNA who administered the anesthesia;
2. At least one practitioner shall remain on the premises until the patient is discharged from the recovery area;
3. The patient shall be provided with written and verbal instructions for follow-up care and with advice concerning possible complications; and
4. The patient shall be discharged into the company of a responsible individual.
(e) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall prepare a patient record which shall include the following:
1. A pre-procedure medical history and physical, appropriate to the practitioner's scope of practice, including such data as allergies, physical and mental impairments, vital signs, drug use, mobility limitations and, as applicable, electrocardiogram results, radiologic findings, laboratory values and the identity of the examining practitioner;
2. Documentation reflecting that informed consent has been obtained;
3. A description of the surgery or special procedure performed, including pre-operative diagnosis, techniques used, names and titles of medical personnel participating, complete findings, post-operative diagnosis, and any unusual occurrence, complications or untoward events. Where similar procedures are performed at the 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;
4. A post-procedure note, entered prior to discharge from the office, which shall include at least such post-procedure data as the patient's general condition, vital signs, any treatments ordered, and all drugs prescribed, administered or dispensed including dosages, quantities and strengths;
5. The identity of healthcare personnel providing services, as evidenced by a legible signature following that staff member's notation in the patient's record; and
6. The plan for follow-up care and documentation of results of follow-up efforts.
(f) No practitioner who performs surgery (other than minor surgery) or special procedures in an office shall:
1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or
2. Accept for the performance of surgery or a special procedure a patient to whom an anesthetic agent had been administered for that surgery or special procedure prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances, unless the patient is accompanied by medical personnel from an acute care facility.

13:35-4A.7 Standards for administering or supervising the administration of anesthesia services in an office; pre-anesthesia counseling; patient monitoring; recovery; patient record; discharge of patient
(a) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall be privileged by a hospital to provide the particular anesthesia service. If a practitioner is not
privileged but wishes to administer or supervise the administration of anesthesia services, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35-4A.12 to seek Board-approved privileging.

(b) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall provide pre-anesthesia counseling and preparation as follows:

1. Any patient to whom anesthesia services are to be provided shall be appropriately screened by the individual administering anesthesia services. Patients who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) shall be referred to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility. Only patients with an ASA physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

2. A medical history shall be conducted including a review of abnormalities in any organ system; previous adverse experience with anesthesia services; any history of stridor, snoring or sleep apnea, or of advanced rheumatoid arthritis or spinal disorder; current medications being taken; drug allergies; or any history of substance abuse;

3. The risks and benefits of anesthesia and alternative methods or treatments shall be fully explained by the physician or certified registered nurse anesthetist (CRNA), and written informed consent for the anesthesia services contemplated shall be obtained from the patient, guardian or authorized representative;

4. An appropriate fasting protocol shall be explained and timely provided to the patient, guardian or authorized representative;

5. Pre-procedure laboratory test results shall be reviewed and recorded;

6. A focused physical examination shall be conducted, including auscultation of the heart and lungs, and an evaluation of the airway, particularly an assessment of anatomical abnormalities (that is, jaw, mouth, head and neck) which may increase the likelihood of an airway obstruction;

7. A plan of anesthesia shall be developed by the physician administering anesthesia services or personally reviewed by the supervising physician if the plan has been developed by other authorized personnel;

8. A patient shall be counseled prior to the procedure that the procedure will be canceled if the patient plans to drive home after the procedure and has not made arrangements to be accompanied home by an individual who accepts responsibility for the patient; and

9. Prior to the administration of anesthesia services, the physician shall ensure that the patient removes all cosmetics, jewelry, contact lenses, dental appliances and prosthetic devices which might reasonably jeopardize patient safety.

(c) A physician who administers or supervises the administration or monitoring of any anesthesia services (general anesthesia, regional anesthesia or conscious sedation) in an office shall ensure that monitoring is provided as follows when clinically feasible for the patient:

1. Direct observation of the patient and, to the extent practicable, observation of the patient's responses to verbal commands;

2. Pulse oximetry shall be performed continuously. Any alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness;

3. An electrocardiogram monitor shall be used continuously on the patient;

4. The patient's blood pressure, pulse rate, and respirations shall be measured at least every five minutes; and

5. The body temperature of a pediatric patient shall be measured continuously.

(d) In addition to the monitoring requirements in (c) above, a physician who administers or supervises the administration or monitoring of general anesthesia services in an office shall ensure that additional monitoring is provided as follows:

1. End-tidal carbon dioxide monitoring shall be performed on the patient continuously during endotracheal anesthesia;

2. An in-circuit oxygen analyzer shall be used to monitor the oxygen concentration within the breathing circuit, displaying the oxygen percent of the total inspiratory mixture;
3. A respirometer (volumeter) shall be used to measure exhaled tidal volume whenever the breathing circuit of a patient allows;
4. The body temperature of each patient shall be measured continuously; and
5. An esophageal or precordial stethoscope shall be available and utilized on the patient when indicated.

(e) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall establish within that office a recovery area and ensure that recovery services are provided as follows:

1. Immediately after the surgery or special procedure, the practitioner who performed the surgery or the individual who administered the anesthesia shall evaluate the patient;
2. The individual responsible for the administration or monitoring of anesthesia shall accompany the patient into the recovery area;
3. Healthcare personnel who were present with the patient at the anesthetizing location shall remain with the patient in the recovery area at least until the patient’s vital signs, including blood pressure, pulse, and respiration are recorded;
4. An oral report on the patient's condition shall be given to any healthcare personnel in the recovery area not present in the anesthetizing location;
5. Whenever a patient is present in the recovery area, the recovery area shall be staffed by at least one registered professional nurse or physician assistant who is trained and experienced in advanced cardiac life support and post anesthesia care. This includes recognizing the actions and interactions of anesthetic techniques, managing of airway and ventilatory function and managing patients during altered states of consciousness, as well as cardiopulmonary resuscitation, monitoring of cardiac function, recognition of arrhythmias, and the recognition and treatment of life-threatening emergencies. For every additional two patients present in the recovery area, there shall be one additional professional registered nurse or physician assistant present, having the requisite training;
6. In addition to the healthcare personnel specified in (e)5 above, at least one other additional healthcare personnel shall remain on site in a position to render immediate assistance whenever a patient is in the recovery room; and
7. From the time of entry into the recovery area until discharge, the condition of the patient shall be regularly evaluated and the patient’s vital signs checked at least every five minutes. If the patient's vital signs remain unchanged, documentation can be reflected with a straight line on the chart; any changes shall be specifically noted. Electrocardiographic monitoring and pulse oximetry monitoring shall be continued in the recovery area for each patient who has received anesthesia services.

(f) A practitioner who administers or supervises the administration and monitoring of anesthesia services may allow a patient dischargeable to home pursuant to N.J.A.C. 13:35-4A.4(a)9 and 4A.6(d) to remain in the office for a period not to exceed 23 hours in an overnight stay area, if the patient may benefit from additional care. The overnight stay area shall be staffed by at least one registered professional nurse or physician assistant for each two patients in the overnight stay area, the patient's vital signs shall be taken and recorded at least every four hours and a physician shall be able to reach the office within 20 minutes. Appropriate sleeping accommodations, as well as food, shall be provided for the patient.

(g) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall ensure the following prior to discharge:

1. That at least one practitioner shall remain on the premises until the patient is discharged to home or transferred to the special overnight stay area;
2. That the patient shall be given written and verbal instructions for follow-up care and advice concerning complications;
3. That before the patient leaves the office or is transferred to the overnight stay area, the physician shall evaluate the patient and shall review and sign the postanesthesia record; and
4. That the patient shall be discharged only into the company of a responsible individual.

(h) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall ensure that a patient record is prepared which contains the following:
1. A pre-anesthesia note, including pre-anesthesia vital signs (blood pressure, temperature, respiration rate and pulse), and a plan of anesthesia;
2. Signed informed consent from the patient, guardian or authorized representative;
3. An intra-procedure record which includes anesthetic agents and techniques used, any changes since the inception of anesthesia in vital signs, oxygen saturation, electrocardiogram interpretation, temperature and end-tidal carbon dioxide measurements when required, as well as the volume and type of fluids administered;
4. A post-anesthesia note entered prior to the patient's discharge from the office which shall include at least such post-procedure data as the patient's vital signs and general condition, respiration, consciousness, circulation, special problems or precautions and a summary of fluids received during surgery or any complication or untoward event which occurred;
5. The identity of each healthcare personnel providing services, as evidenced by the staff member's legible signature on each entry made by that staff member in the patient record; and
6. The plan for follow-up care.

(i) No practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall:
1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or
2. Accept for the performance of surgery or a special procedure a patient to whom an anesthetic agent had been administered for that surgery or special procedure prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances, unless the patient is accompanied by medical personnel from an acute care facility.

13:35-4A.8 Performance of general anesthesia; authorized personnel
(a) General anesthesia shall be administered and monitored in an office only by the following individuals:
1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide general anesthesia services and who, during every consecutive three-year period beginning July 1, 2004, completes at least 60 Category I hours of continuing medical education in anesthesia which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or
2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.
(b) The administration and monitoring of general anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or special procedure. This subsection shall not be construed to preclude the conversion of conscious sedation to general anesthesia in an emergency to protect the health of the patient, even if there is no physician present who would be qualified to administer and monitor general anesthesia pursuant to (a)1 above.
(c) When the administration and monitoring of general anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.
(d) An advanced cardiac life support-trained physician, registered professional nurse or physician assistant shall remain with the patient at all times that the patient is receiving or recovering from general anesthesia.

13:35-4A.9 Administration of regional anesthesia; authorized personnel
(a) Regional anesthesia shall be administered and monitored in an office only by the following individuals:
1. A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide regional anesthesia and who, during every consecutive three-year period beginning July 1, 2004, completes at least eight Category I hours of continuing medical education in anesthesia exclusively, or in anesthesia as it relates to the physician's field of practice, which either meet the criteria for credit towards the Physician's
Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or
2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.

(b) The administration and monitoring of regional anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or the special procedure.
(c) When the administration and monitoring of regional anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency, without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.
(d) An advanced cardiac life support trained physician, registered professional nurse or physician assistant shall be present at all times when a patient is receiving or recovering from regional anesthesia.

13:35-4A.10 Administration of conscious sedation; authorized personnel
(a) Conscious sedation shall be administered in an office only by the following individuals:
1. A practitioner privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide conscious sedation and who, during every consecutive three-year period beginning July 1, 2004, completes at least eight Category I or II hours of continuing medical education in any anesthesia services, including conscious sedation exclusively, or in anesthesia as it relates to the physician's field of practice, which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association;
2. A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above; or
3. A registered professional nurse or physician assistant, who is trained and has experience in the use and monitoring of anesthetic agents, at the specific direction of a physician qualified under (a)1 above, but only for the purpose of administering through an established intravenous line, a specifically prescribed supplemental dose of conscious sedation which was selected and initially administered by the physician who remains continuously present in the procedure room. “Continuously present in the procedure room” does not require that a practitioner remain in the procedure room in violation of human exposure safety standards regularly employed during radiological procedures.
(b) A patient under conscious sedation shall be monitored in an office by a physician, CRNA, or a registered professional nurse or physician assistant who has training and experience in the use of monitoring devices, under the supervision of a physician eligible under (a)1 above, to administer conscious sedation.
(c) The monitoring of a patient under conscious sedation shall be provided by an individual who meets the requirements of (b) above and who is at all times present and who is not the practitioner who is performing the surgery or special procedure.
(d) When the administration and monitoring of conscious sedation is being performed by a CRNA, or when the monitoring is being performed by a registered professional nurse or physician assistant, the supervising physician shall be physically present, but may be concurrently responsible for patient care.
(e) An advanced cardiac life support-trained physician, registered nurse or physician assistant shall be present at all times when a patient is receiving or recovering from the administration of conscious sedation.

13:35-4A.11 Administration of minor conduction blocks; authorized personnel
(a) Minor conduction blocks (with the exception of retrobulbar blocks) shall be administered in an office for surgery or special procedures only by the following individuals:
1. A practitioner;
2. A certified registered nurse anesthetist (CRNA); or
3. A certified nurse midwife, an advanced practice nurse or physician assistant who has training and experience in the administration of minor conduction blocks.
(b) Retrobulbar blocks shall be administered in the office only by a physician privileged by a hospital or by the Board pursuant to N.J.A.C. 13:35-4A.12.

13:35-4A.12 Alternative privileging procedure
(a) A practitioner who seeks to provide or supervise the administration and monitoring of general or regional anesthesia, as well as conscious sedation, in an office, but does not hold privileges at a licensed hospital to do so, shall submit to the Board an application for these privileges. To be eligible to apply for these privileges, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:
1. Demonstration of clinical experience, through an attestation as to the number of procedures for which general or regional anesthesia was provided by the applicant in the last two years for all age groups of patients within the applicant's practice for which privileges are requested;
2. Any one of the following:
   i. Current certification in anesthesiology granted by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology or any other certification entity that the applicant demonstrates has standards of comparable rigor;
   ii. Successful completion of a residency training program in anesthesiology accredited by the Accreditation Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA); or
   iii. Supervised training in residency, fellowship or other equivalent experience in another field and active participation in the examination process leading to certification in anesthesiology; and
3. Possess clinical competence to perform the anesthesia services or procedures authorized by the requested privileges, with such competence confirmed by the following:
   i. Three references submitted directly by plenary licensed physicians addressing the applicant's current competence based on personal knowledge obtained either during a residency training completed during the two years preceding the application or through personal observation during the two years preceding the application;
   ii. Submission of a log listing all patients for whom the applicant provided any of the anesthesia services in an office setting or licensed ambulatory care facility setting for which privileges have been requested during the two years preceding the date of the application. The log shall include a patient number, the type of anesthesia service provided, the surgery or special procedure performed and the date(s) of service. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log;
   iii. Identification of any patients in the log who have experienced complications relating to the applicant's provision of anesthesia services in an office setting or licensed ambulatory care facility setting and their resulting outcomes; and
   iv. Submission of no fewer than five patient records or charts (or the pertinent portions thereof with patient names redacted) which have been identified and requested by the Board or other reviewing entity, designated pursuant to (e) below, along with a completed case summary form for each submitted case, utilizing such forms as are provided in the application materials.
(b) A practitioner who seeks to administer or supervise the administration and monitoring of only conscious sedation in an office, but does not currently hold clinical privileges at a licensed hospital to do so, shall submit to the Board an application for this privilege. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:
1. Demonstration of clinical experience, through an attestation as to the number of procedures for which conscious sedation was provided by the applicant in the last two years for all age groups within the applicant's practice of patients for which privileges are requested, except age groups as are specifically excluded from the applicant's practice;
2. Any one of the following:
i. Current certification in anesthesiology granted by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology or any other certification entity the applicant demonstrates has standards of comparable rigor;

ii. Current certification in Critical Care Medicine or Emergency Medicine by a specialty board or certifying entity recognized by the American Board of Medical Specialties (“ABMS”) or the American Osteopathic Association (“AOA”) or any other certification entity the applicant demonstrates has standards of comparable rigor; or

iii. Satisfactory evidence that the applicant is advanced cardiac life support trained with updated training from a recognized accrediting organization and either:

(1) Successful completion of an educational home study program, with a test of basic knowledge obtained from the Board; or

(2) A course in conscious sedation offered by a licensed hospital or for continuing medical education credits; and

3. Submission of a list of all patients who have experienced complications relating to the applicant's provision of conscious sedation in an office setting or licensed ambulatory care facility setting and their resulting outcomes. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log.

(c) A practitioner who seeks to perform surgery (other than minor surgery) or special procedures in an office, but does not hold privileges at a licensed hospital to perform these procedures shall submit to the Board an application for these privileges, including a completed privilege request form appropriate to the privileges requested. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1. Demonstration of clinical experience, through an attestation as to the number and type of procedures performed by the applicant in the last two years for all age groups of patients for which privileges are requested;

2. Any one of the following:

   i. Current certification in the field(s) of practice in which the privileges are sought granted by a specialty board or certifying entity recognized by the American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), the American Podiatric Medicine Association (APMA) or any other certification entity that the applicant demonstrates has standards of comparable rigor;

   ii. Successful completion of an Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) residency or fellowship training program in the field(s) of practice in which privileges are sought; or

   iii. Supervised training in a residency or fellowship training or other equivalent experience in another field and active participation in the examination process leading to certification in the practice field(s) in which privileges are sought; and

3. Possess clinical competence to perform the procedures authorized by the requested privileges, with such competence confirmed by the following:

   i. Three references submitted directly by plenary licensed physicians (or licensed podiatrists as to podiatric applicants) addressing the applicant's current competence based on personal knowledge obtained either during a residency training completed during the two years preceding the application or through personal observation during the two years preceding the application;

   ii. Submission of a log listing all patients for whom the applicant has performed surgery or special procedures in an office setting or licensed ambulatory care facility setting for which privileges have been requested during the two years preceding the date of the application. The log shall include a patient number, the surgery or special procedure performed and the indications for that procedure and the date(s) of service. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log;

   iii. Identification of any patients in the log who have experienced complications relating to the applicant's performance of surgery or special procedures in an office setting or licensed ambulatory care facility setting and their resulting outcomes; and
iv. Submission of no fewer than five patient records or charts (or the pertinent portions thereof with patient names redacted) which have been identified and requested by the Board or other reviewing entity, along with a completed case summary form for each submitted case, utilizing such forms as are provided in the application materials.

(d) A practitioner who seeks to utilize laser surgery techniques in an office, but does not hold privileges at a licensed hospital to do so, shall submit to the Board an application, which shall include:
1. Certification of successful completion of an accredited laser training program, in which the curriculum includes instruction in laser care, physics and clinical indications for utilization of the specific laser; or
2. Documentation from the program director of an accredited residency training program which the applicant has successfully completed, attesting to the inclusion of training in the specific laser therapy for which privileges are being sought during residency training.

(e) The Board may delegate to a reviewing entity the responsibility to conduct a preliminary review of an application to ascertain whether the applicant has met the criteria established in (a) through (d) above, which review shall be undertaken at the expense of the applicant. The Board shall thereafter review the summary report including any recommendation concerning the applicant prepared by the reviewer and make a decision on the application for privileges.

(f) If the Board or any entity or person to which the Board may delegate the preliminary application review finds that the applicant has not submitted sufficient information upon which a determination as to the applicant's current competence may be made, the Board or the reviewing entity may require:
1. A personal interview;
2. The submission of a representative sample of patient records substantiating the experience of the applicant;
3. The submission of any patient records relating to an identified complication;
4. An inspection of the office, which may include a review of additional patient records and written policies and procedures; and/or
5. The submission of such additional information as may be necessary to determine an applicant's clinical competence to perform the privileges requested.

(g) Upon review of the summary report prepared by the Board or the reviewing entity, the Board may take any of the following actions:
1. Grant all or some of the privileges requested;
2. Condition its approval of all or some of the privileges requested on the applicant's successful completion of additional training;
3. Condition its approval of all or some of the privileges on the applicant's successful completion of a period of observation;
4. Deny all or some of the privileges requested; and/or
5. Require such additional information as may be necessary to act on the application.

(h) Practitioners who have been granted privileges through the alternative privileging procedure of this section shall submit a renewal application to the Board within two years from the date on which privileges were granted. Practitioners shall notify the Board within 21 days should there be any change in the information provided in the application and renewal.

13:35-4A.13 Requirements for anesthetizing locations; emergency equipment and supplies

(a) An office in which any anesthesia services are to be provided shall be equipped with the appropriate medical equipment, supplies and pharmacological agents which are required or might be needed in order to provide anesthetic and recovery services, as well as to treat any likely complication which might arise as a result of these services, in such manner that complies with the accepted standards of care as set forth in the “Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists” of the American Society of Anesthesiology (520 Northwest Highway, Park Ridge, IL 60068-2573), appearing in Anesthesiology, Vol. 84, No. 2, February 1996, incorporated herein by reference, as amended and supplemented.

(b) An office in which general anesthesia is to be provided shall be equipped with the following additional emergency equipment:
1. Special equipment to manage a difficult airway;
2. Drugs and equipment to treat malignant hyperthermia, shock and anaphylactic reactions;
3. A precordial stethoscope or esophageal stethoscope; and
4. A peripheral nerve stimulator.
(c) In an office in which anesthesia services are to be provided to infants and children, the required emergency equipment shall be appropriately sized for a pediatric population.

13:35-4A.14 Requirements for anesthetizing locations; safety systems, monitoring devices
(a) An office in which anesthesia services are to be provided shall be equipped with the following safety systems and monitoring devices:
1. A pulse oximeter with appropriate alarms (or an equivalent method of measuring oxygen saturation);
2. A continuous electrocardiograph with paper recorder;
3. Devices for measuring blood pressure, heart rate and respiratory rate;
4. A defibrillator; and
5. An accepted method of identifying and preventing the interchangeability of gases, whenever gases are used.
(b) Any anesthesia machine or built-in anesthesia system utilized in the administration of general anesthesia in an office shall be equipped with the following:
1. An end-tidal carbon dioxide monitor (capnograph);
2. An in-circuit oxygen analyzer designed to monitor the oxygen concentration within the breathing circuit by displaying the oxygen percent of the total inspiratory mixture;
3. A respirometer (volumeter) measuring exhaled tidal volume;
4. Oxygen failure-protection devices (“fail-safe” system) which have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;
5. A vaporizer exclusion (“interlock”) system, which ensures that only one vaporizer, and therefore only a single anesthetic agent, can be actuated on any anesthesia machine at one time;
6. Pressure-compensated anesthesia vaporizers, designed to administer a constant non-pulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;
7. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21 percent from being administered;
8. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and
9. A gas evacuation system.
(c) Anesthesia equipment used in the administration of anesthesia services for the performance of MRI shall be made of nonferrous materials to ensure the quality of the diagnostic studies. Monitoring techniques shall take into consideration the unique characteristics of the magnetic field.
(d) In an office in which anesthesia services are to be provided to infants and children, the required monitoring devices shall be appropriately sized for a pediatric population.

