



Office-Based Surgery States A-M

Board-by-Board Statutes, Regulations and Policies

Alabama

Ala. Admin. Code CHAPTER 540-X-10. OFFICE-BASED SURGERY.

540-X-10-.01. Preamble.

(1) Office-based surgery is surgery¹ performed outside a hospital or outpatient facility licensed by the Alabama Department of Public Health. It is the position of the Alabama Board of Medical Examiners that the physician is responsible for providing a safe environment for office-based surgery. Surgical procedures in medicine have changed over the generations from procedures performed at home or at the surgeon's office to the hospital and, now, often back to outpatient locations. However, the premise for the surgery remains unchanged: that it be performed in the best interest of the patient and under the best circumstances possible for the management of disease and the well-being of the patient. Surgery that is performed in a physician's office at this time varies from a simple incision and drainage with topical anesthesia to semi-complex procedures under general anesthesia. It is imperative that the surgeon evaluate the patient, advise and assist the patient with a decision about the procedure and the location for its performance and, to the best of the surgeon's ability, assure that the quality of care be equal in any facility that the surgeon advises. If the physician performs surgery in the physician's office, it is expected that the physician will require office standards similar to those at other sites where the physician performs such procedures. It is also expected that any physician who performs a surgical procedure is knowledgeable about sterile technique, the need for pathological evaluation of certain surgical specimens, about any drug that the physician administers or orders administered, and about potential untoward reactions and complications and their treatment. Recognizing that there have been serious adverse events in office surgical settings, both in Alabama and in other states, the Board of Medical Examiners, in conjunction with an *ad hoc* committee representing various medical and surgical specialties, has developed guidelines for physicians who perform surgery in their offices. These guidelines are intended to remind the physician of the minimal suggested necessities for various levels of surgery in the office setting. The physician must decide on a case-by-case basis the location and level of service that is best for the physician's particular patient and procedure; this decision must always be made with the patient's best interest in mind.

¹. Definition of surgery: Surgery, which involves the revision, destruction, incision or structural alteration of human tissue performed using a variety of methods and instruments, is a discipline that includes the operative, and non-operative care of individuals in need of such intervention, and demands pre-operative assessment, judgment, technical skills, post-operative management and follow-up.

(2) The Alabama Board of Medical Examiners recommends the following general guidelines for office-based surgery/ procedures:

(a) Training: A procedure, whether done in an office, outpatient surgical facility or hospital, should be performed by physicians operating within their area of professional training. Appropriate training and continuing medical education should be documented and that documentation readily available to patients and the Alabama Board of Medical Examiners. Physicians who perform office-based procedures must have plans for managing emergency complications.

(b) Patient Selection: Patients must be individually evaluated for each procedure to determine if the office is an appropriate setting for the anesthesia required and for the surgical procedure to be performed.

(c) Patient Evaluation: Patients undergoing office-based surgery must have an appropriately documented history and physical examination as well as other indicated consultations and studies.

(d) Anesthesia: When deep sedation, major regional anesthesia or general anesthesia is provided in the office setting, it must be administered by a qualified person(s)² other than the person performing the procedure. Anesthesia personnel should be familiar with variations in technique based on the specifics of the patient and the procedure, particularly patients requiring large volumes of fluids and/or requiring airway management. Patients must be properly monitored before, during and after the procedure. Anesthesia personnel should be currently trained in ACLS.

². The terms “qualified person(s)” and “qualified practitioner” are not defined precisely in these rules. Just as a physician is expected to determine if he is qualified to perform a certain procedure or treat a certain illness or whether he should refer his patient to someone whom he considers to be more qualified, he should assure, to the best of his ability, that the persons in his employ, whether directly or via contract, have the training, skills and ability to assist him as needed for the planned procedure. If questions arise about qualifications, he should explain his rationale as he would for questions about quality medical care.