13:35-4A.15 Equipment requirements for recovery areas
(a) In any office in which anesthesia services are to be provided, a recovery area adjacent to, or within the operating room, shall be established. Access to the recovery area shall be limited to staff and family or significant others, as appropriate. The recovery area shall be equipped with at least the following:
1. A pulse oximeter with appropriate alarms (or an equivalent method of measuring oxygen saturation);
2. A continuous electrocardiogram monitor with paper recorder;
3. A defibrillator;
4. Drugs adequate for cardiopulmonary resuscitation;
5. Emergency equipment for intubation and extubation; and
6. Basic airway management equipment as follows:
1. A source of compressed oxygen (tank with regulator or pipeline supply with flowmeter);
ii. A source of suction, suction catheters, Yankauer-type suction;
iii. Face masks (in appropriate sizes for the patient population);
iv. A self-inflating breathing bag-valve set, oral and nasal airways and lubricant; and
v. A method by which oxygen can be administered (for example, masks, nasal cannulas).

13:35-4A.16 Maintenance requirements
(a) All equipment as required by N.J.A.C. 13:35-4A.13 through 4A.15 is subject to inspection and
maintenance as follows:
1. A record shall be maintained of all service and maintenance including that performed on all anesthesia
machines, ventilators and vaporizers. The record shall include machine identification; the name of the
servicing agent; the problem, if any; the work performed and the date of the work. Maintenance shall
conform with maintenance requirements established by the machine manufacturer. Credentials of each
servicing agent shall be approved by the machine manufacturer or shall be reasonably determined by the
permit holder to be equivalent to the credentials of the manufacturer's servicing agents.
2. All anesthesia equipment shall be inspected fully at the beginning of each day of use by a physician, or a
certified registered nurse anesthetist (CRNA), under the supervision of a physician, credentialed to utilize that
equipment. A record of each such inspection, including the date of the inspection and the identity of the
individual conducting the inspection, shall be maintained for each machine. The inspection shall conform
with a checklist that is supplied by the manufacturer of the machine, or issued by the Federal Food and Drug
Administration or, alternatively, reasonably developed by the physician and set forth in an appropriate
written protocol.
3. Before each use, the physician or the CRNA who is to administer the anesthesia shall inspect all anesthesia
equipment. Inspections shall be documented on the anesthesia record.
(b) A physician shall not permit anyone to tamper with a safety system or any monitoring device or
disconnect an alarm system.

13:35-4A.17 Compliance timetables
(a) A practitioner who does not hold privileges at a hospital shall submit an application to the Board seeking
approval pursuant to the alternative privileging process set forth at N.J.A.C. 13:35- 4A.12, prior to offering
such services. Notwithstanding any other provision in this subchapter, a practitioner who has submitted an
application for alternative privileging by December 16, 2003, may continue to offer services for which
privileges have been requested until such time as the Board acts upon that application.
(b) A practitioner or physician who offers anesthesia services in an office setting shall purchase and install the
equipment and safety systems, as required pursuant to this rule prior to offering such services.

13:35-4A.18 Enforcement
(a) Any violation of N.J.A.C. 13:35-4A.3 through 4A.17 shall be deemed to be professional misconduct
within the meaning of N.J.S.A. 45:1-21(e) and may further constitute violation of other law or rule, as
applicable to the circumstances.

New Mexico – Medical

None

New Mexico – Osteopathic

None
1. The following words or phrases, as used in this section shall have the following meanings:
(a) “Accredited status” means the full accreditation by nationally-recognized accrediting agency(ies) determined by the commissioner.
(b) “Adverse event” means (i) patient death within thirty days; (ii) unplanned transfer to a hospital; (iii) unscheduled hospital admission, within seventy-two hours of the office-based surgery, for longer than twenty-four hours; or (iv) any other serious or life-threatening event.
(c) “Deep sedation” means a drug-induced depression of consciousness during which (i) the patient cannot be easily aroused but responds purposefully following repeated painful stimulation; (ii) the patient's ability to maintain independent ventilatory function may be impaired; (iii) the patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and (iv) the patient’s cardiovascular function is usually maintained without assistance.
(d) “General anesthesia” means a drug-induced depression of consciousness during which (i) the patient is not arousable, even by painful stimulation; (ii) the patient's ability to maintain independent ventilatory function is often impaired; (iii) the patient, in many cases, often requires assistance in maintaining a patent airway and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function; and (iv) the patient’s cardiovascular function may be impaired.
(e) “Moderate sedation” means a drug-induced depression of consciousness during which (i) the patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation; (ii) no interventions are required to maintain a patent airway; (iii) spontaneous ventilation is adequate; and (iv) the patient's cardiovascular function is usually maintained without assistance.
(f) “Minimal sedation” means a drug-induced state during which (i) patients respond normally to verbal commands; (ii) cognitive function and coordination may be impaired; and (iii) ventilatory and cardiovascular functions are unaffected.
(g) “Minor procedures” means (i) procedures that can be performed safely with a minimum of discomfort where the likelihood of complications requiring hospitalization is minimal; (ii) procedures performed with local or topical anesthesia; or (iii) liposuction with removal of less than 500 cc of fat under unsupplemented local anesthesia.
(h) “Office-based surgery” means any surgical or other invasive procedure, requiring general anesthesia, moderate sedation, or deep sedation, and any liposuction procedure, where such surgical or other invasive procedure or liposuction is performed by a licensee in a location other than a hospital, as such term is defined in article twenty-eight of this chapter, excluding minor procedures and procedures requiring minimal sedation.
(i) [Eff. until Feb. 17, 2014. See, also, par. (i) below.] “Licensee” shall mean an individual licensed or otherwise authorized under articles one hundred thirty-one or one hundred thirty-one-B of the education law.
(j) [Eff. Feb. 17, 2014. See, also, par. (i) above.] “Licensee” shall mean an individual licensed or otherwise authorized under article one hundred thirty-one, one hundred thirty-one-B, individuals who have obtained an issuance of a privilege to perform podiatric standard or advanced ankle surgery pursuant to subdivisions one and two of section seven thousand nine of the education law.
2. Licensee practices in which office-based surgery is performed shall obtain and maintain full accredited status.
3. A licensee may only perform office-based surgery in a setting that has obtained and maintains full accredited status.
4. Licensees shall report adverse events to the department’s patient safety center within one business day of the occurrence of such adverse event. Licensees shall also report any suspected health care disease transmission originating in their practices to the patient safety center within one business day of becoming aware of such suspected transmission. For purposes of this section, health care disease transmission shall mean the transmission of a reportable communicable disease that is blood borne from a health care professional to a patient or between patients as a result of improper infection control practices by the health care professional. The reported data shall be subject to all confidentiality provisions provided by section twenty-nine hundred ninety-eight-e of this chapter.
5. The commissioner shall make, adopt, promulgate and enforce such rules and regulations, as he or she may deem appropriate, to effectuate the purposes of this section. Where any rule or regulation under this section would affect the scope of practice of a health care practitioner licensed, registered or certified under title eight of the education law other than those licensed under articles one hundred thirty-one or one hundred thirty-one-B of the education law, the rule or regulation shall be made with the concurrence of the commissioner of education.

McKinney’s Public Health Law § 2998-e. Reporting of adverse events in office based surgery

1. The commissioner shall enter into agreements with accrediting agencies pursuant to which the accrediting agencies shall report, at a minimum, aggregate data on adverse events for all office-based surgical practices accredited by the accrediting agencies to the department. The department may disclose reports of aggregate data to the public.
2. The information required to be collected, maintained and reported directly to the department pursuant to section two hundred thirty-d of this chapter shall be kept confidential and shall not be released, except to the department and except as required or permitted under subdivision nine-a and subparagraph (v) of paragraph (a) of subdivision ten of section two hundred thirty of this chapter. Notwithstanding any other provision of law, none of such information shall be subject to disclosure under article six of the public officers law or article thirty-one of the civil practice law and rules.
3. The commissioner shall make, adopt, promulgate and enforce such rules and regulations, as he or she may deem appropriate, to effectuate the purposes of this section. Where any rule or regulation under this section would affect the scope of practice of a health care practitioner licensed, registered or certified under title eight of the education law other than those licensed under articles one hundred thirty-one or one hundred thirty-one-B of the education law, the rule or regulation shall be made with the concurrence of the commissioner of education.

North Carolina

Office Based Procedures Position Statement
http://www.ncmedboard.org/position_statements/detail/office-based_procedures/

Preface
This Position Statement on Office-Based Procedures is an interpretive statement that attempts to identify and explain the standards of practice for Office-Based Procedures in North Carolina. The Board’s intention is to articulate existing professional standards and not to promulgate a new standard. This Position Statement is in the form of guidelines designed to assure patient safety and identify the criteria by which the Board will assess the conduct of its licensees in considering disciplinary action arising out of the performance of office-based procedures. Thus, it is expected that the licensee who follows the guidelines set forth below will avoid disciplinary action by the Board. However, this Position Statement is not intended to be comprehensive or to set out exhaustively every standard that might apply in every circumstance. The
silence of the Position Statement on any particular matter should not be construed as the lack of an enforceable standard.

General guidelines
The Physician’s professional and legal obligation
The North Carolina Medical Board has adopted the guidelines contained in this Position Statement in order to assure patients have access to safe, high quality office-based surgical and special procedures. The guidelines further assure that a licensed physician with appropriate qualifications takes responsibility for the supervision of all aspects of the perioperative surgical, procedural and anesthesia care delivered in the office setting, including compliance with all aspects of these guidelines. These obligations are to be understood (as explained in the Preface) as existing standards identified by the Board in an effort to assure patient safety and provide licensees guidance to avoid practicing below the standards of practice in such a manner that the licensee would be exposed to possible disciplinary action for unprofessional conduct as contemplated in N.C. Gen. Stat. § 90-14(a)(6).

Exemptions
These guidelines do not apply to Level I procedures.

Written policies and procedures
Written policies and procedures should be maintained to assist office-based practices in providing safe and quality surgical or special procedure care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients.

Emergency procedure and transfer protocol
The physician who performs the surgical or special procedure should assure that a transfer protocol is in place, preferably with a hospital that is licensed in the jurisdiction in which it is located and that is within reasonable proximity of the office where the procedure is performed. All office personnel should be familiar with and capable of carrying out written emergency instructions. The instructions should be followed in the event of an emergency, any untoward anesthetic, medical or surgical complications, or other conditions making hospitalization of a patient necessary. The instructions should include arrangements for immediate contact of emergency medical services when indicated and when advanced cardiac life support is needed. When emergency medical services are not indicated, the instructions should include procedures for timely escort of the patient to the hospital or to an appropriate practitioner.

Infection control
The practice should comply with state and federal regulations regarding infection control. For all surgical and special procedures, the level of sterilization should meet applicable industry and occupational safety requirements. There should be a procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel should be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment should be readily available.

Performance improvement
A performance improvement program should be implemented to provide a mechanism to review yearly the current practice activities and quality of care provided to patients. Performance improvement activities should include, but are not limited to, review of mortalities; the appropriateness and necessity of procedures performed; emergency transfers; reportable complications, and resultant outcomes (including all postoperative infections); analysis of patient satisfaction surveys and complaints; and identification of undesirable trends (such as diagnostic errors, unacceptable results, follow-up of abnormal test results, medication errors, and system problems). Findings of the performance improvement program should be incorporated into the practice’s educational activity.

Medical records and informed consent
The practice should have a procedure for initiating and maintaining a health record for every patient evaluated or treated. The record should include a procedure code or suitable narrative description of the procedure and should have sufficient information to identify the patient, support the diagnosis, justify the treatment, and document the outcome and required follow-up care.
Medical history, physical examination, lab studies obtained within 30 days of the scheduled procedure, and pre-anesthesia examination and evaluation information and data should be adequately documented in the medical record.

The medical records also should contain documentation of the intraoperative and postoperative monitoring required by these guidelines.

Written documentation of informed consent should be included in the medical record.

**Credentialing of physicians**

A physician who performs surgical or special procedures in an office requiring the administration of anesthesia services should be credentialed to perform that surgical or special procedure by a hospital, an ambulatory surgical facility, or substantially comply with criteria established by the Board.

Criteria to be considered by the Board in assessing a physician’s competence to perform a surgical or special procedure include, without limitation:

- state licensure;
- procedure specific education, training, experience and successful evaluation appropriate for the patient population being treated (i.e., pediatrics);
- for physicians, board certification, board eligibility or completion of a training program in a field of specialization recognized by the ACGME or by a national medical specialty board that is recognized by the ABMS for expertise and proficiency in that field. For purposes of this requirement, board eligibility or certification is relevant only if the board in question is recognized by the ABMS, AOA, or equivalent board certification as determined by the Board;
- professional misconduct and malpractice history;
- participation in peer and quality review;
- participation in continuing education consistent with the statutory requirements and requirements of the physician’s professional organization;
- to the extent such coverage is reasonably available in North Carolina, malpractice insurance coverage for the surgical or special procedures being performed in the office;
- procedure-specific competence (and competence in the use of new procedures and technology), which should encompass education, training, experience and evaluation, and which may include the following:
  - adherence to professional society standards;
  - credentials approved by a nationally recognized accrediting or credentialing entity; or
  - didactic course complemented by hands-on, observed experience; training is to be followed by a specified number of cases supervised by a practitioner already competent in the respective procedure, in accordance with professional society standards.

If the physician administers the anesthetic as part of a surgical or special procedure (Level II only), he or she also should have documented competence to deliver the level of anesthesia administered.

**Accreditation**

After one year of operation following the adoption of these guidelines, any physician who performs Level II or Level III procedures in an office should be able to demonstrate, upon request by the Board, substantial compliance with these guidelines, or should obtain accreditation of the office setting by an approved accreditation agency or organization. The approved accreditation agency or organization should submit, upon request by the Board, a summary report for the office accredited by that agency.

All expenses related to accreditation or compliance with these guidelines shall be paid by the physician who performs the surgical or special procedures.

**Patient selection**

The physician who performs the surgical or special procedure should evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician also is responsible for determining that the patient has an adequate support system to provide for necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at undue risk for complications, should be referred to an appropriate specialist for preoperative consultation.
ASA physical status classifications
Patients that are considered high risk or are ASA physical status classification III, IV, or V and require a general anesthetic for the surgical procedure, should not have the surgical or special procedure performed in a physician office setting.

Candidates for Level II procedures
Patients with an ASA physical status classification I, II, or III may be acceptable candidates for office-based surgical or special procedures requiring conscious sedation/analgesia. ASA physical status classification III patients should be specifically addressed in the operating manual for the office. They may be acceptable candidates if deemed so by a physician qualified to assess the specific disability and its impact on anesthesia and surgical or procedural risks.

Candidates for Level III procedures
Only patients with an ASA physical status classification I or II, who have no airway abnormality, and possess an unremarkable anesthetic history are acceptable candidates for Level III procedures.

Surgical or special procedure guidelines

Patient preparation
A medical history and physical examination to evaluate the risk of anesthesia and of the proposed surgical or special procedure should be performed by a physician qualified to assess the impact of co-existing disease processes on surgery and anesthesia. Appropriate laboratory studies should be obtained within 30 days of the planned surgical procedure. A pre-procedure examination and evaluation should be conducted prior to the surgical or special procedure by the physician. The information and data obtained during the course of this evaluation should be documented in the medical record. The physician performing the surgical or special procedure also should:

- ensure that an appropriate pre-anesthetic examination and evaluation is performed proximate to the procedure;
- prescribe the anesthetic, unless the anesthesia is administered by an anesthesiologist in which case the anesthesiologist may prescribe the anesthetic;
- ensure that qualified health care professionals participate;
- remain physically present during the intraoperative period and be immediately available for diagnosis, treatment, and management of anesthesia-related complications or emergencies; and
- ensure the provision of indicated post-anesthesia care.

Discharge criteria
Criteria for discharge for all patients who have received anesthesia should include the following:

- confirmation of stable vital signs;
- stable oxygen saturation levels;
- return to pre-procedure mental status;
- adequate pain control;
- minimal bleeding, nausea and vomiting;
- resolving neural blockade, resolution of neuraxial blockade; and
- eligible to be discharged in the company of a competent adult.

Information to the patient
The patient should receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions should include:

- the procedure performed;
- information about potential complications;
- telephone numbers to be used by the patient to discuss complications or should questions arise;
- instructions for medications prescribed and pain management;
- information regarding the follow-up visit date, time and location; and
- designated treatment hospital in the event of emergency.

Reportable complications
Physicians performing surgical or special procedures in the office should maintain timely records, which
should be provided to the Board within three business days of receipt of a Board inquiry. Records of reportable complications should be in writing and should include:
Records of reportable complications should be in writing and should include:

- physician’s name and license number;
- date and time of the occurrence;
- office where the occurrence took place;
- name and address of the patient;
- surgical or special procedure involved;
- type and dosage of sedation or anesthesia utilized in the procedure; and
- circumstances involved in the occurrence.

**Equipment maintenance**

All anesthesia-related equipment and monitors should be maintained to current operating room standards. All devices should have regular service/maintenance checks at least annually or per manufacturer recommendations. Service/maintenance checks should be performed by appropriately qualified biomedical personnel. Prior to the administration of anesthesia, all equipment/monitors should be checked using the current FDA recommendations as a guideline. Records of equipment checks should be maintained in a separate, dedicated log which must be made available to the Board upon request. Documentation of any criteria deemed to be substandard should include a clear description of the problem and the intervention. If equipment is utilized despite the problem, documentation should clearly indicate that patient safety is not in jeopardy.

The emergency supplies should be maintained and inspected by qualified personnel for presence and function of all appropriate equipment and drugs at intervals established by protocol to ensure that equipment is functional and present, drugs are not expired, and office personnel are familiar with equipment and supplies. Records of emergency supply checks should be maintained in a separate, dedicated log and made available to the Board upon request.

A physician should not permit anyone to tamper with a safety system or any monitoring device or disconnect an alarm system.

**Compliance with relevant health laws**

Federal and state laws and regulations that affect the practice should be identified and procedures developed to comply with those requirements.

Nothing in this position statement affects the scope of activities subject to or exempted from the North Carolina health care facility licensure laws. (1)

**Patient rights**

Office personnel should be informed about the basic rights of patients and understand the importance of maintaining patients’ rights. A patients’ rights document should be readily available upon request.

**Enforcement**

In that the Board believes that these guidelines constitute the accepted and prevailing standards of practice for office-based procedures in North Carolina, failure to substantially comply with these guidelines creates the risk of disciplinary action by the Board.

**Level II guidelines**

**Personnel**

The physician who performs the surgical or special procedure or a health care professional who is present during the intraoperative and postoperative periods should be ACLS certified, and at least one other health care professional should be BCLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (i.e., APLS or PALS certified).

Recovery should be monitored by a registered nurse or other health care professional practicing within the scope of his or her license or certification who is BCLS certified and has the capability of administering medications as required for analgesia, nausea/vomiting, or other indications.
Surgical or special procedure guidelines

**Intraoperative care and monitoring**

The physician who performs Level II procedures that require conscious sedation in an office should ensure that monitoring is provided by a separate health care professional not otherwise involved in the surgical or special procedure. Monitoring should include, when clinically indicated for the patient:

- direct observation of the patient and, to the extent practicable, observation of the patient’s responses to verbal commands;
- pulse oximetry should be performed continuously (an alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness);
- an electrocardiogram monitor should be used continuously on the patient;
- the patient’s blood pressure, pulse rate, and respirations should be measured and recorded at least every five minutes; and
- the body temperature of a pediatric patient should be measured continuously.

Clinically relevant findings during intraoperative monitoring should be documented in the patient’s medical record.

**Postoperative care and monitoring**

The physician who performs the surgical or special procedure should evaluate the patient immediately upon completion of the surgery or special procedure and the anesthesia.

Care of the patient may then be transferred to the care of a qualified health care professional in the recovery area. A registered nurse or other health care professional practicing within the scope of his or her license or certification and who is BCLS certified and has the capability of administering medications as required for analgesia, nausea/vomiting, or other indications should monitor the patient postoperatively.

At least one health care professional who is ACLS certified should be immediately available until all patients have met discharge criteria. Prior to leaving the operating room or recovery area, each patient should meet discharge criteria.

Monitoring in the recovery area should include pulse oximetry and non-invasive blood pressure measurement. The patient should be assessed periodically for level of consciousness, pain relief, or any untoward complication. Clinically relevant findings during post-operative monitoring should be documented in the patient’s medical record.