(e) Office Setting: The office should be set up with patient safety as a primary consideration. Safety issues should include, but not be limited to, accessibility, sterilization and cleaning routines, storage of materials and supplies, supply inventory, emergency equipment, and infection control.

(f) Emergency Planning: Planning should include, but not be limited to, emergency medicines, emergency equipment, and transfer protocols³. Practitioners should be trained and capable of recognizing and managing complications related to anesthesia that he/she administers and the procedures that he/she performs.

³. Definition of transfer protocols: Ensure the continuity of patient care is uninterrupted.

(g) Follow-up Care: As with any surgical treatment or procedure, follow-up care by the responsible surgeon is a requirement. Arrangements shall be made for follow-up care and for treatment of complications outside normal business hours. The patient, or a responsible adult, should be aware of these arrangements and of any medications prescribed after the procedure.

(h) Quality Improvement: Continuous quality improvement should be a goal.

(i) Facility accreditation is encouraged for those settings where deep sedation/analgesia (level 4) and general anesthesia (level 5) are provided.

(3) These rules 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. An oral surgeon licensed to practice dentistry who is also a physician licensed to practice medicine and who performs office-based surgery other than the practice of dentistry shall comply with the requirements of these regulations for those procedures which fall outside the scope of practice of dentistry.

540-X-10-.02. Definitions--Levels Of Anesthesia⁴.

⁴. Reference: Appendix A--American Society of Anesthesiologists (ASA) definitions. This Appendix is included in these Rules only for information.

(1) Local Anesthesia. The administration of an agent which produces a localized and reversible loss of sensation in a circumscribed portion of the body.

(2) Minimal Sedation (anxiolysis). 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.

(3) Moderate Sedation/Analgesia (“Conscious Sedation”). A drug-induced depression of consciousness during which a patient responds 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.

(4) Deep Sedation/Analgesia. A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. Reflex withdrawal from painful stimulation is NOT considered a purposeful response. 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.

(5) 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.

(6) Regional Anesthesia (“Major conduction blockade”) is considered in the same category as General Anesthesia.⁵

⁵. Reference: Appendix A--American Society of Anesthesiologists (ASA) definitions.

(7) Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/ Analgesia should be able to rescue patients who enter a state of general anesthesia.

540-X-10-.03. Standards For Each Level Of Anesthesia--Preoperative Assessment.

A medical history, a physical examination consistent with the type and level of anesthesia and/or analgesia and the level of surgery to be performed, and the appropriate laboratory studies should be performed by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. A pre-anesthetic examination and evaluation should be conducted immediately prior to surgery by the physician or by a qualified person who will be administering or directing the anesthesia. If a qualified person will be administering the anesthesia, the physician shall review with the qualified person the pre-anesthetic examination and evaluation. The data obtained during the course of the pre-anesthesia evaluations (focused history and physical, including airway assessment and significant historical data not usually found in a primary care or surgical history⁶ that may alter care or affect outcome) should be documented in the medical record.

⁶. Reference: Appendix B--Standards of the American Society of Anesthesiologists. This Appendix is included in these Rules only for information.

540-X-10-.04. Standards For Office-Based Procedures--Local Anesthesia.

(1) Equipment and supplies: Oral airway positive pressure ventilation device, epinephrine, and atropine should be available.

(2) Training required: The physician is expected to be knowledgeable in proper drug dosages, recognition and management of toxicity or hypersensitivity to local anesthetic and other drugs. It is recommended that the physician be currently trained in Basic Cardiac Life Support (BCLS).

(3) Assistance of other personnel: No other assistance is required, unless dictated by the scope of the surgical procedure.

540-X-10-.05. Standards For Office-Based Procedures--Minimal Sedation.

(1) Equipment and supplies: Oral airway positive pressure ventilation device, epinephrine, and atropine should be available.

(2) Training required: The physician is expected to be knowledgeable in proper drug dosages, recognition and management of toxicity or hypersensitivity to local anesthetic and other drugs. It is recommended that the physician be currently trained in Basic Cardiac Life Support (BCLS).