**Equipment and supplies**

Unless another availability standard is clearly stated, the following equipment and supplies should be present in all offices where Level II procedures are performed:

- full and current crash cart at the location where the anesthetizing is being carried out. (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);
- age-appropriate sized monitors, resuscitative equipment, supplies, and medication in accordance with the scope of the surgical or special procedures and the anesthesia services provided;
- emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours;
- electrocardiographic monitor;
- noninvasive blood pressure monitor;
- pulse oximeter;
- continuous suction device;
- endotracheal tubes, laryngoscopes;
- positive pressure ventilation device (e.g., Ambu);
- reliable source of oxygen;
- emergency intubation equipment;
- adequate operating room lighting;
- appropriate sterilization equipment; and
- IV solution and IV equipment.
Level III guidelines

Personel

Anesthesia should be administered by an anesthesiologist or a CRNA supervised by a physician. The physician who performs the surgical or special procedure should not administer the anesthesia. The anesthesia provider should not be otherwise involved in the surgical or special procedure.

The physician or the anesthesia provider should be ACLS certified, and at least one other health care professional should be BCLS certified. In an office where anesthesia services are provided to infants and children, personnel should be appropriately trained to handle pediatric emergencies (i.e., APLS or PALS certified).

Surgical or special procedure guidelines

Intraoperative monitoring

The physician who performs procedures in an office that require major conduction blockade, deep sedation/analgesia, or general anesthesia should ensure that monitoring is provided as follows when clinically indicated for the patient:

- direct observation of the patient and, to the extent practicable, observation of the patient’s responses to verbal commands;
- pulse oximetry should be performed continuously. Any alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness;
- an electrocardiogram monitor should be used continuously on the patient;
- the patient’s blood pressure, pulse rate, and respirations should be measured and recorded at least every five minutes;
- monitoring should be provided by a separate health care professional not otherwise involved in the surgical or special procedure;
- end-tidal carbon dioxide monitoring should be performed on the patient continuously during endotracheal anesthesia;
- an in-circuit oxygen analyzer should be used to monitor the oxygen concentration within the breathing circuit, displaying the oxygen percent of the total inspiratory mixture;
- a respirometer (volumeter) should be used to measure exhaled tidal volume whenever the breathing circuit of a patient allows;
- the body temperature of each patient should be measured continuously; and
- an esophageal or precordial stethoscope should be utilized on the patient.

Clinically relevant findings during intraoperative monitoring should be documented in the patient’s medical record.

Postoperative care and monitoring

The physician who performs the surgical or special procedure should evaluate the patient immediately upon completion of the surgery or special procedure and the anesthesia.

Care of the patient may then be transferred to the care of a qualified health care professional in the recovery area. Qualified health care professionals capable of administering medications as required for analgesia, nausea/vomiting, or other indications should monitor the patient postoperatively.

Recovery from a Level III procedure should be monitored by an ACLS certified (PALS or APLS certified when appropriate) health care professional using appropriate criteria for the level of anesthesia. At least one health care professional who is ACLS certified should be immediately available during postoperative monitoring and until the patient meets discharge criteria. Each patient should meet discharge criteria prior to leaving the operating or recovery area.

Monitoring in the recovery area should include pulse oximetry and non-invasive blood pressure measurement. The patient should be assessed periodically for level of consciousness, pain relief, or any untoward complication. Clinically relevant findings during postoperative monitoring should be documented in the patient’s medical record.

27
Equipment and supplies

Unless another availability standard is clearly stated, the following equipment and supplies should be present in all offices where Level I or II procedures are performed:

- full and current crash cart at the location where the anesthetizing is being carried out (the crash cart inventory should include appropriate resuscitative equipment and medications for surgical, procedural or anesthetic complications);
- age-appropriate sized monitors, resuscitative equipment, supplies, and medication in accordance with the scope of the surgical or special procedures and the anesthesia services provided;
- emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours;
- electrocardiographic monitor;
- noninvasive blood pressure monitor;
- pulse oximeter;
- continuous suction device;
- endotracheal tubes, and laryngoscopes;
- positive pressure ventilation device (e.g., Ambu);
- reliable source of oxygen;
- emergency intubation equipment;
- adequate operating room lighting;
- appropriate sterilization equipment;
- IV solution and IV equipment;
- sufficient ampules of dantrolene sodium should be emergently available;
- esophageal or precordial stethoscope;
- emergency resuscitation equipment;
- temperature monitoring device;
- end tidal CO₂ monitor (for endotracheal anesthesia); and
- appropriate operating or procedure table.

Definitions and Acronyms

AAAASF - the American Association for the Accreditation of Ambulatory Surgery Facilities.
AAAHC - the Accreditation Association for Ambulatory Health Care
ABMS - the American Board of Medical Specialties
ACGME - the Accreditation Council for Graduate Medical Education
ACLS certified - a person who holds a current “ACLS Provider” credential certifying that they have successfully completed the national cognitive and skills evaluations in accordance with the curriculum of the American Heart Association for the Advanced Cardiovascular Life Support Program.
Advanced cardiac life support certified - a licensee that has successfully completed and recertified periodically an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee’s field of practice. For example, for those licensees treating adult patients, training in ACLS is appropriate; for those treating children, training in PALS or APLS is appropriate.
Ambulatory surgical facility - a facility licensed under Article 6, Part D of Chapter 131E of the North Carolina General Statutes or if the facility is located outside North Carolina, under that jurisdiction’s relevant facility licensure laws.
Anesthesia provider - an anesthesiologist or CRNA.
Anesthesiologist - a physician who has successfully completed a residency program in anesthesiology approved by the ACGME or AOA, or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.
AOA - the American Osteopathic Association
APLS certified - a person who holds a current certification in advanced pediatric life support from a program approved by the American Heart Association.
Approved accrediting agency or organization - a nationally recognized accrediting agency (e.g., AAAASF; AAAHC, JCAHO, and HFAP) including any agency approved by the Board.
ASA - the American Society of Anesthesiologists
BCLS certified - a person who holds a current certification in basic cardiac life support from a program approved by the American Heart Association.
Board - the North Carolina Medical Board.
Conscious sedation - the administration of a drug or drugs in order to induce that state of consciousness in a patient which allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function and the ability to respond purposefully to verbal command or to tactile stimulation if verbal response is not possible as, for example, in the case of a small child or deaf person. Conscious sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. “Conscious sedation” should be synonymous with the term “sedation/analgesia” as used by the American Society of Anesthesiologists.
Credentialed - a physician that has been granted, and continues to maintain, the privilege by a hospital or ambulatory surgical facility licensed in the jurisdiction in which it is located to provide specified services, such as surgical or special procedures or the administration of one or more types of anesthetic agents or procedures, or can show documentation of adequate training and experience.
CRNA - a registered nurse who is authorized by the North Carolina Board of Nursing to perform nurse anesthesia activities.
Deep sedation/analgesia - the administration of a drug or drugs which produces depression of consciousness during which patients cannot be easily aroused but can respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
FDA - the Food and Drug Administration.
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 patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.
Health care professional - any office staff member who is licensed or certified by a recognized professional or health care organization.
HFAP - the Health Facilities Accreditation Program, a division of the AOA.
Hospital - a facility licensed under Article 5, Part A of Chapter 131E of the North Carolina General Statutes or if the facility is located outside North Carolina, under that jurisdiction’s relevant facility licensure laws.
Immediately available - within the office.
JCAHO - the Joint Commission for the Accreditation of Health Organizations
Level I procedures - any surgical or special procedures:
1. that do not involve drug-induced alteration of consciousness;
2. where preoperative medications are not required or used other than minimal preoperative tranquilization of the patient (anxiolysis of the patient);
3. where the anesthesia required or used is local, topical, digital block, or none; and
4. where the probability of complications requiring hospitalization is remote.
Level II procedures - any surgical or special procedures:
1. that require the administration of local or peripheral nerve block, minor conduction blockade, Bier block, minimal sedation, or conscious sedation; and
2. where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely.
Level III procedures - any surgical or special procedures:
1. that require, or reasonably should require, the use of major conduction blockade, deep sedation/analgesia, or general anesthesia; and

2. where there is only a moderate risk of surgical and/or anesthetic complications and the need for hospitalization as a result of these complications is unlikely.

Local anesthesia - the administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

Major conduction blockade - the injection of local anesthesia to stop or prevent a painful sensation in a region of the body. Major conduction blocks include, but are not limited to, axillary, interscalene, and supraclavicular block of the brachial plexus; spinal (subarachnoid), epidural and caudal blocks.

Minimal sedation (anxiolysis) - the administration of a drug or drugs which produces a state of consciousness that allows the patient to tolerate unpleasant medical procedures while responding normally to verbal commands. Cardiovascular or respiratory function should remain unaffected and defensive airway reflexes should remain intact.

Minor conduction blockade - the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (i.e., infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration. Minor conduction blocks include, but are not limited to, intercostal, retrobulbar, paravertebral, peribulbar, pudendal, sciatic nerve, and ankle blocks.

Monitoring - continuous, visual observation of a patient and regular observation of the patient as deemed appropriate by the level of sedation or recovery using instruments to measure, display, and record physiologic values such as heart rate, blood pressure, respiration and oxygen saturation.

Office - a location at which incidental, limited ambulatory surgical procedures are performed and which is not a licensed ambulatory surgical facility pursuant to Article 6, Part D of Chapter 131E of the North Carolina General Statutes.

Operating room - that location in the office dedicated to the performance of surgery or special procedures.

OSHA - the Occupational Safety and Health Administration.

PALS certified - a person who holds a current certification in pediatric advanced life support from a program approved by the American Heart Association.

Physical status classification - a description of a patient used in determining if an office surgery or procedure is appropriate. For purposes of these guidelines, ASA classifications will be used. The ASA enumerates classification: I-normal, healthy patient; II-a patient with mild systemic disease; III a patient with severe systemic disease limiting activity but not incapacitating; IV-a patient with incapacitating systemic disease that is a constant threat to life; and V-moribund, patients not expected to live 24 hours with or without operation.

Physician - an individual holding an MD or DO degree licensed pursuant to the NC Medical Practice Act and who performs surgical or special procedures covered by these guidelines.

Reasonable Proximity - The Board recognizes that reasonable proximity is a somewhat ambiguous standard. The Board believes that the standard often used by hospitals of thirty (30) minutes travel time is a useful benchmark.

Recovery area - a room or limited access area of an office dedicated to providing medical services to patients recovering from surgical or special procedures or anesthesia.

Reportable complications - untoward events occurring at any time within forty-eight (48) hours of any surgical or special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, pulmonary embolism, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than twenty-four (24) hours, or death.

Special procedure - patient care that requires entering the body with instruments in a potentially painful manner, or that requires the patient to be immobile, for a diagnostic or therapeutic procedure requiring anesthesia services; for example, diagnostic or therapeutic endoscopy; invasive radiologic procedures, pediatric magnetic resonance imaging; manipulation under anesthesia or endoscopic examination with the use of general anesthesia.

Surgical procedure - the revision, destruction, incision, or structural alteration of human tissue performed
using a variety of methods and instruments and includes the operative and non-operative care of individuals in need of such intervention, and demands pre-operative assessment, judgment, technical skill, post-operative management, and follow-up.

Topical anesthesia - an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

**North Dakota**

None

**Ohio**

Chapter 4731–25. Anesthesia Standards

731-25-01 Definition of terms

As used in this chapter of the Administrative Code:

(A) “Anesthesia services” means administration of any drug or combination of drugs with the purpose of creating deep sedation/analgesia, regional anesthesia or general anesthesia. Anesthesia services shall not include the administration of topical or local anesthesia or moderate sedation/analgesia;

(B) “Certified copy of a patient record” means a copy of the patient record with a separate statement, signed by the person making the copy and notarized, attesting that the copy is a “true and accurate copy of the complete patient record”;

(C) “Deep sedation/analgesia” means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained;

(D) “General anesthesia” means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired;

(E) “Local anesthesia” means the injection of a drug or combination of drugs to stop or prevent a painful sensation in a circumscribed area of the body where a painful procedure is to be performed. Local anesthesia includes local infiltration anesthesia, digital blocks and pudendal blocks. Local anesthesia does not involve any systemic sedation;

(F) “Minimal sedation (anxiolysis)” means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. “Minimal sedation” shall not include sedation achieved through intravenous administration of drugs;

(G) “Minor surgery” means surgery that can safely and comfortably be performed under topical or local anesthesia without more than minimal oral or intramuscular preoperative sedation. Minor surgery includes, but is not limited to, surgery of the skin, subcutaneous tissue and other adjacent tissue, the incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, arthrocentesis and closed reduction of simple fractures or small joint dislocations;

(H) “Moderate sedation/analgesia” means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a painful stimulus is not a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained;
(I) “Office setting” means an office or portion thereof which is utilized to provide medical and/or surgical services to the physician's own patients. Office setting does not include an office or portion thereof licensed as an ambulatory surgical facility by the department of health pursuant to division (E)(1) of section 3702.30 of the Revised Code, a hospital registered with the department of health pursuant to section 3701.07 of the Revised Code, or an emergency department located within such a hospital;

(J) “Regional anesthesia” means the administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness and includes epidural, caudal, spinal, axillary, stellate ganglion blocks, regional blocks (such as axillary, bier, retobulbar, peribulbar, interscalene, subarachnoid, supraclavicular, and infraclavicular), and brachial anesthesia. Regional anesthesia does not include digital or pudendal blocks;

(K) “Special procedure” means a diagnostic or therapeutic procedure which is not surgery which requires entering the body with instruments in a potentially painful manner, or which requires the patient to be immobile, and which requires the provision of anesthesia services. Special procedures include, but are not limited to, diagnostic or therapeutic endoscopy that explores existing channels and involves no transverse of a body wall; invasive radiologic procedures; pediatric magnetic resonance imaging; manipulation under anesthesia; or endoscopic examination with the use of general anesthesia;

(L) “Surgery” means 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 being for the 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 be 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 the products of conception from the uterus; and, insertion of natural or artificial implants. Surgery shall not include the suturing of minor lacerations;

(M) “Topical anesthesia” means the application of a drug or combination of drugs directly or by spray to the skin or mucous membranes which is intended to produce a transient and reversible loss of sensation to a circumscribed area.

(N) “Tumescent local anesthesia” means subcutaneous infiltration of high volumes of crystalloid fluid containing low concentrations of lidocaine and epinephrine. For purposes of this chapter of the Administrative Code, “tumescent local anesthesia” shall be considered “local anesthesia” as that term is defined in paragraph (E) of this rule.

4731-25-02 General provisions

(A) Anesthesia services in the office setting shall be provided only by physicians and osteopathic physicians licensed pursuant to Chapter 4731. of the Revised Code; podiatric physicians licensed pursuant to Chapter 4731. of the Revised Code and practicing within the scope of practice for podiatric physicians; and certified registered nurse anesthetists licensed pursuant to Chapter 4723. of the Revised Code and practicing within the scope of practice for certified registered nurse anesthetists; and only in accordance with Chapter 4731-25 of the Administrative Code.

(B) Nothing in this chapter of the Administrative Code shall be interpreted to permit a podiatric physician to perform surgery or procedures in an office setting using general anesthesia.

(C) Nothing in this chapter of the Administrative Code shall be interpreted to prohibit a registered nurse with the appropriate education and training from carrying out a physician's order to maintain a patient within an intensive care unit of a hospital at the level of sedation determined by the physician to be appropriate and necessary for that patient’s care, so long as the patient remains within the intensive care unit with appropriate monitoring and so long as the physician's order is written in compliance with all applicable laws.

(D) A physician or podiatric physician shall not perform on more than one patient at the same time procedures or surgery using moderate sedation/analgesia or anesthesia services.

(E) A certified registered nurse anesthetist providing moderate sedation/analgesia or anesthesia services in the office setting shall be under the direction of a podiatric physician acting within the podiatric physician's scope of practice in accordance with section 4731.51 of the Revised Code or a physician, and, when administering anesthesia, the certified registered nurse anesthetist shall be in the immediate presence of the
podiatric physician or physician. For purposes of this chapter of the Administrative Code, a physician shall not be considered to have supervised the administration and monitoring of moderate sedation/analgesia or anesthesia services if the moderate sedation/analgesia or anesthesia services were administered and monitored by a physician anesthesiologist.

(F) “Surgery” shall not be interpreted so as to prohibit a registered nurse from performing tasks that are within the scope of practice of the registered nurse, so long as the registered nurse’s activities are in accordance with Chapter 4723. of the Revised Code.

(G) This chapter of the Administrative Code shall not apply to surgeries or special procedures in which the level of anesthesia is limited to minimal sedation as that term is defined in this chapter of the Administrative Code, or which use only local or topical anesthetic agents, and which are performed in an office setting except that liposuction procedures performed under tumescent local anesthesia shall be subject to the provisions of rule 4731-25-05 and 4731-25-06.

(H) Procedures or surgery utilizing moderate sedation/analgesia or anesthesia services shall be performed in the office setting only on patients who are evaluated as level P1 or P2 according to the American society of anesthesiologists physical status classification system current at the effective date of this rule.

4731-25-03 Standards for surgery using moderate sedation/analgesia

(A) A physician or podiatric physician performing procedures or surgery in the office setting during which moderate sedation/analgesia is administered shall:

(1) Demonstrate sufficient education, training and experience needed to conform to the minimal standards of care of similar practitioners under the same or similar circumstances by meeting at least one of the following criteria:

(a) Holding current privileges at a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or at a local ambulatory surgical facility licensed by the department of health for the procedure or surgery being performed;

(b) Being board certified by a specialty board recognized by the American board of medical specialties or the American osteopathic association or, if a podiatric physician, is board certified by the American board of podiatric surgery; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty;

(c) Having successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association or, if a podiatric physician, having successfully completed at least a twelve month residency in podiatric surgery approved by the council on podiatric medical education; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty; or

(d) Having successfully completed a didactic course supplemented by direct hands-on, monitored experience in the surgery or procedure being performed, and the surgery or procedure being performed is generally recognized as being within the usual course of practice of the specialty of the physician.

(2) Have current (within the immediately previous two years) advanced cardiac life support/advanced trauma life support training, or, in the case of pediatric patients under the age of thirteen, have current (within the immediately previous two years) pediatric advanced life support training.

(3) Ensure that assisting personnel are competent to administer and monitor moderate sedation/analgesia and to manage emergencies such as loss of airway, compromise of cardiovascular functions or anaphylaxis.

(4) A physician or podiatric physician performing surgeries or procedures using moderate sedation/analgesia in the office setting shall:

(a) Hold privileges to provide moderate sedation/analgesia from a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health; or

(b) Have documented evidence of having completed at least five hours of category I continuing medical education relating to the delivery of moderate sedation/analgesia during the current or most recent past biennial registration period, such requirement to become effective on the one-hundred-eighty-first day following the effective date of this rule.
(B) Moderate sedation/analgesia may be administered in the office setting by only the following:
(1) A physician who holds privileges to provide moderate sedation/analgesia from a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health;
(2) A certified registered nurse anesthetist who is acting under the supervision of and in the immediate presence of a physician or podiatric physician;
(3) A registered nurse who is acting under the supervision and in the immediate presence of a physician or podiatric physician, provided that such registered nurse shall only administer specifically prescribed doses of drugs selected by the physician or podiatric physician who shall be continuously present in the anesthetizing location during the administration of those drugs.
(C) The person administering and monitoring the moderate sedation/analgesia shall be at all times present in the anesthetizing location with the patient and cannot be the practitioner while performing the surgery or procedure. Further, the person administering and monitoring the moderate sedation/analgesia shall meet the training requirements of paragraph (A)(2) of this rule.
(D) A violation of any provision of this rule, as determined by the board, shall constitute “a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

4731-25-04 Standards for surgery using anesthesia services
(A) A physician or podiatric physician performing special procedures or surgery in the office setting during which anesthesia services are provided shall:
(1) Demonstrate sufficient education, training and experience needed to conform to the minimal standards of care of similar practitioners under the same or similar circumstances by meeting at least one of the following criteria:
(a) Holding current privileges at a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or at a local ambulatory surgical facility licensed by the department of health for the special procedure or surgery being performed;
(b) Being board certified by a specialty board recognized by the American board of medical specialties or the American osteopathic association or, if a podiatric physician, is board certified by the American board of podiatric surgery; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty; or,
(c) Having successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association or, if a podiatric physician, having successfully completed at least a twelve month residency in podiatric surgery approved by the council on podiatric medical education; and the surgery or procedure being performed is generally recognized as being within the usual course of practice of that specialty.
(2) Have current (within the immediately previous two years) advanced cardiac life support/advanced trauma life support training or, in the case of pediatric patients under the age of thirteen, have current (within the immediately previous two years) pediatric advanced life support training.
(3) Ensure that assisting personnel are competent to administer and monitor anesthesia services and to manage emergencies.
(4) A physician or podiatric physician performing surgeries or procedures using anesthesia services in the office setting shall:
(a) Hold privileges to provide anesthesia services from a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health; or
(b) Have successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association in anesthesia; or
(c) Have documented evidence of having completed at least twenty hours of category I continuing medical education relating to the delivery of anesthesia services during the current or most recent past biennial registration period, such requirement to become effective on the one-hundred-eighty-first day following the effective date of this rule.

(B) Anesthesia services may be administered in the office setting by only the following:

(1) A physician who holds privileges to provide anesthesia services from a local hospital accredited by the joint commission on accreditation of healthcare organizations or the American osteopathic association or from a local ambulatory surgical facility licensed by the department of health;

(2) A physician who has successfully completed a residency training program approved by the accreditation council for graduate medical education of the American medical association or the American osteopathic association in anesthesia and who is actively and directly engaged in the clinical practice of medicine as an anesthesiologist;

(3) A certified registered nurse anesthetist who is acting under the supervision and in the immediate presence of a physician or podiatric physician.