(3) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners who have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Practitioners must have documented competence and training to administer local anesthesia with sedation and to assist in any support or resuscitation measures as required. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician.

540-X-10-.06. Standards For Office-Based Procedures--Moderate Sedation/Analgesia.

(1) Physician Registration Requirement: The Alabama Board of Medical Examiners requires each physician who offers office-based surgery that requires moderate sedation, deep sedation or general anesthesia, as defined in these rules to register with the State Board of Medical Examiners as an office-based surgery physician.⁷

⁷. Reference: Appendix D--Physician Registration Form

(2) Equipment and supplies: Emergency resuscitation equipment, emergency life-saving medications, suction, and a reliable source of oxygen with a backup tank must be readily available. When medication for sedation and/or analgesia is administered intravenously (IV), monitoring equipment should include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Patient's vital signs, oxygen saturation, and level of consciousness should be documented prior to the procedure, during regular intervals throughout the procedure, and prior to discharge. Facility, in terms of general preparation, should have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.

(3) Training required: The physician must be able to document satisfactory completion of training such as being Board certified or being an active candidate for certification by a Board approved by the American Board of Medical Specialties or comparable formal training. Alternative credentialing for procedures outside the physician's core curriculum must be applied for through the Alabama Board of Medical Examiners and must be approved by the Board. The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).

(4) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners. Practitioners must have documented competence and training to administer moderate sedation/analgesia and to assist in any support or resuscitation measures as required. The individual administering moderate sedation/analgesia and/or monitoring the patient cannot assist the physician in performing the surgical procedure. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician. At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. At least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the facility.

540-X-10-.07. Standards For Office-Based Procedures--Deep Sedation/Analgesia.

(1) Physician Registration Requirement: The Alabama Board of Medical Examiners requires each physician who offers office-based surgery that requires moderate sedation, deep sedation or general anesthesia, as defined in these rules to register with the State Board of Medical Examiners as an office-based surgery physician.⁸

⁸. Reference: Appendix D--Physician Registration Form

(2) Equipment and supplies: Emergency resuscitation equipment, emergency life-saving medications, suction, and a reliable source of oxygen with a backup tank must be readily available. Monitoring equipment should include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Patient's vital signs, oxygen saturation, and level of consciousness should be documented prior to the procedure, during regular intervals throughout the procedure, and prior to discharge. Facility, in terms of general preparation, should have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.

(3) Training required: The physician must be able to document satisfactory completion of training such as being Board certified or being an active candidate for certification by a Board approved by the American Board of Medical Specialties or comparable formal training. Alternative credentialing for procedures outside the physician's core curriculum must be applied for through the Alabama Board of Medical Examiners and must be approved by the Board. The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).

(4) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners. Practitioners must have documented competence and training to administer deep sedation/analgesia and to assist in any support or resuscitation measures as required. The individual administering deep sedation/analgesia and/or monitoring the patient cannot assist the physician in performing the surgical procedure. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician. At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. At least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the facility.

540-X-10-.08. Standards For Office-Based Procedures--General And Regional Anesthesia.

(1) Physician Registration Requirement: The Alabama Board of Medical Examiners requires each physician who offers office-based surgery that requires moderate sedation, deep sedation or general anesthesia, as defined in these rules to register with the State Board of Medical Examiners as an office-based surgery physician.⁹

⁹. Reference: Appendix D--Physician Registration Form

(2) Equipment and supplies: Emergency resuscitation equipment, suction and a reliable source of oxygen with a backup tank must be readily available. When triggering agents are in the office, at least 12 ampules of dantrolene sodium must be readily available within 10 minutes with additional ampules available from another source. Monitoring equipment should include: blood pressure apparatus, stethoscope, pulse oximetry, continuous EKG, capnography, and temperature monitoring for procedures lasting longer than thirty (30) minutes. Monitoring equipment and supplies should be in compliance with currently adopted ASA standards¹⁰. Facility, in terms of general preparation, must have adequate equipment and supplies, provisions for proper record keeping, and the ability to recover patients after anesthesia.

¹⁰ Reference: Appendix C--Guidelines for Office-Based Anesthesia, section entitled "Monitoring and Equipment." This Appendix is included in these Rules only for information.

(3) Training required: The physician must be able to document satisfactory completion of training such as being Board certified or being an active candidate for certification by a Board approved by the American Board of Medical Specialties or comparable formal training. Alternative credentialing for procedures outside the physician's core curriculum must be applied for through the Alabama Board of Medical Examiners and must be approved by the Board. The physician and at least one assistant must be currently trained in Advanced Cardiac Life Support (ACLS).

(4) Assistance of other personnel: Anesthesia should be administered only by licensed, qualified and competent practitioners. Practitioners must have documented competence and training to administer general and regional anesthesia and to assist in any support or resuscitation measures as required. The individual administering general and regional anesthesia and/or monitoring the patient cannot assist the physician in performing the surgical procedure. Scrub or Circulating nurse(s) and/or assistant(s) must be trained in their specific job skills as determined by the supervising physician. Direction of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately and physically present, who is licensed to practice medicine in the state of Alabama, and who is responsible for the direction of administration of the anesthetic. The physician providing direction should assure that an appropriate pre-anesthetic examination is performed, assure that qualified practitioners participate, be available for diagnosis treatment and management of anesthesia related complications or emergencies, and assure the provision of indicated post anesthesia care. At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. At least one practitioner currently trained in ACLS must be immediately and physically available until the last patient is discharged from the facility¹¹.

¹¹ Reference: Appendix D--Physician Registration Form and Appendix E--ASF Sterilization (Appendix E is included in these Rules only for information).

540-X-10-.09. Recovery Area And Assessment For Discharge With Moderate And Deep Sedation/General Anesthesia--Monitoring Requirement.

Monitoring in the recovery area should be performed by a dedicated person, trained in their specific job skills as determined by the supervising physician, and 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 should meet discharge criteria as established by the practice, prior to leaving the facility. Documented recovery from anesthesia should include the following: 1) vital signs and oxygen saturation stable within acceptable limits; 2) no more than minimal nausea, vomiting or dizziness; and 3) sufficient time (up to 2 hours) should have elapsed following the last administration of reversal agents to ensure the patient does not become sedated after reversal effects have worn off. The patient should be given appropriate discharge instructions and discharge under the care of a responsible third party after meeting discharge criteria. Discharge instructions should include: 1) the procedure performed; 2) information about potential complications; 3) telephone numbers to be used by the patient to discuss complications or questions that may arise; 4) instructions for medications prescribed and pain management; 5) information regarding the follow-up visit date, time and location; and 6) designated treatment facility in the event of an emergency (office-based physician's number, not the emergency room).

540-X-10-10. Tumescent Liposuction And Similarly Related Procedures.

- (1) In the performance of liposuction when infiltration methods such as the tumescent technique are used, they should be regarded as regional or systemic anesthesia because of the potential for systemic toxic effects.
- (2) When infiltration methods such as the tumescent technique are used in the performance of liposuction, the Standards for Office Based Procedures--General and Regional Anesthesia stated in Rule 540-X-10-.08 shall be met, including the physician registration requirement, the equipment and supplies requirement, the training requirement and the assistance of other personnel requirement.
- (3) When infiltration methods such as the tumescent technique are used in the performance of liposuction, the monitoring requirement found in Rule 540-X-10-.09, Recovery Area and Assessment for Discharge with Moderate and Deep Sedation/General Anesthesia--Monitoring Requirement, must be met.

540-X-10-11. Reporting Requirement.