(C) The person administering and monitoring the anesthesia services shall be at all times present in the anesthetizing location with the patient and shall not function in any other capacity during the surgery or special procedure. Further, the person administering and monitoring the anesthesia services shall meet the training requirements of paragraph (A)(2) of this rule.

(D) Whenever general anesthesia is being administered to a patient in the office setting, the office shall have sufficient equipment and supplies to appropriately manage malignant hyperthermia.

(E) A violation of any provision of this rule, as determined by the board, shall constitute “a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

4731-25-05 Liposuction in the office setting

(A) A physician performing liposuction in the office setting shall meet the training requirements set forth in paragraph (A) of rule 4731-25-03 of the Administrative Code and must be in compliance with this rule.

(B) Liposuction in the office setting shall be performed in compliance with rules 4731-25-03 and 4731-25-04 of the Administrative Code as appropriate to the level of sedation being administered and in compliance with the following standards:

(1) The cannula utilized shall be no larger than 4.5 millimeters in diameter;

(2) The concentration of lidocaine in the solution shall not be greater than 0.1 per cent and the total dosage of lidocaine received by the patient during the procedure shall not exceed fifty milligrams per kilogram of body weight;

(3) The concentration of epinephrine in the solution shall not be greater than 1.5:1,000,000 and the total dosage of epinephrine received by the patient during the procedure shall not exceed fifty micrograms per kilogram of body weight;

(4) Intravenous access shall be maintained if the total aspirate is less than or equal to one hundred milliliters;

(5) If the total aspirate is more than one hundred milliliters, an intravenous line shall be running at a rate sufficient to prevent hypovolemia and must be monitored appropriately;

(6) Appropriate monitoring shall be performed. Such monitoring shall include:

(a) Recording the baseline vital signs, including blood pressure and heart rate, both preoperatively and postoperatively.

(b) If more than one hundred milliliters of aspirate is to be removed, a second person who is a health care professional as that term is defined in section 2305.234 of the Revised Code and who is acting within that health care professional's scope of practice shall be continuously within the room to monitor the patient.

(c) Continuous blood pressure monitoring and cardiac monitoring with pulse oximetry shall be performed and documented; supplemental oxygen shall be available.

(d) Patients who receive oral anxiolytics, sedatives, narcotic analgesics, moderate sedation or anesthesia services shall be monitored postoperatively until fully recovered and ready for discharge.
Liposuction in the office setting shall be performed only on patients who are evaluated as level P1 or P2 according to the version of the American society of anesthesiologists physical status classification system current at the effective date of this rule.

Liposuction shall not be performed in an office setting in combination with other procedures except as specifically authorized in paragraph (F) of this rule.

Liposuction performed in an office setting shall not exceed four thousand five hundred milliliters of total aspirate.

Liposuction using moderate sedation/analgesia or anesthesia services performed in an office shall be accredited in accordance with rule 4731-25-07.

The written discharge instructions given to the patient shall include specific information concerning the symptoms of lidocaine toxicity, the period of time during which such symptoms might appear and specific instructions for the patient to follow should the patient experience such symptoms.

Nothing in this rule shall be interpreted to prohibit a physician from performing in the office setting procedures involving a focused, local small liposuction that is a routine part of the main procedure, provided that the physician complies with all other applicable rules.

A violation of any provision of this rule, as determined by the board, shall constitute “a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

4731-25-07 Accreditation of office settings
(A) No physician or podiatric physician shall perform procedures or surgery using moderate sedation/analgesia or anesthesia services in an office setting unless that office setting is accredited by an accrediting agency approved by the board, except that physicians and podiatric physicians who are performing such procedures or surgeries in office settings that are not accredited on the effective date of this rule shall apply for accreditation within eighteen months of the effective date of this rule and shall receive accreditation within three years of the effective date of this rule.

(B) Accrediting agencies approved by the board include the following:
(1) The joint commission on accreditation of healthcare organizations;
(2) The accreditation association for ambulatory health care, inc.;
(3) The American association for accreditation of ambulatory surgery facilities, inc.;
(4) The healthcare facilities accreditation program of the American osteopathic association; or,
(5) Any other accrediting agency that demonstrates to the satisfaction of the board that it has:
(a) Standards pertaining to patient care, record keeping, equipment, personnel, facilities and other related matters that are in accordance with acceptable and prevailing standards of care as determined by the board;
(b) Processes that assure a fair and timely review and decision on any applications for accreditation or renewals thereof;
(c) Processes that assure a fair and timely review and resolution of any complaints received concerning accredited facilities; and
(d) Resources sufficient to allow the accrediting agency to fulfill its duties in a timely manner.

(C) A violation of paragraph (A) of this rule, as determined by the board, shall constitute “a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

Oklahoma – Medical

GUIDELINES FOR OFFICE-BASED SURGERY AND OTHER INVASIVE PROCEDURES

These Guidelines are intended to assist Oklahoma medical doctors who are considering or currently practice ambulatory surgery or other invasive procedures which require anesthesia analgesia or sedation in an office setting. These recommendations focus on quality care and patient safety in the office. These are minimal guidelines and may be exceeded at any time based on the judgment of the involved physicians. Minor procedures in which unsupplemented local anesthesia is used in quantities equal to or less than the manufacturer’s recommended dose adjusted for weight, are excluded from these guidelines. Nevertheless, it is expected that any practice performing office-based surgery regardless of anesthesia will have the necessary equipment and personnel to be able to handle emergencies resulting from the procedure and/or anesthesia.

The OSMBLS wants physicians to be aware that compared with acute care hospitals and licensed ambulatory surgical facilities, office operatories currently have little or no regulation, oversight or control by federal, state or local laws. Therefore, physicians must satisfactorily investigate areas taken for granted in the hospital or ambulatory surgical facility such as governance, organization, construction and equipment, as well as policies and procedures, including fire, safety, drugs, emergencies, staffing, training and unanticipated patient transfers.

The following issues should be addressed in an office setting to provide a high standard of patient safety and to reduce risk and liability.

1. Quality of Care
   
   A. All health care practitioners and nurses should hold a valid license or certificate to perform their assigned duties.
   B. All personnel who provide clinical care in the office-based surgical setting should be qualified to perform services commensurate with appropriate levels of education, training and experience.
   C. Policies and procedures should be written for the orderly conduct of the facility and reviewed on an annual basis.
   D. The facility should be under the supervision and control of a qualified physician.
   E. All surgical personnel must wear suitable operative attire.

2. Facility and Safety
   
   A. Facilities should comply with all applicable federal, state and local laws, codes and regulations pertaining to fire prevention, building construction and occupancy, accommodations for the disabled, occupational safety and health, and disposal of medical waste and hazardous waste.
   B. Policies and procedures should comply with laws and regulations pertaining to controlled drug supply, storage and administration.
   C. All premises must be kept neat and clean. Sterilization of operating materials must be adequate.

3. Clinical Care

   Patient and Procedure Selection

   A. Procedures to be undertaken should be within the scope of practice of the health care practitioners and the capabilities of the facility.
   B. The procedure should be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility.
   C. Patients who by reason of pre-existing medical or other conditions may be at undue risk for complications should be referred to an appropriate facility for performance of the procedure and the administration of anesthesia.
4. Preoperative Care

A. The anesthesia provider should adhere to the listed Anesthesia:Desiderata.
B. The anesthesia provider should be physically present during the intraoperative period and be available until the patient has been discharged from anesthesia care.
C. Discharge of a patient should be documented in the medical record and effected by a licensed independent practitioner.
D. Personnel with training in advanced resuscitative techniques (e.g., ACLS, PALS) should be immediately available until all patients are discharged home.

5. Monitoring and Equipment

A. At a minimum, all facilities should have a reliable source of oxygen, suction, resuscitation equipment and emergency drugs.
B. There should be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine (when present) and all monitoring equipment.
C. All equipment should be maintained, tested and inspected according to the manufacturer’s specifications.
D. Back-up battery power sufficient to ensure patient protection in the event of an emergency should be available.
E. In any location in which anesthesia is administered, there should be appropriate anesthesia apparatus and equipment which allow monitoring consistent with the Anesthesia:Desiderata and documentation of regular preventive maintenance as recommended by the manufacturer.
F. In an office where anesthesia services are to be provided to infants and children, the required equipment, medication and resuscitative capabilities should be appropriately sized for a pediatric population.

6. Emergencies and Transfers

A. All facility personnel should be appropriately trained in and regularly review the facility’s written emergency protocols.
B. There should be written protocols for cardiopulmonary emergencies and other internal and external disasters such as fire.
C. The facility should have medications, equipment and written protocols available to treat malignant hyperthermia when triggering agents are used.
D. The facility should have a written protocol in place for the safe and timely transfer of patients to a prespecified alternate care facility when extended or emergency services are needed to protect the health or well-being of the patient. Pre-existing arrangements for definite care of the patient shall be established.

DESIDERATA: ANESTHESIA

In order to promote optimum patient care in the practice of anesthesia, the Oklahoma State Board of Medical Licensure and Supervision recommends these desiderata:

1. An orderly preoperative anesthetic risk evaluation is to be done by the responsible physician and recorded on the chart in all elective cases, and in urgent emergency cases, the anesthetic evaluations will be recorded as soon as feasible.
2. Every patient receiving general anesthesia, spinal anesthesia, or managed intravenous anesthesia (i.e., local standby, monitored anesthesia or conscious sedation), shall have arterial blood pressure and heart rate
measured and recorded at least every five minutes where not clinically impractical, in which case the responsible physician may waive this requirement stating the clinical circumstances and reasons in writing in the patient’s chart.

3. Every patient shall have the electrocardiogram continuously displayed from the induction and during maintenance of general anesthesia. In patients receiving managed intravenous anesthesia, electrocardiographic monitoring should be used in patients with significant cardiovascular disease as well as during procedures where dysrhythmias are anticipated.

4. During all anesthetics, patient oxygenation will be continuously monitored with a pulse oximeter, and whenever an endotracheal tube or Laryngeal Mask Airway (LMA) is inserted, correct positioning in the trachea and function will be monitored by end-tidal CO2 analysis (capnography) throughout the time of placement.

A. Additional monitoring for ventilation will include palpation or observation of the reservoir breathing bag, and auscultation of breath sounds.

B. Additional monitoring for circulation will include at least one of the following: Palpation of the pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, pulse plethysmography, or ultrasound peripheral pulse monitoring.

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

6. During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient’s breathing system will be measured by a functioning oxygen analyzer with low concentration audible limit alarm in use.

7. During every administration of general anesthesia, there shall be readily available a means to measure the patient’s temperature.

8. Availability of qualified trained personnel dedicated solely to patient monitoring.

These desiderata apply for any administration of anesthesia, including general, spinal, and managed intravenous anesthetics (i.e., local standby, monitored anesthesia or conscious sedation), administered in designated anesthetizing locations and any location where conscious sedation is performed.

“Conscious sedation” means a minimally depressed level of consciousness that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command, produced by a pharmacologic or non-pharmacologic method, or a combination thereof.

In emergency circumstances in any situation, immediate life support measures can be started with attention returning to these monitoring criteria as soon as possible and practical.
Licensees of the Oregon Medical Board providing office-based invasive procedures are accountable for the welfare and safety of their patients.

847-017-0005 Definitions
For the purpose of these rules, the following terms are defined:
(1) “Advanced Cardiac Life Support (ACLS) trained” means that a practitioner has successfully completed and maintains certification with advanced resuscitative techniques appropriate to the practitioner's field of practice. For example, for those practitioners treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (APLS) is appropriate.
(2) “Anesthesia, continuum of sedation:” Level of Sedation -- Responsiveness Airway -- Spontaneous Ventilation -- Cardiovascular Function:

(A) Conscious (Moderate) Sedation/ Analgesia -- Purposeful response to verbal or tactile stimulation -- No intervention required -- Adequate -- Usually maintained;

(B) Deep Sedation/ Analgesia -- Purposeful response following repeated or painful stimulation 1 -- Intervention may be required -- May be inadequate -- Usually maintained;

(C) General Anesthesia -- Unarousable, even with painful stimulus -- Intervention often required -- Frequently inadequate -- May be impaired. Reflex withdrawal from a painful stimulus is not considered a purposeful response.

(3) “Anesthetic agent” means any drug or combination of drugs administered with the purpose of creating conscious (moderate) sedation, deep sedation, regional anesthesia, or general anesthesia.

(4) “Adverse incident” means an untoward event occurring at any time within seven (7) days of any surgery, special procedure, or the administration of anesthetic agent(s) in an office setting.

(5) “Basic Life Support (BLS)” trained means that a practitioner has successfully completed and maintains certification in cardiopulmonary resuscitation. BLS training includes teaching the use of an automated external defibrillator (AED).

(6) “Board” means the Oregon Medical Board.

(7) “Local anesthesia” means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

(8) “Major conduction block anesthesia” means the injection of a local anesthetic agent in close proximity to a specific nerve or nerves to stop or prevent a painful sensation in a region of the body. Major conduction anesthesia includes, but is not limited to, all blocks and approaches to the brachial or lumbar plexus, subarachnoid blocks, epidural and caudal blocks and regional intravenous blocks.

(9) “Minor procedures” means surgery that can safely and comfortably be performed under topical or local anesthesia without more than minimal oral or intramuscular preoperative sedation. Minor procedures include, but are not limited to, surgery of the skin, subcutaneous tissue and other adjacent tissue, the incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, arthrocentesis and closed reduction of simple fractures or small joint dislocations.

(10) “Monitoring” means continuous or regular visual observation of the patient (as deemed appropriate by the level of sedation or recovery) and the use of instruments to measure, display, and record physiologic values, such as heart rate, blood pressure, respiration, and oxygen saturation.

(11) “Office” means a location at which medical or surgical services are rendered and which is not subject to a jurisdiction and licensing requirements of the Oregon Department of Human Services.

(12) “Office-based surgery” means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, which results in patient stay of less than 24 consecutive hours, and is performed by a practitioner in a location other than a hospital, diagnostic treatment center, or free-standing ambulatory surgery center.

(13) “Governing body of the facility” means the licensee or group of licensees who establish the office-based surgery facility.

847-017-0010 Patient Safety
(1) Offices in which only minor procedures are performed do not require accreditation or the presence of ACLS certified providers.

(2) The facility in which the office-based surgeries or procedures are performed must be appropriately equipped and maintained to ensure patient safety through accreditation by an appropriate, Board recognized, national or state organization, i.e., the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF), the American Osteopathic Association (AOA), the Institute for Medical Quality (IMQ), the Oregon Society of Oral Maxillofacial Surgeons (OSOMS), or the Oregon Medical Association (OMA). Effective August 1, 2007, for an office or facility in which office-based surgeries are already being performed, the office or facility must become accredited within two years, or by August 1, 2009. When licensees of the Board start performing office-based procedures in a new office or facility, the new office or facility must be accredited within one year of the start date of the office-based procedures being performed. During the period of time the facility is in the accreditation process, the facility will make changes to come into compliance with the Administrative Rules in this Division.

(3) The licensee must be able to demonstrate qualifications and competency for the procedures performed by becoming or being board certified and maintaining board certification by a member of the American Board of Medical Specialties (ABMS). Alternatively, the governing body of the office facility is responsible for a peer review process for privileging physicians based on nationally recognized credentialing standards.

(4) The licensee must insure that a practitioner administering deep sedation or anesthesia and or monitoring the patient shall not play an integral role in performing the procedure.

(5) At least one physician who is currently certified in advanced resuscitative techniques appropriate for the patient age group (e.g., ACLS, PALS or APLS) must be present or immediately available with age-size-appropriate resuscitative equipment until the patient has met the criteria for discharge from the facility. In addition other medical personnel with direct patient contact must at a minimum be trained in Basic Life Support (BLS).

(6) The governing body of the facility is responsible for providing healthcare providers who have appropriate education and training for administration of moderate sedation/analgesia, deep sedation/analgesia or general anesthesia.

(7) A licensee who holds a MD or DO degree as well as a DDS (Doctor of Dental Surgery) or DMD (Doctor of Dental Medicine) degree and is an active member of the Oregon Society of Oral Maxillofacial Surgeons (OSOMS) may perform maxillofacial procedures in a facility approved by the OSOMS and function under the administrative rules of the Oregon Board of Dentistry, OAR chapter 818, division 026. For all procedures that are not oral maxillofacial in nature, licensees with medical and dental licenses must follow rules laid out in OAR chapter 847, division 017.

847-017-0015 Selection of Procedures and Patients
(1) The licensee who performs the surgical procedure and/or anesthetic must evaluate and document the condition of the patient and the potential risks associated with the proposed treatment plan, and be satisfied that the procedure to be undertaken is within the scope of practice of the health care providers, the capabilities of the facility and the condition of the patient.

(2) Informed consent for the nature and objectives of the anesthesia planned and surgery to be performed must be in writing and obtained from patients before the procedure is performed. Informed consent is only to be obtained after a discussion of the risks, benefits, and alternatives and must be documented in the medical record.

847-017-0020 Patient Medical Records
(1) A legible, complete, comprehensive and accurate medical record must be maintained for each patient evaluated or treated. The record must include:
(a) Identity of the patient;
(b) History and physical, diagnosis and plan;
(c) Appropriate lab, x-ray or other diagnostic reports;
(d) Appropriate preanesthesia evaluation;
(e) Narrative description of procedure;
(f) Pathology reports;
(g) Procedure code; and
(h) Documentation of the outcome and the follow-up plan.

(2) If the nature of the surgery is such that analgesia/sedation, major conduction blockage, conscious (moderate) sedation, or general anesthesia are provided, the patient record must include a separate anesthetic record that contains documentation of anesthetic provider, procedure, and technique employed. This must include the type of anesthesia used, drugs (type and dose) and fluids administered during the procedure, patient weight, level of consciousness, estimated blood loss, duration of procedure, and any complication or unusual events related to the procedure or anesthesia.

(3) The medical records must contain documentation of the intraoperative and postoperative monitoring required.

(4) The patient record must document if tissues and other specimens have been submitted for histopathologic diagnosis.

(5) Provision for continuity of post-operative care must be documented in each patient's medical chart.

(6) Procedures must be established to assure patient confidentiality and security of all patient data and information.

47-017-0025 Discharge Evaluation
The licensee performing the procedure is responsible for the determination that the patient is safe to be discharged from the office after the procedure.

847-017-0030 Emergency Care and Transfer Protocols
The licensee is responsible for insuring that, in the event of an anesthetic, medical or surgical complication or emergency all office personnel are familiar with a written documented plan for the timely and safe transfer of patients to a nearby hospital. This plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.

847-017-0035 Quality Assessment
(1) Office-based surgical practices must develop a system of quality assessment that effectively and efficiently strives for continuous quality improvement.
(2) Documentation of adverse incident review must be available.

847-017-0040 Facility Administration and Equipment
The office facility must document that specific and current arrangements are in place for obtaining laboratory, radiological, pathological and other ancillary services as may be required to support the surgical and/or anesthetic procedures undertaken.

Pennsylvania – Medical
None

Pennsylvania – Osteopathic
None

A. Statement of Intent and Goals

The purpose of this regulation is to promote patient safety in the non-hospital office-based setting during procedures that require the administration of local anesthesia, sedation/analgesia, or general anesthesia, or minor or major conduction block. Moreover, this regulation has been developed to provide physicians performing office-based surgery (including cryosurgery and laser surgery), that requires anesthesia (including tumescent anesthesia), analgesia or sedation, the benefit of uniform professional standards regarding qualification of practitioners and staff, equipment, facilities and policies and procedures for patient assessment and monitoring. Level I procedures as defined in (B)(13) are excluded from this regulation.

B. Definitions

For the purpose of this regulation, the following terms are defined:

1. “Advanced resuscitative technique” means current certification in Advanced Trauma Life Support (ATLS), Advanced Cardiac Life Support (ACLS), or Pediatrics Advanced Life Support (PALS) as appropriate for the individual patient and surgical situation involved. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) is appropriate.

2. “Anesthesiologist” means a physician who has successfully completed a residency program in anesthesiology approved by the Accreditation Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

3. “Anesthesiologist's assistant (AA)” means a person licensed by the Board as an anesthesiologist's assistant who is an allied health graduate of an accredited anesthesiologist's assistant program who is currently certified by the National Commission for Certification of Anesthesiologist’s Assistants and who works under the direct supervision of an anesthesiologist who is immediately available in the operating suite and is physically present during the most demanding portions of the anesthetic including, but not limited to, induction and emergence.

4. “Board” means the South Carolina State Board of Medical Examiners.

5. “Certified registered nurse anesthetist (CRNA)” means a person licensed by the South Carolina State Board of Nursing as an Advanced Practice Registered Nurse in the category of Certified Registered Nurse Anesthetist.

6. “Complications” means untoward events occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia in an office setting including, but not limited to, any of the following: paralysis, malignant hypothermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than 24 hours, or death.

7. “Deep sedation/analgesia” means the administration of a drug or drugs that produce sustained depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients
may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

8. “DHEC” means the S.C. Department of Health and Environmental Control.

9. “General anesthesia” means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

10. “Health care personnel” means any office staff member who is licensed or certified by a recognized professional or health care organization such as but not limited to a professional registered nurse, licensed practical nurse, physician assistant or certified medical assistant.