- (1) Reporting to the Alabama Board of Medical Examiners is required within three (3) business days of the occurrence and will include all surgical related deaths and all events related to a procedure(s) that resulted in an emergency transfer of the surgical patient to the hospital, anesthetic or surgical events requiring CPR, unscheduled hospitalization related to the surgery, and surgical site deep wound infection.
- (2) Office Administration. The following summarizes some of the important written documents and policies and procedures that office-based practices are encouraged to develop and implement. The policies and procedures should undergo periodic review and updating. Office-based surgery practices are encouraged to utilize on-site patient safety surveys that are performed by professional trade associations, nationally recognized accrediting agencies and/or other organizations experienced in providing emerging risk-reduction strategies associated with office-based surgery.
 - (a) Policies and Procedures. Written policies and procedures can assist office-based practices in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients. The following are important aspects of an office-based practice that should benefit from simple policy and procedure statements.
 1. Emergency Care and Transfer Plan: A plan shall 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.
 - (i) Age appropriate emergency supplies, equipment and medication should be provided in accordance with the scope of surgical and anesthesia services provided at the practitioner's office.
 - (ii) In an office where anesthesia services are provided to infants and children, the required emergency equipment should be appropriately sized for a pediatric population, and personnel should be appropriately trained to handle pediatric emergencies (currently trained in APLS or PALS).
 - (iii) At least one physician currently trained in ACLS must be immediately and physically available until the last patient is past the first stage of recovery. A practitioner who is qualified in resuscitation techniques and emergency care should be present and available until all patients having more than local anesthesia or minor

conductive block anesthesia have been discharged from the office (Advanced adult or pediatric life support certified).

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

2. Medical Record Maintenance and Security: 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. For procedures requiring patient consent, there should be a documented informed written consent. If analgesia/sedation, minor or major conduction blockade or general anesthesia are provided, the record should include documentation of the type of anesthesia used, drugs (type, time 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 should also be established to assure patient confidentiality and security of all patient data and information.

3. Infection Control Policy: The practice should comply with state and federal regulations regarding infection control. For all surgical procedures, the level of sterilization should meet current OSHA 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 available¹².

4. Federal and State Laws and Regulations: Federal and state laws and regulations that affect the practice should be identified and procedures developed to comply with those requirements. The following are some of the key requirements upon which office-based practices should focus:

- (i) Non-Discrimination (see Civil Rights statutes and the Americans with Disabilities Act).
- (ii) Personal Safety (see Occupational Safety and Health Administration information)
- (iii) Controlled Substance Safeguards.
- (iv) Laboratory Operations and Performance (CLIA).
- (v) Personnel Licensure Scope of Practice and Limitations

540-X-10-.12. Registration Of Office-Based Surgery/Procedures Physician.

(1) A physician who is licensed to practice medicine in Alabama, who maintains a practice location in Alabama, and who performs or offers to perform the following:

- (a) Any office-based surgery/procedure which requires moderate sedation, deep sedation or general anesthesia, as defined in these rules, or
- (b) Liposuction when infiltration methods such as the tumescent technique are used, or
- (c) any procedure in which propofol is administered, given or used, is hereby required to register with the State Board of Medical Examiners as an office-based surgery/procedures physician, prior to performing any office-based surgery/procedure as defined in this rule.

(2) Registration shall be accomplished on a form provided by the Board. After initially registering as an office-based surgery/procedures physician, it shall be the obligation of the registrant to advise the Board of any change in the practice location within the State of Alabama of that office-based surgery/procedures physician.

(3) The form for registration of an office-based surgery/procedures physician is incorporated as Appendix D to these rules.

(4) For the purposes of these rules an “office-based surgery/procedures physician” shall mean any physician licensed to practice medicine in Alabama who performs or offers to perform in an office setting within the state of Alabama, any procedure that requires moderate sedation, deep sedation or general anesthesia, as

defined in these rules, or who performs or offers to perform liposuction when infiltration methods such as the tumescent technique are used, or who performs or offers to perform any procedure in which propofol is administered, given, or used.

(5) In January 2012, the Board of Medical Examiners shall cause a notice to be mailed to every physician who is licensed in the State of Alabama notifying them of the requirements contained in this Chapter.

(6) Beginning January 2012, annual registration as an office-based surgery/procedures physician shall be required, and registration shall be by electronic means.

(7) Beginning February 2013, and in February of each subsequent year, annual registration notification will be generated pursuant to an affirmative answer on the annual medical license renewal application regarding the practice of office-based surgery.

(8) Annual registration as an office-based surgery/procedures physician shall be due by March 1 of each year.

540-X-10-.13. Penalty.

(1) A physician may be guilty of unprofessional conduct within the meaning of Code of Ala. 1975, §34-24-360(2) if he fails to comply with the requirements of these rules concerning any of the following:

(a) Standards for office-based procedures for moderate sedation/analgesia or general/regional anesthesia;

(b) Reporting;

(c) Emergency care and transfer;

(d) Registration.

(2) A physician who has been found to be not in compliance with the requirements of this Chapter 540-X-10 may have his license revoked, suspended or otherwise disciplined by the Medical Licensure Commission.

Alaska

Guideline Regarding the Use of Lasers and Laser Surgery.

http://www.commerce.state.ak.us/occ/pub/CME_To_Whom_May_Perform.pdf

The Alaska State Medical Board has adopted the policies of the American Medical Association, following, to be its guidelines to its licensees in Alaska with regard to who may perform laser surgery.

Performance of Laser Surgery:

Laser surgery should be performed only by individuals licensed to practice medicine and surgery or by those categories of practitioners currently licensed by the state to perform surgical services.

The board opines that revision, destruction, incision or other structural alteration of human tissue using laser is surgery.

Arizona – Medical

Article 7. Office-Based Surgery Using Sedation A.A.C. R4-16-701

R4-16-701. Health Care Institution License

A physician who uses general anesthesia in the physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center when performing office-based surgery using sedation shall obtain a health care institution license as required by the Arizona Department of Health Services under A.R.S. Title 36, Chapter 4 and 9 A.A.C. 10.

R4-16-702. Administrative Provisions

A. A physician who performs office-based surgery using sedation in the physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center shall:

1. Establish, document, and implement written policies and procedures that cover:
 - a. Patient's rights,
 - b. Informed consent,
 - c. Care of patients in an emergency, and
 - d. The transfer of patients;
 2. Ensure that a staff member who assists with or a healthcare professional who participates in office-based surgery using sedation:
 - a. Has sufficient education, training, and experience to perform duties assigned;
 - b. If applicable, has a current license or certification to perform duties assigned; and
 - c. Performs only those acts that are within the scope of practice established in the staff member's or health care professional's governing statutes;
 3. Ensure that the office where the office-based surgery using sedation is performed has all equipment necessary:
 - a. For the physician to safely perform the office-based surgery using sedation,
 - b. For the physician or health care professional to safely administer the sedation,
 - c. For the physician or health care professional to monitor the use of sedation, and
 - d. For the physician and health care professional administering the sedation to rescue a patient after the sedation is administered to the patient and the patient enters into a deeper state of sedation than what was intended by the physician.
 4. Ensure that a copy of the patient's rights policy is provided to each patient before performing office-based surgery using sedation;
 5. Obtain informed consent from the patient before performing an office-based surgery using sedation that:
 - a. Authorizes the office-based surgery, and
 - b. Authorizes the office-based surgery to be performed in the physician's office; and
 6. Review all policies and procedures every 12 months and update as needed.
- B. A physician who performs office-based surgery using sedation shall comply with:
1. The local jurisdiction's fire code;
 2. The local jurisdiction's building codes for construction and occupancy;
 3. The biohazardous waste and hazardous waste standards in 18 A.A.C. 13, Article 14; and
 4. The controlled drug administration, supply, and storage standards in 4 A.A.C. 23.