11. “Hospital” means a hospital licensed by the state in which it is situated.

12. “Immediately available” means being located within the office and ready for immediate utilization when needed.

13. “Level I Surgery” means minor procedures in which p.o. preoperative medication and/or unsupplemented local anesthesia is used in quantities equal to or less than the manufacturer's recommended dose adjusted for weight and where the likelihood of complications requiring hospitalization is remote. No drug-induced alteration of consciousness other than preoperative minimal p.o. anxiolysis of the patient is permitted in Level I Office Surgery; the chances of complications requiring hospitalization must be remote.

14. “Local anesthesia” means the administration of an agent that produces a transient and reversible loss of sensation in a circumscribed portion of the body.

15. “Major conduction block” means the injection of local anesthesia to stop or prevent a painful sensation in a region of the body. Major conduction blocks include, but are not limited to, axillary, interscalene, and supraclavicular block of the brachial plexus, spinal (subarachnoid), epidural and caudal blocks.

16. “Minimal sedation” (anxiolysis) means the administration of a drug or drugs that produces a state of consciousness that allows the patient to tolerate unpleasant medical procedures while responding normally to verbal commands. Cardiovascular or respiratory function should remain unaffected and defensive airway reflexes should remain intact.

17. “Minor conduction block” means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration. Minor conduction blocks include, but are not limited to, intercostal, retrobulbar, paravertebral, peribulbar, pudendal, sciatic nerve, and ankle blocks.

18. “Moderate sedation/analgesia” means the administration of a drug or drugs, which produces depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from painful stimulation is NOT considered a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. This includes dissociative anesthesia, which does not meet the criteria as defined under sustained deep anesthesia or general anesthesia.

19. “Monitoring” means continuous visual observation of a patient and regular observation of the patient as deemed appropriate by the level of sedation or recovery using instruments to measure, display, and record physiologic values such as heart rate, blood pressure, respiration and oxygen saturation.

20. “Office” means a location at which medical or surgical services are performed and which is not subject to regulation by DHEC.

21. “Office-based practice” means procedures performed under this regulation that occur in a physician's office or location other than a hospital or facility licensed by DHEC.

22. “Office-based surgery” means the performance of any surgical or other invasive procedure requiring anesthesia, analgesia, or sedation, including cryosurgery and laser surgery, which results in a necessary patient stay of less than twenty-four consecutive hours and is performed by a physician in a location other than a hospital or a diagnostic treatment center, including free-standing ambulatory surgery centers.

23. “Operating room” means that location in the office or facility dedicated to the performance of surgery or special procedures.
24. “Physical status classification” means a description of a patient used in determining if an office surgery or procedure is appropriate. The American Society of Anesthesiologists (ASA) enumerates classification: I - Normal, healthy patient; II - a patient with mild systemic disease; III - a patient with severe systemic disease limiting activity but not incapacitating; IV - a patient with incapacitating systemic disease that is a constant threat to life; and V - Moribund, patients not expected to live 24 hours with or without operation.

25. “Physician” means an individual holding an M.D. or D.O. degree who is authorized to practice medicine in accordance with the South Carolina Medical Practice Act.

26. “Practitioner” means a physician or anesthesiologist assistant, registered nurse or CRNA licensed and practicing within the scope of practice pursuant to South Carolina law.

27. “Recovery area” means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

28. “Special procedure” means patient care which requires entering the body with instruments in a potentially painful manner, or which requires the patient to be immobile, for a diagnostic or therapeutic procedure requiring anesthesia services; for example, diagnostic or therapeutic endoscopy, invasive radiologic procedures, pediatric magnetic resonance imaging; manipulation under anesthesia or endoscopic examination with the use of general anesthetic.

29. “Sufficient knowledge” means a physician holds staff privileges in a South Carolina hospital or ambulatory surgical center which would permit the physician to supervise the anesthesia, or the physician must be able to document certification or eligibility by a specialty board approved by the American Board of Medical Specialties or American Osteopathic Association, or the physician must be able to demonstrate comparable background, formal training, or experience in supervising the anesthesia, as approved by the Board.

30. “Surgery” means any operative or manual procedure performed for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering, or any elective procedure for aesthetic or cosmetic purposes. This includes, but is not limited to, incision or curettage of tissue or an organ, suture or other repair of tissue or an organ, extraction of tissue from the uterus, insertion of natural or artificial implants, closed or open fracture reduction, or an endoscopic examination with use of local or general anesthetic. This also includes, but is not limited to, the use of lasers and any other devices or instruments in performing such procedures.

31. “Topical anesthesia” means the effect produced by an anesthetic agent applied directly or indirectly to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

C. Office Administration

Each office-based practice, at a minimum, must develop and implement policies and procedures on the topics listed below. The policies and procedures must be periodically reviewed and updated. The purpose of the policies and procedures is to assist in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients.

1. Emergency Care and Transfer Plan: A plan must be developed for the provision of emergency medical care as well as the safe and timely transfer of patients to a nearby hospital, should hospitalization be necessary.

a. Age appropriate emergency supplies, equipment and medication must be provided in accordance with the scope of surgical and anesthesia services provided at the physician's office.

b. In an office where anesthesia services are provided to infants and children, the required emergency equipment must be appropriately sized for a pediatric population, and personnel must be appropriately trained to handle pediatric emergencies (e.g. PALS certified).

c. A practitioner who is qualified in resuscitation techniques and emergency care must be present and available until all patients having more than local anesthesia or minor conduction block anesthesia have been discharged from the operating room or recovery area.

d. In the event of untoward anesthetic, medical or surgical complications or emergencies, personnel must be familiar with the procedures and plan to be followed, and able to take the necessary actions. All office personnel must be familiar with a documented plan for the timely and safe transfer of patients to a nearby hospital.
hospital. This plan must include arrangements for emergency medical services, if necessary, or when appropriate, escort of the patient to the hospital or to an appropriate practitioner. If advanced cardiac life support is instituted, the plan must include immediate contact with emergency medical services.

2. Medical Record Maintenance and Security: The practice must have a written procedure for initiating and maintaining a health record for every patient evaluated or treated. The record must include a procedure code or suitable narrative description of the procedure and must have sufficient information to identify the patient, support the diagnosis, justify the treatment and document the outcome and required follow-up care. For procedures requiring patient consent, there must be a documented, informed consent in the patient record. If analgesia/sedation, minor or major conduction block or general anesthesia are provided, the record must include documentation of the type of anesthesia used, drugs (type and dose) and fluids administered, the record of monitoring of vital signs, level of consciousness during the procedure, patient weight, estimated blood loss, duration of the procedure, and any complications related to the procedure or anesthesia. Procedures must also be established to assure patient confidentiality and security of all patient data and information.

3. Infection Control Policy: The practice must comply with state and federal regulations regarding infection control. For all surgical procedures, the level of sterilization must meet current OSHA requirements. There must be a written procedure and schedule for cleaning, disinfecting and sterilizing equipment and patient care items. Personnel must be trained in infection control practices, implementation of universal precautions, and disposal of hazardous waste products. Protective clothing and equipment must be available.

4. Performance Improvement:
   a. A performance improvement program must be implemented to provide a mechanism to periodically review (minimum of every six months) the current practice activities and quality of care provided to patients, including peer review by members not affiliated with the same practice. Performance improvement (PI) can be established by:
      (1) Establishment of a PI program by the practice; or
      (2) A cooperative agreement with a hospital-based performance or quality improvement program; or
      (3) A cooperative agreement with another practice to jointly conduct PI activities; or
      (4) A cooperative agreement with a peer review organization, a managed care organization, specialty society, or other appropriate organization dedicated to performance improvement approved by the Board.
   b. PI activities must include, but not be limited to review of mortalities, review of the appropriateness and necessity of procedures performed, emergency transfers, surgical and anesthetic complications, and resultant outcomes (including all postoperative infections), analysis of patient satisfaction surveys and complaints, and identification of undesirable trends, such as diagnostic errors, unacceptable results, follow-up of abnormal test results, and medication errors and system problems. Findings of the PI program must be incorporated into the practice’s educational activity.

5. Reporting of Adverse Events: Anesthetic or surgical events requiring resuscitation, emergency transfer, or resulting in death must be reported to the South Carolina Board of Medical Examiners within three business days using a form approved by the Board. Such reports shall be considered initial complaints under the S.C. Medical Practice Act.

6. Federal and State Laws and Regulations: Federal and state laws and regulations that affect the practice must be identified and procedure developed to comply with those requirements. The following are some of the key requirements upon which office-based practices must focus:
   a. Non-Discrimination (see Civil Rights statutes and the Americans with Disabilities Act)
   b. Personal Safety (see Occupational Safety and Health Administration information)
   c. Controlled Substance Safeguards
   d. Laboratory Operations and Performance (CLIA)
   e. Personnel Licensure Scope of Practice and Limitations.

7. Patients' Bill of Rights: Office personnel must recognize the basic rights of patients and understand the importance of maintaining patients' rights. A patients’ rights document must be immediately available upon request.

D. Credentialing
1. Facility Accreditation: Practices performing office-based surgery or procedures that require the administration of moderate or deep sedation/analgesia, or general anesthesia (Level II and III facilities as defined below) must be accredited within the first year of operation by an accreditation agency, including the American Association of Ambulatory Surgery Facilities (AAASF); Accreditation Association for Ambulatory Health Care (AAAHC); the Joint Commission on Accreditation of Healthcare Organizations (JCAHO); or the Healthcare Facilities Accreditation Program (HFAP), a division of the American Osteopathic Association; or any other agency approved by the South Carolina Board of Medical Examiners. The accrediting agency must submit a biannual summary report for each facility to the South Carolina Board of Medical Examiners. Any physician performing Level II or Level III office surgery must register with the South Carolina Board of Medical Examiners. Such registration must include each address at which Level II or Level III office surgery is performed and identification of the accreditation agency that accredits each location (when applicable). Rule of Thumb: The capacity of the patient at all times to retain his/her life-protective reflexes and to respond to sensory stimuli (i.e., the depth of sedation or anesthesia), rather than the specific procedure performed, lies at the core of differentiating Level II from Level III surgery.

a. Scope of Level II Office Surgery: Level II office surgery includes any procedure which requires the administration of minimal or moderate intravenous, intramuscular, or rectal sedation/analgesia, thus making post-operative monitoring necessary. Level II office surgery must be limited to procedures where there is only a moderate risk of surgical and/or anesthetic complications and the likelihood of hospitalization as a result of these complications is unlikely. Level II office surgery includes local or peripheral nerve block, minor conduction block, and Bier block.

b. Scope of Level III Office Surgery: Level III office surgery includes any procedure that requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia, or major conduction block, and/or in which the known complications of the proposed surgical procedure may be serious or life threatening.

2. Practitioners:

a. The specific office-based surgical procedures and anesthesia services that each respective practitioner involved is qualified and competent to perform must be commensurate with each practitioner's level of training and experience. Criteria to be considered to demonstrate competence include:

   (1) State licensure.
   (2) Procedure-specific education, training, experience and successful evaluation appropriate for the patient population being treated (e.g. pediatrics).
   (3)(a) For physicians, staff privileges in a hospital to perform the same procedure or service as that being performed in the office setting or board certification, board eligibility or completion of a training program in a field of specialization recognized by the ACGME for expertise and proficiency in that field, or comparable background, formal training, or experience as approved by the Board. Board certification is understood as American Board of Medical Specialists (ABMS), American Osteopathic Association (AOA), or equivalent board certification as determined by the Board.
   (b) For non-physician practitioners, certification that is appropriate and applicable for the practitioner, as recognized by the practitioner's licensing board or this Board.
   (4) Professional misconduct and malpractice history.
   (5) Participation in peer and quality review proceedings.
   (6) Participation in continuing competency activities consistent with the statutory requirements and requirements of the practitioner's professional organization.
   (7) Malpractice insurance coverage adequate for the specialty.
   (8) Procedure-specific competence (and competence in the use of new procedures/technology), which encompasses education, training, experience and evaluation, and which includes:
      (a) Adherence to professional society standards;
      (b) Hospital and/or ambulatory surgical privileges for the scope of services performed in the office-based setting at Levels II and III or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties,
American Osteopathic Association, or comparable background, formal training, or experience as approved by the Board;
(c) Credentials approved by a nationally recognized accrediting/credentialing organization;
(d) For physicians, didactic course complemented by hands-on, observed experience. Training is to be followed by a specified number of cases supervised by a practitioner already competent in the respective procedure, in accordance with professional society standards and guidelines.

b. Unlicensed or uncertified personnel may not be assigned duties or responsibilities that require professional licensure or certification. Duties assigned to unlicensed or uncertified personnel must be in accordance with their training, education and experience and under the direct supervision of a qualified, licensed practitioner.

E. Standards for Office Procedures
1. Level II Office Procedures:
a. Training Required:
(1) The physician must have staff privileges in a hospital to perform the same procedure as that being performed in the office setting or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties, American Osteopathic Association, or must demonstrate comparable background, formal training, or experience as approved by the Board. The physician must maintain current certification in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).
(2) One assistant or other health care personnel that is immediately available (immediately available is defined as being located within the office and not necessarily the person assisting in the procedure) must be certified in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

b. Equipment and Supplies Required:
(1) Emergency resuscitation equipment and a reliable source of oxygen must be current and immediately available.
(2) Monitoring equipment must include a continuous suction device, pulse oximeter, and noninvasive blood pressure apparatus and stethoscope. Electrocardiographic monitoring must be available for patients with a history of cardiac disease. Age- and size-appropriate monitors and resuscitative equipment must be available for patients.

c. Assistance of Other Personnel Required:
(1) Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately available, who possesses sufficient knowledge, and who is qualified in accordance with law supervise the administration of the sedation/analgesia or minor conduction block. The physician providing supervision must:
(a) ensure that an appropriate pre-sedation/analgesia or anesthesia examination and evaluation is performed proximate to the procedure;
(b) order the sedation/analgesia or anesthesia;
(c) ensure that qualified health care personnel participate;
(d) remain immediately available until discharge criteria are met; and
(e) ensure the provision of indicated post-sedation/analgesia or anesthesia care.
(2) Sedation/analgesia or anesthesia must be administered or supervised only by a duly licensed, qualified and competent physician. CRNAs, AAs, or other qualified practitioners who administer sedation/analgesia or anesthesia as part of a medical procedure must have training and experience appropriate to the level of sedation/analgesia or anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented competence to administer sedation/analgesia or anesthesia and to assist in any support or resuscitation measures as required. The individual administering sedation/analgesia or anesthesia and/or monitoring the patient must not play an integral role in performing the surgical procedure. This is not intended to restrict or limit the physician’s ability to delegate medical tasks to other qualified practitioners in Level II office procedures.
(3) A registered nurse or other licensed health care personnel practicing within the scope of their practice who is currently certified in advanced resuscitative techniques must monitor the patient postoperatively and have the capability of administering medications as required for analgesia, nausea/vomiting, or other
indications. Monitoring in the recovery area must include pulse oximetry and non-invasive blood pressure measurement. The patient must be assessed periodically for level of consciousness, pain relief, or any untoward complication. Each patient must meet discharge criteria as established by the practice, prior to leaving the operating room or recovery area.

d. Transfer and Emergency Protocols: The physician must have a transfer protocol in effect with a hospital within reasonable proximity.

e. Facility Accreditation: The physician must obtain and maintain accreditation of the office setting by an approved accreditation agency.

2. Level III Office Procedures

a. Training Required:
   (1) The physician must have documentation of training to perform the particular surgical procedure(s). The physician must have staff privileges in a hospital to perform the same procedure as that being performed in the office setting or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties, American Osteopathic Association, or comparable background, formal training, or experience as approved by the Board. In the event the physician is supervising the administration of anesthesia by a CRNA, the physician must have sufficient knowledge of the anesthesia specified for the procedure to provide effective care in the case of emergency. If the physician does not possess the sufficient knowledge of anesthesia, the anesthesia must be administered by or under the supervision of a qualified physician. The physician must maintain current certification in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).
   (2) One assistant or other health care personnel that is immediately available (immediately available is defined as being located within the office and not necessarily the person assisting in the procedure) must be currently certified in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

b. Equipment and Supplies Required:
   (1) Emergency resuscitation equipment, a continuous suction device, and a reliable source of oxygen must be current and immediately available. At least 12 ampules of dantrolene sodium must be immediately available. Age-and size-appropriate monitors and resuscitative equipment must be available for patients.
   (2) Monitoring equipment must include:
      (a) blood pressure apparatus and stethoscope
      (b) pulse oximetry
      (c) continuous EKG
      (d) capnography
      (e) temperature monitoring for procedures lasting longer than 30 minutes.
   (3) Facility, in terms of general preparation, equipment and supplies, must be comparable to a free standing ambulatory surgical center, have provisions for proper record keeping, and the ability to recover patients after anesthesia.

c. Assistance of Other Personnel Required:
   (1) Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately available, who possesses sufficient knowledge, and who is qualified in accordance with law to supervise the administration of the sedation/analgesia or minor conduction block. The physician providing supervision must:
      (a) ensure that an appropriate pre-sedation/analgesia or anesthesia examination and evaluation is performed proximate to the procedure;
      (b) order the sedation/analgesia or anesthesia;
      (c) ensure that qualified health care personnel participate;
      (d) remain immediately available until discharge criteria are met; and
      (e) ensure the provision of indicated post-sedation/analgesia or anesthesia care.
   (2) Sedation/analgesia or anesthesia must be administered or supervised only by a duly licensed, qualified and competent physician. CRNAs or AAs who administer sedation/analgesia or anesthesia as part of a medical procedure must have training and experience appropriate to the level of sedation/analgesia or anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented
competence to administer sedation/analgesia or anesthesia and to assist in any support or resuscitation measures as required. The individual administering sedation/analgesia or anesthesia and/or monitoring the patient must not play an integral role in performing the surgical procedure.

(3) A registered nurse or other licensed health care personnel practicing within the scope of their practice who is currently certified in advanced resuscitative techniques must monitor the patient postoperatively and have the capability of administering medications as required for analgesia, nausea/vomiting, or other indications. Monitoring in the recovery area must include pulse oximetry and non-invasive blood pressure measurement. The patient must be assessed periodically for level of consciousness, pain relief, or any untoward complication. Each patient must meet discharge criteria as established by the practice, prior to leaving the operating room or recovery area.

d. Transfer and Emergency Protocols: The physician must have a transfer protocol in effect with a hospital within reasonable proximity.

e. Facility Accreditation and Inspection. The physician must obtain and maintain accreditation of the office setting by an approved accreditation agency.

F. Patient Admission and Discharge

1. Patient Selection. The physician must evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician is also responsible for providing a post-operative plan to the patient and ensuring the patient is aware of the need for the necessary follow-up care. Patients with pre-existing medical problems or other conditions, who are at undue risk for complications, must be referred to an appropriate specialist for pre-operative consultation. Patients that are considered high risk or are a physical classification status III or greater and require a general anesthetic for the surgical procedure must have the surgery performed in a hospital setting or in ambulatory surgery centers. Patients with a physical status classification of III or greater may be acceptable candidates for moderate sedation/analgesia. ASA Class III patients must be specifically addressed in the operating procedures of the office-based practice. They may be acceptable candidates if deemed so by a physician qualified to assess the specific disability and its impact on anesthesia and surgical risks. Acceptable candidates for deep sedation/analgesia, general anesthesia, or major conduction block in office settings are patients with a physical status classification of I or II, no airway abnormality, and possess an unremarkable anesthetic history.

2. Informed Consent. The risks, benefits, and potential complications of both the surgery and anesthetic must be discussed with the patient and/or, if applicable, the patient’s legal guardian prior to the surgical procedure. Written documentation of informed consent must be included in the medical record.

3. Preoperative Assessment. A specialty specific medical history and physical examination must be performed, and appropriate laboratory studies obtained within 30 days prior to the planned surgical procedure, by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. The physician must assure that a preanesthetic examination and evaluation is conducted immediately prior to surgery by the practitioner who will be administering or supervising the anesthesia. Monitoring must be available for patients with a history of cardiac disease. Age and size appropriate monitors and resuscitative equipment must be available for patients. The information and data obtained during the course of these evaluations must be documented in the medical record.

4. Discharge Evaluation. The physician must evaluate the patient immediately upon completion of the surgery and anesthesia. Care of the patient may then be transferred to qualified health care personnel in the recovery area. A qualified physician must remain immediately available until the patient meets discharge criteria. Criteria for discharge for all patients who have received anesthesia must include the following:

a. confirmation of stable vital signs
b. stable oxygen saturation levels
c. return to pre-procedure mental status
d. adequate pain control
e. minimal bleeding, nausea and vomiting
f. resolving neural block, resolution of the neuraxial block
g. discharged in the company of a competent adult.
5. Patient Instructions. The patient must receive verbal instruction understandable to the patient or guardian, confirmed by written post-operative instructions and emergency contact numbers. The instructions must include:
   a. The procedure performed
   b. Information about potential complications
   c. Telephone numbers to be used by the patient to discuss complications or should questions arise
   d. Instructions for medications prescribed and pain management
   e. Information regarding the follow-up visit date, time and location
   f. Designated treatment facility in the event of emergency.

G. Inapplicability to dentistry. These regulations shall not apply to an oral surgeon licensed to practice dentistry who is also a physician licensed to practice medicine, if the procedure is exclusively for the practice of dentistry.

South Dakota

None

Tennessee – Medical

T. C. A. § 63-6-221 Office-based surgery
(a) For the purposes of this section, unless the context otherwise requires:
(1) “Board” means the board of medical examiners;
(2) “Level II office-based surgery” means Level II surgery, as defined by the board of medical examiners in its rules and regulations, that is performed outside of a hospital, an ambulatory surgical treatment center or other medical facility licensed by the department of health;
(3) “Office-based surgery” or “Level III office-based surgery” means Level III surgery requiring a level of sedation beyond the level of sedation defined by the board of medical examiners as Level II surgery that is performed outside a hospital, an ambulatory surgical treatment center or other medical facility licensed by the department of health;
(4) “Physician” means any person licensed under this chapter; and
(5) “Surgical suite” means both the operating and recovery room or rooms located in a physician's office where Level III office-based surgery is to be performed.
(b) The board shall have the duty and responsibility to regulate the practice of office-based surgery, including the promulgation of rules necessary to promote patient health and safety in such practices, including, but not limited to, a mechanism by which allooffice-based surgical suites are surveyed and certified by the board.
(c) The board shall specifically identify in rules the parameters to be used in determining Level III surgical procedures and multiple procedures that may be performed in an office-based setting pursuant to the level of anesthesia involved in the procedures. In addition, the board shall promulgate age and risk classification criteria of patients eligible for Level III office-based surgical procedures.
(d) By December 30, 2007, the board shall adopt rules establishing a specific list of approved Level III surgical procedures that can be performed in a physician's office in this state. The ambulatory surgical center covered procedures list promulgated by the centers of medicare and medicaid shall be used as a guide. No physician shall perform any Level III surgical procedures that are not included on the list promulgated by the board. The board may modify the list as the board deems necessary. The board shall also promulgate rules addressing the minimum requirements deemed necessary by the board for the safe performance of office-based surgery.
(e) Using the rules established for ambulatory surgical treatment centers as guidelines, the board shall promulgate rules relative to infection control, life safety, patient rights, hazardous waste and equipment and supplies necessary to assure the safety of patients undergoing office-based surgery. Any provision in the
ambulatory surgical treatment center rules addressing infection control, life safety, patient rights, hazardous waste and equipment and supplies that is not adopted by the board shall require a statement entered into the official minutes from the board justifying the board's decision.

(f) No more than three (3) patients undergoing Level III office-based surgery in a physician's office may be incapable of self-preservation at the same time. The board shall promulgate rules requiring physician offices that perform office-based surgery to adopt bylaws that put in place a management system and documentation that will ensure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time. The bylaws and documentation of the management system shall be included in the application for surgical suite certification.

(g) 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.

(h) The board shall enter into a memorandum of understanding, contract or other written arrangement with the department of health such that the department:

(1) Provides a site survey of the surgical suites sought to be certified to perform office-based surgery. A physician office at which office-based surgeries are being performed as of October 1, 2007, shall submit both a request for a site survey on an application form developed by the board and remit payment of the office-based surgery fee to the department by October 1, 2007. If the office makes a timely filing in accordance with this subdivision (h)(1), 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 or suites. A physician office at which office-based surgeries are not being performed as of October 1, 2007, shall not perform any such procedures until an application form and payment of the office-based surgery fee is submitted to the board and a site survey is completed by the department and a certification of the surgical suite is issued by the board;

(2) Is authorized to require plans of correction and to verify that the plans of correction have been implemented;

(3) Is authorized to initiate subsequent, unannounced site surveys during regular business hours as long as the physician office continues to be used to perform office-based surgeries, but no more frequently than once every twelve (12) months; and

(4) Is authorized to 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 office-based surgery is being performed at the request of the office of investigations.

(i) The results of all site surveys shall be transmitted by the department to the board. The results shall include any requirement for plans of correction, the department's determination of the acceptability of the submitted plans of correction and the department's verification that the plans of correction have been implemented. The board shall make a final determination on certifying the surgical suite for performance of office-based surgeries. The results of site surveys and board determinations shall be shared on a routine basis with the board for licensing health care facilities.

(j) The results of all complaint investigations by department staff shall be transmitted to the board for resolution; however, that information shall at all times be maintained as confidential and not available to the public except to the extent § 63-1-117(g) applies.

(k) Any physician office that desires to be certified to perform office-based surgery shall pay to the department an annual office-based surgery fee as set by the board.

(l) A physician office at which office-based surgery is being performed shall ensure that claims data is reported to the commissioner of health on a form approved by the department of health. The data shall be submitted through a third party approved by the department of health for the purpose of editing the data according to rules and regulations established by the commissioner. The physician office shall be responsible for the costs associated with processing of the data by the approved vendors. The claims data shall be reported at least quarterly to the commissioner. No information shall be made available to the public by the commissioner that reasonably could be expected to reveal the identity of any patient. The claims data reported to the commissioner under this section are confidential and not available to the public until the
commissioner processes and verifies the data. The commissioner shall prescribe conditions under which the processed and verified data are available to the public.

(m)(1) Except as provided in subdivision (h)(1), a physician office surgical suite is required to be certified by the board in order to perform office-based surgery. A physician office that proposes to perform office-based surgery shall submit to the board, on an application form provided by the board, at least the following:

(A) Level III procedures expected to be performed by each physician;
(B) The specialty board certification or board eligibility of the physician or physicians performing Level III procedures, if any;
(C) Verification of health care liability coverage for all physicians performing Level III procedures;
(D) Verification of hospital staff privileges for all physicians performing Level III procedures;
(E) The name of a responsible physician in whose name the surgical suite certification shall be issued for that office and a list of the physicians with the practice who are going to be performing Level III office-based surgeries; and
(F) The documentation required by subsection (f) regarding incapacitated patient limits.

(2) The form required by subdivision (m)(1) shall serve as an application form, but the information on the form shall be updated as appropriate when any information on it has changed.

(n) The board shall notify all physicians of the office-based surgery certification requirements. Failure of a physician performing office-based surgery or a physician office at which office-based surgery is being performed to abide by this section, any rules promulgated pursuant to this section or of § 68-11-211 may be grounds for disciplinary action or termination of either the rights of the physician to perform office-based surgery or the surgical suite's certification by the physician's licensing board, or both disciplinary action and termination. For purposes of § 4-5-320(c), the public health, safety and welfare imperatively require emergency action at any time that a previously authorized surgical suite fails to maintain the standards set by the board.

(o) Applicants for initial licensure or reinstatement of a previously issued license shall indicate to the board on the appropriate licensure application if they intend to perform Level II office-based surgery procedures as defined by the rules of the board of medical examiners and that are integral to a planned treatment regimen and not performed on an urgent or emergent basis.

(p) Licensed physicians who perform Level II office-based surgery at the time of licensure renewal shall indicate to the board on the licensure renewal application if the licensee currently performs Level II office-based surgery procedures as defined in the rules of the board of medical examiners and that are integral to a planned treatment regimen and not performed on an urgent or emergent basis.

(q) In order for health care providers and the board to work together to collect meaningful health care data, so as to minimize the frequency and severity of certain unexpected events and improve the delivery of health care services, each physician who performs any Level II office-based surgery or Level III office-based surgery that results in any of the following unanticipated events shall notify the board in writing within fifteen (15) calendar days following the physician's discovery of the event:

(1) The death of a patient during any Level II office-based surgery or Level III office-based surgery or within seventy-two (72) hours thereafter;
(2) The transport of a patient to a hospital emergency department except those related to a natural course of the patient's illness or underlying condition;
(3) The unplanned admission of a patient to a hospital within seventy-two (72) hours of discharge, only if the admission is related to the Level II office-based surgery or Level III office-based surgery, except those related to a natural course of the patient's illness or underlying condition;
(4) The discovery of a foreign object erroneously remaining in a patient from a Level II office-based surgery or Level III office-based surgery at that office; or
(5) The performance of the wrong surgical procedure, surgery on the wrong site or surgery on the wrong patient.

(r) Records of reportable events should be in writing and should include at a minimum the following:

(1) The physician's name and license number;
(2) The date and time of the occurrence or discovery of the incident;
(3) The office and address where the incident took place;
(4) The name and address of the patient;
(5) The type of Level II office-based surgery or Level III office-based surgery that was performed;
(6) The type and dosage of sedation or anesthesia utilized during the procedure;
(7) The circumstances surrounding the incident; and
(8) The type or types of events required to be reported as provided in subsection (q).

(s) The filing of a report as required by subsection (q) does not, in and of itself, constitute an acknowledgement or admission of health care liability, error or omission. Upon receipt of the report, the board may, in its discretion, obtain patient and other records pursuant to authority granted to it in § 63-1-117. The reporting form and any supporting documentation reviewed or obtained by the board pursuant to this section and any amendments to the reports shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity; nor shall they be admissible in any civil or administrative proceeding, other than a disciplinary proceeding by the board; nor shall they be subject to any open records request made pursuant to title 10, chapter 7, part 5 or any other law. This section shall not affect any of the provisions of or limit the protections provided by §§ 63-6-219 and 63-9-114.

t) Failure to comply with the requirements of subsections (o)-(s) constitutes grounds for disciplinary action by the board in its discretion pursuant to § 63-6-214.

**Tenn. Comp. R. & Regs. 0880-02-21 OFFICE BASED SURGERY**

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

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

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

(b) Application - These rules do not apply to physicians or the governing body of entities lawfully authorized to practice medicine whose practice location(s) has as its primary purpose the provision of Level I, II, IIA and III surgical or surgical preparatory services and/or procedures. Those types of practice locations must comply with all laws, rules and regulations applicable to ambulatory surgical treatment centers including rules 0720-10, 11 and 12.

(3) Definitions
(a) Acceptable Plan of Correction. The Department approves an Office Based Surgery 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. The date upon which each deficiency will be corrected;
3. What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and
4. How the corrective action will be monitored to ensure that the deficient practice does not recur.

(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 extremityplexus 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, caudal blocks, and intravenous regional anesthetic.

(f) Board - The Tennessee Board of Medical 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 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) Physician - A person licensed to practice medicine and surgery pursuant to Tennessee Code Annotated Title 63, Chapter 6.

(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.

(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 preoperative 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 preoperative 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 preoperative 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.
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 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 preprinted 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 preoperative 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, 2, and 3 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 officebased 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 physicians' 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 Department of Health to determine compliance with the standards set forth in this rule. The Department of Health 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 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 department 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 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 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 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 and recovery areas 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 and recovery areas 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) and recovery area(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) and recovery area(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 in surgical suites and recovery areas 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 all the following rooms encompassed within the surgical suites and recovery areas: the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces. A positive air pressure shall be maintained in all clean areas encompassed within the surgical suites and recovery areas including, but not limited to, clean linen rooms and clean utility rooms.
(vi) The emergency power system for surgical suites and recovery areas shall:
(I) Use either propane, gasoline or diesel fuel. The generator shall be designed to meet the surgical suite and recovery area'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 Surgery 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 suite shall have trained staff familiar with the generator's operation.
(IV) Emergency generators are not required if the suite does not utilize anesthesia that renders the patient incapable of self preservation. However, the suite 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 (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 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 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 Surgery 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 within 30 days prior to surgeryand updated within 24 hours 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.

7. Reporting

(i) Surgery Suites are subject to all reporting requirements in Tenn. Code Ann. §§63-6-221(1) and 68-11-211, as well as any other reporting required by law.

(ii) The Surgery Suite 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.
(iii) The Surgery Suite shall report to the Department of Health each case of communicable disease detected in the center. Repeated failure to report communicable diseases shall be cause for revocation of a Surgery Suite’s license.

8. 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.

9. 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.

10. 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; 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.

11. Level III surgical suites shall be used exclusively for surgery and recovery, respectively and for no other purpose.

12. 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.

13. 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.

(c) 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 nontumescent 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. § 63-6-214 (b) (1), (2) or (4) or Public Chapter 373 of the Public Acts of 2007.

(a) When an office-based surgical suite is found by the department to have committed a violation of this rule, the department will issue to the office a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the office must return a plan 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) Failure to submit a plan of correction in a timely manner, a finding by the department that the plan of correction is unacceptable, or a finding that the plan of correction was not implemented shall subject the office based surgical suite's certification to possible disciplinary action.

Tennessee – Osteopathic

T. C. A. § 63-9-117. Office-based surgery

(a) For the purposes of this section, unless the context otherwise requires:

(1) “Board” means the board of osteopathic examination;
(2) “Level II office-based surgery” means Level II surgery as defined by the board of osteopathic medical examination in its rules and regulations that is performed outside of a hospital, ambulatory surgical treatment center or other medical facility licensed by the department of health;
(3) “Office-based surgery” means Level III surgery requiring a level of sedation beyond the level of sedation defined by the board of medical examiners as Level II surgery that is performed outside a hospital, an ambulatory surgical treatment center or other medical facility licensed by the department of health;
(4) “Physician” means any person licensed under this chapter; and
(5) “Surgical suite” means both the operating and recovery room or rooms located in a physician's office where Level III office-based surgery is to be performed.

(b) The board shall have the duty and responsibility to regulate the practice of office-based surgery, including the promulgation of rules necessary to promote patient health and safety in such practices, including, but not limited to, a mechanism by which all office-based surgical suites are surveyed and certified by the board.

(c) The board shall specifically identify in rules the parameters to be used in determining Level III surgical procedures and multiple procedures that may be performed in an office-based setting pursuant to the level of anesthesia involved in the procedures. In addition, the board shall promulgate age and risk classification criteria of patients eligible for Level III office-based surgical procedures.

(d) By December 30, 2007, the board shall adopt rules establishing a specific list of approved Level III surgical procedures that can be performed in a physician's office in this state. The ambulatory surgical center covered procedures list promulgated by the centers of medicare and medicaid shall be used as a guide. No physician shall perform any Level III surgical procedures that are not included on the list promulgated by the
board. The board may modify the list as the board deems necessary. The board shall also promulgate rules addressing the minimum requirements deemed necessary by the board for the safe performance of office-based surgery.

e) Using the rules established for ambulatory surgical treatment centers as guidelines, the board shall promulgate rules relative to infection control, life safety, patient rights, hazardous waste and equipment and supplies necessary to assure the safety of patients undergoing office-based surgery. Any provision in the ambulatory surgical treatment center rules addressing infection control, life safety, patient rights, hazardous waste and equipment and supplies that is not adopted by the board shall require a statement entered into the official minutes from the board justifying the board's decision.

f) No more than three (3) patients undergoing Level III office-based surgery in a physician's office may be incapable of self-preservation at the same time. The board shall promulgate rules requiring physician offices that perform office-based surgery to 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. The bylaws and documentation of the management system shall be included in the application for surgical suite certification.

g) 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.

h) The board shall enter into a memorandum of understanding, contract or other written arrangement with the department of health such that the department:

(1) Provides a site survey of the surgical suites sought to be certified to perform office-based surgery. A physician office at which office-based surgeries are being performed as of October 1, 2007, shall submit both a request for a site survey on an application form developed by the board and remit payment of the office-based surgery fee to the department by October 1, 2007. If the office makes a timely filing in accordance with this subdivision (h)(1), 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 or suites. A physician office at which office-based surgeries are not being performed as of October 1, 2007, shall not perform any such procedures until an application form and payment of the office-based surgery fee is submitted to the board and a site survey is completed by the department and a certification of the surgical suite is issued by the board;

(2) Is authorized to require plans of correction and to verify that the plans of correction have been implemented;

(3) Is authorized to initiate subsequent, unannounced site surveys during regular business hours as long as the physician office continues to be used to perform office-based surgeries, but no more frequently than once every twelve (12) months; and

(4) Is authorized to 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 office-based surgery is being performed at the request of the office of investigations.

i) The results of all site surveys shall be transmitted by the department to the board. The results shall include any requirement for plans of correction, the department's determination of the acceptability of the submitted plans of correction, and the department's verification that the plans of correction have been implemented. The board shall make a final determination on certifying the surgical suite for performance of office-based surgeries. The results of site surveys and board determinations shall be shared on a routine basis with the board for licensing health care facilities.

j) The results of all complaint investigations by department staff shall be transmitted to the board for resolution; however, the information shall at all times be maintained as confidential and not available to the public except to the extent § 63-1-117(b) applies.

k) Any physician office that desires to be certified to perform office-based surgery shall pay to the department an annual office-based surgery fee as set by the board.

l) A physician office at which office-based surgery is being performed shall ensure that claims data is reported to the commissioner of health on a form approved by the department of health. The data shall be
submitted through a third party approved by the department of health for the purpose of editing the data according to rules and regulations established by the commissioner. The physician office shall be responsible for the costs associated with processing of the data by the approved vendors. The claims data shall be reported at least quarterly to the commissioner. No information shall be made available to the public by the commissioner that reasonably could be expected to reveal the identity of any patient. The claims data reported to the commissioner under this section are confidential and not available to the public until the commissioner processes and verifies the data. The commissioner shall prescribe conditions under which the processed and verified data are available to the public.

(m)(1) Except as provided in subdivision (h)(1), a physician office surgical suite is required to be certified by the board in order to perform office-based surgery. A physician office that proposes to perform the surgery shall submit to the board, on an application form provided by the board, at least the following:
(A) Level III procedures expected to be performed by each physician;
(B) The specialty board certification or board eligibility of the physician or physicians performing Level III procedures, if any;
(C) Verification of health care liability coverage for all physicians performing Level III procedures;
(D) Verification of hospital staff privileges for all physicians performing Level III procedures;
(E) The name of a responsible physician in whose name the surgical suite certification shall be issued for that office and a list of the physicians with the practice who are going to be performing Level III office-based surgeries; and
(F) The documentation required by subsection (f) regarding incapacitated patient limits.

(2) The form required by subdivision (m)(1) shall serve as an application form, but the information on the form shall be updated as appropriate when any information on it has changed.

(n) The board shall notify all physicians of the office-based surgery certification requirements. Failure of a physician performing office-based surgery, or a physician office at which office-based surgery is being performed, to abide by this section, any rules promulgated pursuant to this section or of § 68-11-211 may be grounds for disciplinary action or termination of either the rights of the physician to perform office-based surgery or the surgical suite's certification by the physician's licensing board, or both disciplinary action and termination. For purposes of § 4-5-320(c), the public health, safety and welfare imperatively require emergency action at any time that a previously authorized surgical suite fails to maintain the standards set by the board.

(o) Applicants for initial licensure or reinstatement of a previously issued license shall indicate to the board on the appropriate licensure application if they intend to perform Level II office-based surgery procedures as defined by the rules of the board of osteopathic examination and that are integral to a planned treatment regimen and not performed on an urgent or emergent basis.

(p) Licensed osteopathic physicians who perform Level II office-based surgery at the time of licensure renewal shall indicate to the board on the licensure renewal application if the licensee currently performs Level II office-based surgery procedures as defined in the rules of the board of osteopathic examination and that are integral to a planned treatment regimen and not performed on an urgent or emergent basis.

(q) In order for health care providers and the board to work together to collect meaningful health care data, so as to minimize the frequency and severity of certain unexpected events and improve the delivery of health care services, each osteopathic physician who performs any Level II office-based surgery that results in any of the following unanticipated events shall notify the board in writing within fifteen (15) calendar days following the physician's discovery of the event:
(1) The death of a patient during any Level II office-based surgery or within seventy-two (72) hours thereafter;
(2) The transport of a patient to a hospital emergency department except those related to a natural course of the patient's illness or underlying condition;
(3) The unplanned admission of a patient to a hospital within seventy-two (72) hours of discharge, only if the admission is related to the Level II office-based surgery except those related to a natural course of the patient's illness or underlying condition;
(4) The discovery of a foreign object erroneously remaining in a patient from a Level II office-based surgery at that office; or
(5) The performance of the wrong surgical procedure, surgery on the wrong site or surgery on the wrong patient.

(r) Records of reportable events should be in writing and should include at a minimum the following:
(1) The physician's name and license number;
(2) The date and time of the occurrence or discovery of the incident;
(3) The office and address where the incident took place;
(4) The name and address of the patient;
(5) The type of Level II office-based surgery that was performed;
(6) The type and dosage of sedation or anesthesia utilized during the procedure;
(7) The circumstances surrounding the incident; and
(8) The type or types of events required to be reported as provided in subsection (q).

(s) The filing of a report as required by subsection (q) does not, in and of itself, constitute an acknowledgement or admission of health care liability, error or omission. Upon receipt of the report, the board may, in its discretion, obtain patient and other records pursuant to authority granted to it in § 63-1-117. The reporting form and any supporting documentation reviewed or obtained by the board pursuant to this section and any amendments to the reports shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity; nor shall they be admissible in any civil or administrative proceeding, other than a disciplinary proceeding by the board; nor shall they be subject to any open records request made pursuant to title 10, chapter 7, part 5 or any other law. This section shall not affect any of the provisions of or limit the protections provided by §§ 63-6-219 and 63-9-114.

(t) Failure to comply with the requirements of subsections (o)-(s) constitutes grounds for disciplinary action by the board in its discretion pursuant to § 63-9-111.