R4-16-703. Procedure and Patient Selection

A. A physician shall ensure that each office-based surgery using sedation performed:

1. Can be safely performed with the equipment, staff members, and health care professionals at the physician's office;
 2. Is of duration and degree of complexity that allows a patient to be discharged from the physician's office within 24 hours;
 3. Is within the education, training, experience skills, and licensure of the physician; and
 4. Is within the education, training, experience, skills, and licensure of the staff members and health care professionals at the physician's office.
- B. A physician shall not perform office-based surgery using sedation if the patient:
1. Has a medical condition or other condition that indicates the procedure should not be performed in the physician's office, or
 2. Will require inpatient services at a hospital.

R4-16-704. Sedation Monitoring Standards

A physician who performs office-based surgery using sedation shall ensure from the time sedation is administered until post-sedation monitoring begins:

1. A quantitative method of assessing a patient's oxygenation, such as pulse oximetry, is used when minimal sedation is administered to the patient, and
2. When moderate or deep sedation is administered to a patient:
 - a. A quantitative method of assessing the patient's oxygenation, such as pulse oximetry, is used;
 - b. The patient's ventilatory function is monitored by any of the following:
 - i. Direct observation,
 - ii. Auscultation, or
 - iii. Capnography;
 - c. The patient's circulatory function is monitored during the surgery by:
 - i. Having a continuously displayed electrocardiogram,
 - ii. Documenting arterial blood pressure and heart rate at least every five minutes, and
 - iii. Evaluating the patient's cardiovascular function by pulse plethysmography,
 - d. The patient's temperature is monitored if the physician expects the patient's temperature to fluctuate; and
 - e. That a licensed and qualified healthcare professional, other than the physician performing the office-based surgery, whose sole responsibility is attending to the patient, is present throughout the office-based surgery.

R4-16-705. Perioperative Period; Patient Discharge

A physician performing office-based surgery using sedation shall ensure all of the following:

1. During office-based surgery using sedation, the physician is physically present in the room where office-based surgery is performed;
2. After the office-based surgery using sedation is performed, a physician is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient's post-sedation monitoring is discontinued;
3. If using minimal sedation, the physician or a health care professional certified in ACLS, PALS, or BLS is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient is discharged;
4. If using deep or moderate sedation, the physician or a health care professional certified in ACLS or PALS is at the physician's office and sufficiently free of other duties to respond to an emergency until the patient is discharged;
5. A discharge is documented in the patient's medical record including:
 - a. The time and date of the patient's discharge, and
 - b. A description of the patient's medical condition at the time of discharge; and
6. A patient receives discharge instructions and documents in the patient's medical record that the patient received the discharge instructions.

A. In addition to the requirements in R4-16-702(A)(3) and R4-16-703(A)(1), a physician who performs office-based surgery using sedation shall ensure that the physician's office has at a minimum:

1. The following:
 - a. A reliable oxygen source with a SaO₂ monitor;
 - b. Suction;
 - c. Resuscitation equipment, including a defibrillator;
 - d. Emergency drugs; and
 - e. A cardiac monitor;
2. The equipment for patient monitoring according to the standards in R4-16-704;
3. Space large enough to:
 - a. Allow for access to the patient during office-based surgery using sedation, recovery, and any emergency;
 - b. Accommodate all equipment necessary to perform the office-based surgery using sedation; and
 - c. Accommodate all equipment necessary for sedation monitoring;
4. A source of auxiliary electrical power available in the event of a power failure; and
5. Equipment, emergency drugs, and resuscitative capabilities required under this Section for patients less than 18 years of age, if office-based surgery using sedation is performed on these patients; and

6. Procedures to minimize the spread of infection.

B. A physician who performs office-based surgery using sedation shall:

1. Ensure that all equipment used for office-based surgery using sedation is maintained, tested, and inspected according to manufacturer specifications, and
2. Maintain documentation of manufacturer-recommended maintenance of all equipment used in office-based surgery using sedation.