Texas

Chapter 192. Office-Based Anesthesia Services
The following words and terms, when used in this chapter, shall have the following meanings, unless the contents indicate otherwise.
(1) ACLS--Advanced Cardiac Life Support, as defined by the AHA.
(2) AED--Automatic External Defibrillator.
(3) AHA--American Heart Association.
(4) ASHI--American Safety and Health Institute.
(5) Analgesics--Dangerous or scheduled drugs that alleviate pain.
(6) Anesthesia--The loss of feeling or sensation resulting from the use of dangerous or scheduled drugs to depress nerve function. Anesthetics are scheduled or dangerous drugs used to induce anesthesia.
(7) Anesthesia Services--The use of dangerous and scheduled drugs, including anesthetics, analgesics, and anxiolytics, for the performance of Level II-IV services.
(8) Anxiolytics--Dangerous or scheduled drugs used to treat episodes of anxiety.
(9) Anesthesiologist assistant--A graduate of an approved anesthesiologist assistant training program.
(10) Anesthesiology resident--A physician who is presently in an approved Texas anesthesiology residency program who is either licensed as a physician in Texas or holds a postgraduate resident permit issued by the Texas Medical Board.
(11) BLS--Basic Life Support, as defined by the AHA.
(12) Certified registered nurse anesthetist--A person licensed by the Texas Board of Nursing (TBN) as a registered professional nurse, authorized by the TBN as an advanced practice nurse in the role of nurse anesthetist, and certified by a national certifying body recognized by the TBN.
(13) Dangerous drugs--Medications defined by the Texas Dangerous Drug Act, Chapter 483, Texas Health and Safety Code. Dangerous drugs require a prescription, but are not included in the list of scheduled drugs.
A dangerous drug bears the legend “Caution: federal law prohibits dispensing without a prescription” or “Prescription Only.”

(14) Level I services--Delivery of analgesics or anxiolytics by mouth, as prescribed for the patient on order of a physician, at a dose level low enough to allow the patient to remain ambulatory.

(15) Level II services--The administration of tumescent anesthesia or the delivery of analgesics or anxiolytics by mouth in dosages greater than allowed at Level I, as prescribed for the patient on order of a physician.

(16) Level III services--Delivery of analgesics or anxiolytics other than by mouth, including intravenously, intramuscularly, or rectally.

(17) Level IV services--Delivery of general anesthetics, including regional anesthetics and monitored anesthesia care.

(18) Monitored anesthesia care--Situations where a patient undergoing a diagnostic or therapeutic procedure receives doses of medication that create a risk of loss of normal protective reflexes or loss of consciousness and the patient remains able to protect the airway during the procedure. If the patient is rendered unconscious and loses normal protective reflexes, then anesthesia care shall be considered a general anesthetic.

(19) Outpatient setting--Any facility, clinic, center, office, or other setting that is not a part of a licensed hospital or a licensed ambulatory surgical center with the exception of all of the following listed in subparagraphs (A)-(D) of this paragraph:

(A) a clinic located on land recognized as tribal land by the federal government and maintained or operated by a federally recognized Indian tribe or tribal organization as listed by the United States secretary of the interior under 25 U.S.C. § 479-1 or as listed under a successor federal statute or regulation;

(B) a facility maintained or operated by a state or governmental entity;

(C) a clinic directly maintained or operated by the United States or by any of its departments, officers, or agencies; and

(D) an outpatient setting accredited by either the Joint Commission on Accreditation of Healthcare Organizations relating to ambulatory surgical centers, the American Association for the Accreditation of Ambulatory Surgery Facilities, or the Accreditation Association for Ambulatory Health Care.

(20) Board--The Texas Medical Board.

(21) PALS--Pediatric Advanced Life Support, as defined by the AHA.

(22) Physician--A person licensed by the Texas Medical Board as a medical doctor or doctor of osteopathic medicine who diagnoses, treats, or offers to treat any disease or disorder, mental or physical, or any physical deformity or injury by any system or method or effects cures thereof and charges therefor, directly or indirectly, money or other compensation. “Physician” and “surgeon” shall be construed as synonymous.

(23) Scheduled Drugs--Medications defined by the Texas Controlled Substances Act, Chapter 481, Texas Health and Safety Code. This Act establishes five categories, or schedules of drugs, based on risk of abuse and addiction. (Schedule I includes drugs that carry an extremely high risk of abuse and addiction and have no legitimate medical use. Schedule V includes drugs that have the lowest abuse/addiction risk.)

§ 192.2. Provision of Anesthesia Services in Outpatient Settings

(a) The purpose of these rules is to identify the roles and responsibilities of physicians providing, or overseeing by proper delegation, anesthesia services in outpatient settings and to provide the minimum acceptable standards for the provision of anesthesia services in outpatient settings.

(b) The rules promulgated under this title do not apply to physicians who practice in the following settings listed in paragraphs (1)-(8) of this subsection:

(1) an outpatient setting in which only local anesthesia, peripheral nerve blocks, or both are used;

(2) any setting physically located outside the State of Texas;

(3) a licensed hospital, including an outpatient facility of the hospital that is separately located apart from the hospital;

(4) a licensed ambulatory surgical center;
(5) a clinic located on land recognized as tribal land by the federal government and maintained or operated by a federally recognized Indian tribe or tribal organization as listed by the United States secretary of the interior under 25 U.S.C. § 479-1 or as listed under a successor federal statute or regulation;
(6) a facility maintained or operated by a state or governmental entity;
(7) a clinic directly maintained or operated by the United States or by any of its departments, officers, or agencies; and
(8) an outpatient setting accredited by:
   (A) the Joint Commission on Accreditation of Healthcare Organizations relating to ambulatory surgical centers;
   (B) the American Association for the Accreditation of Ambulatory Surgery Facilities; or
   (C) the Accreditation Association for Ambulatory Health Care.
(c) Standards for Anesthesia Services. The following standards are required for outpatient settings providing anesthesia services that are administered within two hours before an outpatient procedure. If personnel and equipment meet the requirements of a higher level, lower level anesthesia services may also be provided.
(1) Level I services:
   (A) at least two personnel must be present, including the physician who must be currently certified by AHA or ASHI, at a minimum, in BLS; and
   (B) the following age-appropriate equipment must be present:
      (i) bag mask valve;
      (ii) oxygen;
      (iii) AED or other defibrillator; and
      (iv) epinephrine, atropine, adreno-corticoids, and antihistamines.
(2) Level II services:
   (A) at least two personnel must be present, including the physician who must be currently certified by AHA or ASHI, at a minimum, in ACLS or PALS, as appropriate;
      (i) another person must be currently certified by AHA or ASHI, at a minimum, in BLS; and
      (ii) a licensed health care provider, who may be one of the two required personnel, must attend the patient, until the patient is ready for discharge; and
   (B) a crash cart must be present containing drugs and equipment necessary to carry out ACLS protocols, including, but not limited to, the following age-appropriate equipment:
      (i) bag mask valve and appropriate airway maintenance devices;
      (ii) oxygen;
      (iii) AED or other defibrillator;
      (iv) pre-measured doses of first line cardiac medications, including epinephrine, atropine, adreno-corticoids, and antihistamines;
      (v) IV equipment;
      (vi) pulse oximeter; and
      (vii) EKG Monitor.
(3) Level III services:
   (A) at least two personnel must be present, including the physician who must be currently certified by AHA or ASHI, at a minimum, in ACLS or PALS, as appropriate;
      (i) another person must be currently certified by AHA or ASHI, at a minimum, in BLS;
      (ii) a licensed health care provider, which may be either of the two required personnel, must attend the patient, until the patient is ready for discharge; and
      (iii) a person, who may be either of the two required personnel, must be responsible for monitoring the patient during the procedure; and
   (B) the same equipment required for Level II.
(4) Level IV services: Physicians who practice medicine in this state and who administer anesthesia or perform a procedure for which anesthesia services are provided in outpatient settings at Level IV shall follow current, applicable standards and guidelines as put forth by the American Society of Anesthesiologists (ASA) including, but not limited to, the following listed in subparagraphs (A)-(H) of this paragraph:
(A) Basic Standards for Preanesthesia Care;
(B) Standards for Basic Anesthetic Monitoring;
(C) Standards for Postanesthesia Care;
(D) Position on Monitored Anesthesia Care;
(E) The ASA Physical Status Classification System;
(F) Guidelines for Nonoperating Room Anesthetizing Locations;
(G) Guidelines for Ambulatory Anesthesia and Surgery; and
(H) Guidelines for Office-Based Anesthesia.

d) A physician delegating the provision of anesthesia or anesthesia-related services to a certified registered nurse anesthetist shall be in compliance with ASA standards and guidelines when the certified registered nurse anesthetist provides a service specified in the ASA standards and guidelines to be provided by an anesthesiologist.

e) In an outpatient setting, where a physician has delegated to a certified registered nurse anesthetist the ordering of drugs and devices necessary for the nurse anesthetist to administer an anesthetic or an anesthesia-related service ordered by a physician, a certified registered nurse anesthetist may select, obtain and administer drugs, including determination of appropriate dosages, techniques and medical devices for their administration and in maintaining the patient in sound physiologic status. This order need not be drug-specific, dosage specific, or administration-technique specific. Pursuant to a physician’s order for anesthesia or an anesthesia-related service, the certified registered nurse anesthetist may order anesthesia-related medications during perianesthesia periods in the preparation for or recovery from anesthesia. In providing anesthesia or an anesthesia-related service, the certified registered nurse anesthetist shall select, order, obtain and administer drugs which fall within categories of drugs generally utilized for anesthesia or anesthesia-related services and provide the concomitant care required to maintain the patient in sound physiologic status during those experiences.

f) The anesthesiologist or physician providing anesthesia or anesthesia-related services in an outpatient setting shall perform a pre-anesthetic evaluation, counsel the patient, and prepare the patient for anesthesia per current ASA standards. If the physician has delegated the provision of anesthesia or anesthesia-related services to a CRNA, the CRNA may perform those services within the scope of practice of the CRNA. Informed consent for the planned anesthetic intervention shall be obtained from the patient/legal guardian and maintained as part of the medical record. The consent must include explanation of the technique, expected results, and potential risks/complications. Appropriate pre-anesthesia diagnostic testing and consults shall be obtained per indications and assessment findings. Pre-anesthetic diagnostic testing and specialist consultation should be obtained as indicated by the pre-anesthetic evaluation by the anesthesiologist or suggested by the nurse anesthetist's pre-anesthetic assessment as reviewed by the surgeon. If responsibility for a patient's care is to be shared with other physicians or non-physician anesthesia providers, this arrangement should be explained to the patient.

g) Physiologic monitoring of the patient shall be determined by the type of anesthesia and individual patient needs. Minimum monitoring shall include continuous monitoring of ventilation, oxygenation, and cardiovascular status. Monitors shall include, but not be limited to, pulse oximetry and EKG continuously and non-invasive blood pressure to be measured at least every five minutes. If general anesthesia is utilized, then an O2 analyzer and end-tidal CO2 analyzer must also be used. A means to measure temperature shall be readily available and utilized for continuous monitoring when indicated per current ASA standards. An audible signal alarm device capable of detecting disconnection of any component of the breathing system shall be utilized. The patient shall be monitored continuously throughout the duration of the procedure. Postoperatively, the patient shall be evaluated by continuous monitoring and clinical observation until stable by a licensed health care provider. Monitoring and observations shall be documented per current ASA standards. In the event of an electrical outage which disrupts the capability to continuously monitor all specified patient parameters, at a minimum, heart rate and breath sounds will be monitored on a continuous basis using a precordial stethoscope or similar device, and blood pressure measurements will be reestablished using a non-electrical blood pressure measuring device until electricity is restored. There should be in each location, sufficient electrical outlets to satisfy anesthesia machine and monitoring equipment requirements,
including clearly labeled outlets connected to an emergency power supply. A two-way communication source not dependent on electrical current shall be available. Sites shall also have a secondary power source as appropriate for equipment in use in case of power failure.

(h) All anesthesia-related equipment and monitors shall be maintained to current operating room standards. All devices shall have regular service/maintenance checks at least annually or per manufacturer recommendations. Service/maintenance checks shall be performed by appropriately qualified biomedical personnel. Prior to the administration of anesthesia, all equipment/monitors shall be checked using the current FDA recommendations as a guideline. Records of equipment checks shall be maintained in a separate, dedicated log which must be made available upon request. Documentation of any criteria deemed to be substandard shall include a clear description of the problem and the intervention. If equipment is utilized despite the problem, documentation must clearly indicate that patient safety is not in jeopardy. All documentation relating to equipment shall be maintained for seven years or for a period of time as determined by the board.

(i) Each location must have emergency supplies immediately available. Supplies should include emergency drugs and equipment appropriate for the purpose of cardiopulmonary resuscitation. This must include a defibrillator, difficult airway equipment, and drugs and equipment necessary for the treatment of malignant hyperthermia if “triggering agents” associated with malignant hyperthermia are used or if the patient is at risk for malignant hyperthermia. Equipment shall be appropriately sized for the patient population being served. Resources for determining appropriate drug dosages shall be readily available. The emergency supplies shall be maintained and inspected by qualified personnel for presence and function of all appropriate equipment and drugs at intervals established by protocol to ensure that equipment is functional and present, drugs are not expired, and office personnel are familiar with equipment and supplies. Records of emergency supply checks shall be maintained in a separate, dedicated log and made available upon request. Records of emergency supply checks shall be maintained for seven years or for a period of time as determined by the board.

(j) The operating surgeon shall verify that the appropriate policies or procedures are in place. Policies, procedure, or protocols shall be evaluated and reviewed at least annually. Agreements with local emergency medical service (EMS) shall be in place for purposes of transfer of patients to the hospital in case of an emergency. EMS agreements shall be evaluated and re-signed at least annually. Policies, procedure, and transfer agreements shall be kept on file in the setting where procedures are performed and shall be made available upon request. Policies or procedures must include, but are not limited to the following listed in paragraphs (1)-(2) of this subsection:

(1) Management of outpatient anesthesia. At a minimum, these must address:
   (A) patient selection criteria;
   (B) patients/providers with latex allergy;
   (C) pediatric drug dosage calculations, where applicable;
   (D) ACLS (advanced cardiac life support) or PALS (pediatric advanced life support) algorithms;
   (E) infection control;
   (F) documentation and tracking use of pharmaceuticals, including controlled substances, expired drugs and wasting of drugs; and
   (G) discharge criteria.

(2) Management of emergencies. At a minimum, these must include, but not be limited to:
   (A) cardiopulmonary emergencies;
   (B) fire;
   (C) bomb threat;
   (D) chemical spill; and
   (E) natural disasters.

(k) All equipment and anesthesia-related services must remain available at the office-based anesthesia site until the patient is discharged.

(l) Physicians or surgeons must notify the board in writing within 15 days if a procedure performed in any of the settings under these rules resulted in an unanticipated and unplanned transport of the patient to a
hospital for observation or treatment for a period in excess of 24 hours, or a patient's death intraoperatively or within the immediate postoperative period. Immediate postoperative period is defined as 72 hours.

§ 192.3. Compliance with Office-Based Anesthesia Rules
(a) A physician who provides anesthesia services or performs a procedure for which anesthesia services are provided in an outpatient setting shall comply with the rules adopted under this title.
(b) The board may require a physician to submit and comply with a corrective action plan to remedy or address any current or potential deficiencies with the physician's provision of anesthesia services in an outpatient setting in accordance with the Medical Practice Act, Title 3 Subtitle C §§ 162.101-.107 of the Texas Occupations Code, or rules of the board.
(c) Any physician who violates these rules shall be subject to disciplinary action and/or termination of the registration issued by the board as authorized by the Medical Practice Act or rules of the board.

§ 192.4. Registration
(a) Each physician who provides anesthesia services or performs a procedure for which anesthesia services are provided in an outpatient setting, excluding level I services, shall register with the board on a form prescribed by the board and pay a fee to the board in an amount established by the board.
(b) The board shall coordinate the registration required under this section with the registration required under the Medical Practice Act, Texas Occupations Code Chapter 156, so that the times of registration, payment, notice, and imposition of penalties for late payment are similar and provide a minimum of administrative burden to the board and to physicians.

§ 192.5. Inspections
(a) The board may conduct inspections to enforce these rules, including inspections of an office site and of documents of a physician's practice. The board may contract with another state agency or qualified person to conduct these inspections.
(b) Unless it would jeopardize an ongoing investigation, the board shall provide at least five business days' notice before conducting an on-site inspection under this section.
(c) This section does not require the board to make an on-site inspection of a physician's office.

§ 192.6. Requests for Inspection and Advisory Opinion
(a) The board may consider a request by a physician for an on-site inspection offering office-based anesthesia. The board may, in its discretion and on payment of a fee in an amount established by the board, conduct the inspection and issue an advisory opinion.
(b) An advisory opinion issued by the board under this section is not binding on the board, and the board, except as provided by subsection (c) of this section, may take any action under the Medical Practice Act, in relation to the situation addressed by the advisory opinion that the board considers appropriate.
(c) A physician who requests and relies on an advisory opinion of the board may use the opinion as mitigating evidence in an action or proceeding to impose an administrative or civil penalty under the Medical Practice Act. The board or court, as appropriate, shall take proof of reliance on an advisory opinion into consideration and mitigate the imposition of administrative or civil penalties accordingly.

Utah – Medical
None

Utah – Osteopathic
None
Part VIII. Office-Based Anesthesia

18 VAC 85-20-310. Definitions.

“Advanced resuscitative techniques” means methods learned in certification courses for Advanced Cardiopulmonary Life Support (ACLS), or Pediatric Advanced Life Support (PALS).

“Deep sedation” means 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 patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

“General anesthesia” means a drug-induced loss of consciousness during which patients are not arousable even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive-pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

“Local anesthesia” means a transient and reversible loss of sensation in a circumscribed portion of the body produced by a local anesthetic agent.

“Minimal sedation/anxiolysis” means a drug-induced state during which a patient responds normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are usually not affected.

“Moderate sedation/conscious sedation” means 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 patent airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.

“Monitoring” means the continual clinical observation of patients and the use of instruments to measure and display the values of certain physiologic variables such as pulse, oxygen saturation, level of consciousness, blood pressure and respiration.

“Office-based” means any setting other than (i) a licensed hospital as defined in § 32.1-123 of the Code of Virginia or state-operated hospitals or (ii) a facility directly maintained or operated by the federal government.

“Physical status classification” means a description used in determining the physical status of a patient as specified by the American Society of Anesthesiologists. Classifications are Class 1 for a normal healthy patient; Class 2 for a patient with mild systemic disease; Class 3 for a patient with severe systemic disease limiting activity but not incapacitation; Class 4 for a patient with incapacitating systemic disease that is a
constant threat to life; and Class 5 for a moribund patient not expected to live 24 hours with or without surgery.

"Regional anesthesia" means the administration of anesthetic agents to a patient to interrupt nerve impulses without the loss of consciousness and includes minor and major conductive blocks.

"Minor conductive block" means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (local infiltration or local nerve block), or the block of a nerve by refrigeration. Minor conductive nerve blocks include, but are not limited to, peribulbar blocks, pudendal blocks and ankle blocks.

"Major conductive block" means the use of local anesthesia to stop or prevent the transmission of painful sensations from large nerves, groups of nerves, nerve roots or the spinal cord. Major nerve blocks include, but are not limited to epidural, spinal, caudal, femoral, interscalene and brachial plexus.

"Topical anesthesia" means an anesthetic agent applied directly to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

A. Applicability of requirements for office-based anesthesia.
1. The administration of topical anesthesia, local anesthesia, minor conductive blocks, or minimal sedation/anxiolysis, not involving a drug-induced alteration of consciousness other than minimal preoperative tranquilization, is not subject to the requirements for office-based anesthesia. A health care practitioner administering such agents shall adhere to an accepted standard of care as appropriate to the level of anesthesia or sedation, including evaluation, drug selection, administration and management of complications.
2. The administration of moderate sedation/conscious sedation, deep sedation, general anesthesia, or regional anesthesia consisting of a major conductive block are subject to these requirements for office-based anesthesia.
3. Levels of anesthesia or sedation referred to in this chapter shall relate to the level of anesthesia or sedation intended by the practitioner in the anesthesia plan.
B. A doctor of medicine, osteopathic medicine, or podiatry administering office-based anesthesia or supervising such administration shall:
1. Perform a preanesthetic evaluation and examination or ensure that it has been performed;
2. Develop the anesthesia plan or ensure that it has been developed;
3. Ensure that the anesthesia plan has been discussed and informed consent obtained;
4. Ensure patient assessment and monitoring through the pre-, peri-, and post-procedure phases, addressing not only physical and functional status, but also physiological and cognitive status;
5. Ensure provision of indicated post-anesthesia care; and
6. Remain physically present or immediately available, as appropriate, to manage complications and emergencies until discharge criteria have been met.
C. All written policies, procedures and protocols required for office-based anesthesia shall be maintained and available for inspection at the facility.

18 VAC 85-20. Qualifications of providers.
A. Doctors who utilize office-based anesthesia shall ensure that all medical personnel assisting in providing patient care are appropriately trained, qualified and supervised, are sufficient in numbers to provide adequate care, and maintain training in basic cardiopulmonary resuscitation.
B. All providers of office-based anesthesia shall hold the appropriate license and have the necessary training and skills to deliver the level of anesthesia being provided.
1. Deep sedation, general anesthesia or a major conductive block shall be administered by an anesthesiologist or by a certified registered nurse anesthetist. If a major conductive block is performed for diagnostic or therapeutic purposes, it may be administered by a doctor qualified by training and scope of practice.
2. Moderate sedation/conscious sedation may be administered by the operating doctor with the assistance of and monitoring by a licensed nurse, a physician assistant or a licensed intern or resident.
C. Additional training.
1. On or after December 18, 2003, the doctor who provides office-based anesthesia or who supervises the administration of anesthesia shall maintain current certification in advanced resuscitation techniques.
2. Any doctor who administers office-based anesthesia without the use of an anesthesiologist or certified registered nurse anesthetist shall obtain four hours of continuing education in topics related to anesthesia within the 60 hours required each biennium for licensure renewal, which are subject to random audit by the board.

A. A written protocol shall be developed and followed for procedure selection to include but not be limited to:
1. The doctor providing or supervising the anesthesia shall ensure that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.
2. The procedure shall be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility in less than 24 hours.
3. The level of anesthesia used shall be appropriate for the patient, the surgical procedure, the clinical setting, the education and training of the personnel, and the equipment available. The choice of specific anesthesia agents and techniques shall focus on providing an anesthetic that will be effective, appropriate and will address the specific needs of patients while also ensuring rapid recovery to normal function with maximum efforts to control post-operative pain, nausea or other side effects.
B. A written protocol shall be developed for patient evaluation to include but not be limited to:
1. The preoperative anesthesia evaluation of a patient shall be performed by the health care practitioner administering the anesthesia or supervising the administration of anesthesia. It shall consist of performing an appropriate history and physical examination, determining the patient's physical status classification, developing a plan of anesthesia care, acquainting the patient or the responsible individual with the proposed plan and discussing the risks and benefits.
2. The condition of the patient, specific morbidities that complicate anesthetic management, the specific intrinsic risks involved, and the nature of the planned procedure shall be considered in evaluating a patient for office-based anesthesia.
3. Patients who have pre-existing medical or other conditions that may be of particular risk for complications shall be referred to a facility appropriate for the procedure and administration of anesthesia. Nothing relieves the licensed health care practitioner of the responsibility to make a medical determination of the appropriate surgical facility or setting.
C. Office-based anesthesia shall only be provided for patients in physical status classifications for Classes I, II and III. Patients in Classes IV and V shall not be provided anesthesia in an office-based setting.

18 VAC 85-20-350. Informed consent.
Prior to administration, the anesthesia plan shall be discussed with the patient or responsible party by the health care practitioner administering the anesthesia or supervising the administration of anesthesia.
Informed consent for the nature and objectives of the anesthesia planned shall be in writing and obtained from the patient or responsible party before the procedure is performed. Informed consent shall only be obtained after a discussion of the risks, benefits, and alternatives, contain the name of the anesthesia provider and be documented in the medical record.

18 VAC 85-20-360. Monitoring.
A. A written protocol shall be developed for monitoring equipment to include but not be limited to:
1. Monitoring equipment shall be appropriate for the type of anesthesia and the nature of the facility. At a minimum, provisions shall be made for a reliable source of oxygen, suction, resuscitation equipment and emergency drugs.
2. In locations where anesthesia is administered, there shall be adequate anesthesia apparatus and equipment to ensure appropriate monitoring of patients. All equipment shall be maintained, tested and inspected.
according to manufacturer's specifications, and backup power shall be sufficient to ensure patient protection in the event of an emergency.

3. When anesthesia services are provided to infants and children, the required equipment, medication and resuscitative capabilities shall be appropriately sized and calibrated for children.

B. To administer office-based moderate sedation/conscious sedation, the following equipment, supplies and pharmacological agents are required:

1. Appropriate equipment to manage airways;
2. Drugs and equipment to treat shock and anaphylactic reactions;
3. Precordial stethoscope;
4. Pulse oximeter with appropriate alarms or an equivalent method of measuring oxygen saturation;
5. Continuous electrocardiograph;
6. Devices for measuring blood pressure, heart rate and respiratory rate;
7. Defibrillator; and
8. Accepted method of identifying and preventing the interchangeability of gases.

C. In addition to requirements in subsection B of this section, to administer general anesthesia, deep sedation or major conductive blocks, the following equipment, supplies and pharmacological agents are required:

1. Drugs to treat malignant hyperthermia, when triggering agents are used;
2. Peripheral nerve stimulator, if a muscle relaxant is used; and
3. If using an anesthesia machine, the following shall be included:
   a. End-tidal carbon dioxide monitor (capnograph);
   b. In-circuit oxygen analyzer designed to monitor oxygen concentration within breathing circuit by displaying oxygen percent of the total respiratory mixture;
   c. Oxygen failure-protection devices (fail-safe system) that have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;
   d. Vaporizer exclusion (interlock) system, which ensures that only one vaporizer, and therefore only a single anesthetic agent can be actualized on any anesthesia machine at one time;
   e. Pressure-compensated anesthesia vaporizers, designed to administer a constant non-pulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;
   f. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21% from being administered;
   g. Alarm systems for high (disconnect), low (subatmospheric) and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and
   h. A gas evacuation system.

D. A written protocol shall be developed for monitoring procedures to include but not be limited to:

1. Physiologic monitoring of patients shall be appropriate for the type of anesthesia and individual patient needs, including continuous monitoring and assessment of ventilation, oxygenation, cardiovascular status, body temperature, neuromuscular function and status, and patient positioning.
2. Intraoperative patient evaluation shall include continuous clinical observation and continuous anesthesia monitoring.
3. A health care practitioner administering general anesthesia or deep sedation shall remain present and available in the facility to monitor a patient until the patient meets the discharge criteria. A health care practitioner administering moderate sedation/conscious sedation shall routinely monitor a patient according to procedures consistent with such administration.

18 VAC 85-20-370. Emergency and transfer protocols.

A. There shall be written protocols for handling emergency situations, including medical emergencies and internal and external disasters. All personnel shall be appropriately trained in and regularly review the protocols and the equipment and procedures for handling emergencies.

B. There shall be written protocols for the timely and safe transfer of patients to a prespecified hospital or hospitals within a reasonable proximity. There shall be a transfer agreement with such hospital or hospitals.
18 VAC 85-20-380. Discharge policies and procedures.
A. There shall be written policies and procedures outlining discharge criteria. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting.
B. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall only occur when patients have met specific physician-defined criteria.
C. Written instructions and an emergency phone number shall be provided to the patient. Patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.
D. At least one person trained in advanced resuscitative techniques shall be immediately available until all patients are discharged.

18 VAC 85-20-390. Reporting requirements.
The doctor administering the anesthesia or supervising such administration shall report to the board within 30 days any incident relating to the administration of anesthesia that results in patient death, either intraoperatively or within the immediate 72-hour postoperative period or in transport of a patient to a hospital for a stay of more than 24 hours.

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**Washington – Medical**

WAC 246-919-601. Safe and effective analgesia and anesthesia administration in office-based surgical settings.
(1) Purpose. The purpose of this rule is to promote and establish consistent standards, continuing competency, and to promote patient safety. The medical quality assurance commission establishes the following rule for physicians licensed under this chapter who perform surgical procedures and use anesthesia, analgesia or sedation in office-based settings.
(2) Definitions. The following terms used in this subsection apply throughout this rule unless the context clearly indicates otherwise:
(a) ‘Commission’ means the medical quality assurance commission.
(b) ‘Deep sedation’ or ‘analgesia’ means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
(c) ‘General anesthesia’ means a state of unconsciousness intentionally produced by anesthetic agents, with absence of pain sensation over the entire body, in which the patient is without protective reflexes and is unable to maintain an airway. Sedation that unintentionally progresses to the point at which the patient is without protective reflexes and is unable to maintain an airway is not considered general anesthesia.
(d) ‘Local infiltration’ means the process of infusing a local anesthetic agent into the skin and other tissues to allow painless wound irrigation, exploration and repair, and other procedures, including procedures such as retrobulbar or periorbital ocular blocks only when performed by a board eligible or board certified ophthalmologist. It does not include procedures in which local anesthesia is injected into areas of the body other than skin or muscle where significant cardiovascular or respiratory complications may result.
(e) ‘Major conduction anesthesia’ means the administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness, such as epidural, caudal, or spinal anesthesia, lumbar or brachial plexus blocks, and intravenous regional anesthesia. Major conduction anesthesia does not include isolated blockade of small peripheral nerves, such as digital nerves.
(f) ‘Minimal sedation’ means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Minimal sedation is limited to oral or intramuscular medications, or both.
(g) ‘Moderate sedation’ or ‘analgesia’ means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(h) ‘Office-based surgery’ means any surgery or invasive medical procedure requiring analgesia or sedation, including, but not limited to, local infiltration for tumescent liposuction, performed in a location other than a hospital or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

(i) ‘Physician’ means an individual licensed under chapter 18.71 RCW.

(3) Exemptions. This rule does not apply to physicians when:
(a) Performing surgery and medical procedures that require only minimal sedation (anxiolysis), or infiltration of local anesthetic around peripheral nerves. Infiltration around peripheral nerves does not include infiltration of local anesthetic agents in an amount that exceeds the manufacturer's published recommendations.
(b) Performing surgery in a hospital or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.
(c) Performing surgery utilizing general anesthesia. Facilities in which physicians perform procedures in which general anesthesia is a planned event are regulated by rules related to hospital or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.
(d) Performing oral and maxillofacial surgery, and the physician:
(i) Is licensed both as a physician under chapter 18.71 RCW and as a dentist under chapter 18.32 RCW;
(ii) Complies with dental quality assurance commission regulations;
(iii) Holds a valid:
(A) Moderate sedation permit; or
(B) Moderate sedation with parenteral agents permit; or
(C) General anesthesia and deep sedation permit; and
(iv) Practices within the scope of his or her specialty.

(4) Application of rule.
This rule applies to physicians practicing independently or in a group setting who perform office-based surgery employing one or more of the following levels of sedation or anesthesia:
(a) Moderate sedation or analgesia; or
(b) Deep sedation or analgesia; or
(c) Major conduction anesthesia.

(5) Accreditation or certification. Within three hundred sixty-five calendar days of the effective date of this rule, a physician who performs a procedure under this rule must ensure that the procedure is performed in a facility that is appropriately equipped and maintained to ensure patient safety through accreditation or certification and in good standing from one of the following:
(a) The Joint Commission;
(b) The Accreditation Association for Ambulatory Health Care;
(c) The American Association for Accreditation of Ambulatory Surgery Facilities;
(d) The Centers for Medicare and Medicaid Services; or
(e) Planned Parenthood Federation of America or the National Abortion Federation, for facilities limited to office-based surgery for abortion or abortion-related services.

(6) Competency. When an anesthesiologist or certified registered nurse anesthetist is not present, the physician performing office-based surgery and using a form of sedation defined in subsection (4) of this section must be competent and qualified both to perform the operative procedure and to oversee the administration of intravenous sedation and analgesia.

(7) Qualifications for administration of sedation and analgesia may include:
(a) Completion of a continuing medical education course in conscious sedation;
(b) Relevant training in a residency training program; or
(c) Having privileges for conscious sedation granted by a hospital medical staff.

(8) At least one licensed health care practitioner currently certified in advanced resuscitative techniques appropriate for the patient age group (e.g., ACLS, PALS or APLS) must be present or immediately available with age-size-appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility.

(9) Sedation assessment and management.
(a) Sedation is a continuum. Depending on the patient's response to drugs, the drugs administered, and the dose and timing of drug administration, it is possible that a deeper level of sedation will be produced than initially intended.
(b) If an anesthesiologist or certified registered nurse anesthetist is not present, a physician intending to produce a given level of sedation should be able to 'rescue' a patient who enters a deeper level of sedation than intended.
(c) If a patient enters into a deeper level of sedation than planned, the physician must return the patient to the lighter level of sedation as quickly as possible, while closely monitoring the patient to ensure the airway is patent, the patient is breathing, and that oxygenation, heart rate and blood pressure are within acceptable values. A physician who returns a patient to a lighter level of sedation in accordance with this subsection (c) does not violate subsection (10) of this section.

(10) Separation of surgical and monitoring functions.
(a) The physician performing the surgical procedure must not administer the intravenous sedation, or monitor the patient.
(b) The licensed health care practitioner, designated by the physician to administer intravenous medications and monitor the patient who is under moderate sedation, may assist the operating physician with minor, interruptible tasks of short duration once the patient's level of sedation and vital signs have been stabilized, provided that adequate monitoring of the patient's condition is maintained. The licensed health care practitioner who administers intravenous medications and monitors a patient under deep sedation or analgesia must not perform or assist in the surgical procedure.

(11) Emergency care and transfer protocols. A physician performing office-based surgery must ensure that in the event of a complication or emergency:
(a) All office personnel are familiar with a written and documented plan to timely and safely transfer patients to an appropriate hospital.
(b) The plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.

(12) Medical record. The physician performing office-based surgery must maintain a legible, complete, comprehensive and accurate medical record for each patient.
(a) The medical record must include:
(i) Identity of the patient;
(ii) History and physical, diagnosis and plan;
(iii) Appropriate lab, X ray or other diagnostic reports;
(iv) Appropriate preanesthesia evaluation;
(v) Narrative description of procedure;
(vi) Pathology reports, if relevant;
(vii) Documentation of which, if any, tissues and other specimens have been submitted for histopathologic diagnosis;
(viii) Provision for continuity of postoperative care; and
(ix) Documentation of the outcome and the follow-up plan.
(b) When moderate or deep sedation, or major conduction anesthesia is used, the patient medical record must include a separate anesthesia record that documents:
(i) The type of sedation or anesthesia used;
(ii) Drugs (name and dose) and time of administration;
(iii) Documentation at regular intervals of information obtained from the intraoperative and postoperative monitoring;
(iv) Fluids administered during the procedure;
(v) Patient weight;
(vi) Level of consciousness;
(vii) Estimated blood loss;
(viii) Duration of procedure; and
(ix) Any complication or unusual events related to the procedure or sedation/anesthesia.

Washington – Osteopathic

WAC 246-853-650. Safe and effective analgesia and anesthesia administration in office-based settings.

(1) Purpose. The purpose of this rule is to promote and establish consistent standards, continuing competency, and to promote patient safety. The board of osteopathic medicine and surgery establishes the following rule for physicians licensed under chapter 18.57 RCW who perform surgical procedures and use analgesia, analgesia or sedation in office-based settings.

(2) Definitions. The following terms used in this subsection apply throughout this rule unless the text clearly indicates otherwise:

(a) ‘Board’ means the board of osteopathic medicine and surgery.

(b) ‘Deep sedation’ or ‘analgesia’ means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is maintained.

(c) ‘General anesthesia’ means a state of unconsciousness intentionally produced by anesthetic agents, with absence of pain sensation over the entire body, in which the patient is without protective reflexes and is unable to maintain an airway. Sedation that unintentionally progresses to the point at which the patient is without protective reflexes and is unable to maintain an airway is not considered general anesthesia.

(d) ‘Local infiltration’ means the process of infusing a local anesthetic agent into the skin and other tissues to allow painless wound irrigation, exploration and repair, and other procedures, including procedures such as retrobulbar or periorbital ocular blocks only when performed by a board eligible or board certified ophthalmologist. It does not include procedures in which local anesthesia is injected into areas of the body other than skin or muscle where significant cardiovascular or respiratory complications may result.

(e) ‘Major conduction anesthesia’ means the administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness, such as epidural, caudal, or spinal anesthesia, lumbar or brachial plexus blocks, and intravenous regional anesthesia. Major conduction anesthesia does not include isolated blockade of small peripheral nerves, such as digital nerves.

(f) ‘Minimal sedation’ or ‘analgesia’ means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Minimal sedation is limited to oral or intramuscular medications, or both.

(g) ‘Moderate sedation’ or ‘analgesia’ means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained.

(h) ‘Office-based surgery’ means any surgery or invasive medical procedure requiring analgesia or sedation, including, but not limited to, local infiltration for tumescent liposuction performed in a location other than a hospital, or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

(i) ‘Physician’ means an osteopathic physician licensed under chapter 18.57 RCW.

(3) Exemptions. This rule does not apply to physicians when:

(a) Performing surgery and medical procedures that require only minimal sedation (anxiolysis), or infiltration of local anesthetic around peripheral nerves. Infiltration around peripheral nerves does not include
infiltration of local anesthetic agents in an amount that exceeds the manufacturer's published recommendations.

(b) Performing surgery in a hospital or hospital-associated surgical center licensed under chapter 70.41 RCW, or an ambulatory surgical facility licensed under chapter 70.230 RCW.

(c) Performing surgery using general anesthesia. Facilities in which physicians perform procedures in which general anesthesia is a planned event are regulated by rules related to hospitals or hospital-associated surgical centers licensed under chapter 70.41 RCW, or ambulatory surgical facilities licensed under chapter 70.230 RCW.

(d) Performing oral and maxillofacial surgery, and the physician:
   (i) Is licensed both as a physician under chapter 18.57 RCW and as a dentist under chapter 18.32 RCW;
   (ii) Complies with dental quality assurance commission regulations;
   (iii) Holds a valid:
       (A) Moderate sedation permit; or
       (B) Moderate sedation with parenteral agents permit; or
       (C) General anesthesia and deep sedation permit; and
   (iv) Practices within the scope of his or her specialty.

(4) Application of rule. This rule applies to physicians practicing independently or in a group setting who perform office-based surgery employing one or more of the following levels of sedation or anesthesia:

(a) Moderate sedation or analgesia; or
(b) Deep sedation or analgesia; or
(c) Major conduction anesthesia.

(5) Accreditation or certification. Within three hundred sixty-five calendar days of the effective date of this rule, a physician who performs a procedure under this rule must ensure that the procedure is performed in a facility that is appropriately equipped and maintained to ensure patient safety through accreditation or certification and in good standing from one of the following:

(a) The Joint Commission (JC);
(b) The Accreditation Association for Ambulatory Health Care (AAAHC);
(c) The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF);
(d) The Centers for Medicare and Medicaid Services (CMS); or
(e) Planned Parenthood Federation of America or the National Abortion Federation, for facilities limited to office-based surgery for abortion or abortion-related services.

(6) Competency. When an anesthesiologist or certified registered nurse anesthetist is not present, the physician performing office-based surgery and using a form of sedation defined in subsection (4) of this section must be competent and qualified both to perform the operative procedure and to oversee the administration of intravenous sedation and analgesia.

(7) Qualifications for administration of sedation and analgesia may include:

(a) Completion of a continuing medical education course in conscious sedation; or
(b) Relevant training in a residency training program; or
(c) Having privileges for conscious sedation granted by a hospital medical staff.

(8) Resuscitative preparedness. At least one licensed health care practitioner currently certified in advanced resuscitative techniques appropriate for the patient age group (e.g., advanced cardiac life support (ACLS), pediatric advanced life support (PALS) or advanced pediatric life support (APLS)) must be present or immediately available with age-size appropriate resuscitative equipment throughout the procedure and until the patient has met the criteria for discharge from the facility.

(9) Sedation, assessment and management.

(a) Sedation is a continuum. Depending on the patient's response to drugs, the drugs administered, and the dose and timing of drug administration, it is possible that a deeper level of sedation will be produced than initially intended.

(b) If an anesthesiologist or certified registered nurse anesthetist is not present, a physician intending to produce a given level of sedation should be able to ‘rescue’ patients who enter a deeper level of sedation than intended.
(c) If a patient enters into a deeper level of sedation than planned, the physician must return the patient to the lighter level of sedation as quickly as possible, while closely monitoring the patient to ensure the airway is patent, the patient is breathing, and that oxygenation, the heart rate, and blood pressure are within acceptable values. A physician who returns a patient to a lighter level of sedation in accordance with this subsection (c) does not violate subsection (10) of this section.

(10) Separation of surgical and monitoring functions.
(a) The physician performing the surgical procedure must not administer the intravenous sedation, or monitor the patient.
(b) The licensed health care practitioner, designated by the physician to administer intravenous medications and monitor the patient who is under moderate sedation, may assist the operating physician with minor, interruptible tasks of short duration once the patient's level of sedation and vital signs have been stabilized, provided that adequate monitoring of the patient's condition is maintained. The licensed health care practitioner who administers intravenous medications and monitors a patient under deep sedation or analgesia must not perform or assist in the surgical procedure.

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(a) All office personnel are familiar with a written and documented plan to timely and safely transfer patients to an appropriate hospital.
(b) The plan must include arrangements for emergency medical services and appropriate escort of the patient to the hospital.

(12) Medical record. The physician performing office-based surgery must maintain a legible, complete, comprehensive and accurate medical record for each patient.
(a) The medical record must include:
(i) Identity of the patient;
(ii) History and physical, diagnosis and plan;
(iii) Appropriate lab, X ray or other diagnostic reports;
(iv) Appropriate preanesthesia evaluation;
(v) Narrative description of procedure;
(vi) Pathology reports, if relevant;
(vii) Documentation of which, if any, tissues and other specimens have been submitted for histopathologic diagnosis;
(viii) Provision for continuity of postoperative care; and
(ix) Documentation of the outcome and the follow-up plan.
(b) When moderate or deep sedation or major conduction anesthesia is used, the patient medical record must include a separate anesthesia record that documents:
(i) Type of sedation or anesthesia used;
(ii) Drugs (name and dose) and time of administration;
(iii) Documentation at regular intervals of information obtained from intraoperative and postoperative monitoring;
(iv) Fluids administered during the procedure;
(v) Patient weight;
(vi) Level of consciousness;
(vii) Estimated blood loss;
(viii) Duration of procedure; and
(ix) Any complication or unusual events related to the procedure or sedation/anesthesia.
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