R4-16-706. Emergency Drugs; Equipment and Space Used for Office-Based Surgery Using Sedation

A. In addition to the requirements in R4-16-702(A)(3) and R4-16-703(A)(1), a physician who performs office-based surgery using sedation shall ensure that the physician's office has at a minimum:

1. The following:

- a. A reliable oxygen source with a SaO₂ monitor;
- b. Suction;
- c. Resuscitation equipment, including a defibrillator;
- d. Emergency drugs; and
- e. A cardiac monitor;

2. The equipment for patient monitoring according to the standards in R4-16-704;

3. Space large enough to:

- a. Allow for access to the patient during office-based surgery using sedation, recovery, and any emergency;
- b. Accommodate all equipment necessary to perform the office-based surgery using sedation; and
- c. Accommodate all equipment necessary for sedation monitoring;
4. A source of auxiliary electrical power available in the event of a power failure; and
5. Equipment, emergency drugs, and resuscitative capabilities required under this Section for patients less than 18 years of age, if office-based surgery using sedation is performed on these patients; and
6. Procedures to minimize the spread of infection.

B. A physician who performs office-based surgery using sedation shall:

1. Ensure that all equipment used for office-based surgery using sedation is maintained, tested, and inspected according to manufacturer specifications, and
2. Maintain documentation of manufacturer-recommended maintenance of all equipment used in office-based surgery using sedation.

R4-16-707. Emergency and Transfer Provisions

A. A physician who performs office-based surgery using sedation shall ensure that before a health care professional participates in or staff member assists with office-based surgery using sedation, the health care professional and staff member receive instruction in the following:

1. Policy and procedure in cases of emergency,
2. Policy and procedure for office evacuation, and
3. Safe and timely patient transfer.

B. When performing office-based surgery using sedation, a physician shall not use any drug or agent that trigger malignant hyperthermia.

A.R.S. § 32-1401 Definitions

20. "Office based surgery" means a medical procedure conducted in a physician's office or other outpatient setting that is not part of a licensed hospital or licensed ambulatory surgical center.

Arkansas

None

California

CA Bus & Prof D. 2, Ch. 5, Art. 11.5 Surgery in Certain Outpatient Settings

§ 2215. Findings and intent

The Legislature finds and declares that in this state, significant surgeries are being performed in unregulated out-of-hospital settings. The Legislature further finds and declares that without appropriate oversight, some of these settings may be operating in a manner which is injurious to the public health, welfare, and safety. Although the health professionals delivering health care services in these settings are licensed, further quality assurance is needed to ensure that health care services are safely and effectively performed in these settings. The Legislature further recognizes that there is a wide range of surgical procedures safely performed in a myriad of outpatient settings, and the degree of patient risk varies greatly. It is the intent of the Legislature to create regulations that directly impact patient safety. It is not the intent of the Legislature to require standards in excess of those requirements in Section 1248.15, or to require physical modifications to facilities unless the modifications or standards directly impact patient safety and are cost-effective. The cost effectiveness of any modifications shall be taken into consideration by the Division of Licensing of the Medical Board of California, and shall ensure that the least costly and effective method of achieving patient safety is required.

§ 2216. Procedures prohibited in outpatient setting

On or after July 1, 1996, no physician and surgeon shall perform procedures in an outpatient setting using anesthesia, except local anesthesia or peripheral nerve blocks, or both, complying with the community standard of practice, in doses that, when administered, have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes, unless the setting is specified in Section 1248.1. Outpatient settings where anxiolytics and analgesics are administered are excluded when administered, in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.

The definition of "outpatient settings" contained in subdivision (c) of Section 1248 shall apply to this section.

§ 2216.1. Unprofessional conduct; minimum number of staff persons; licensure

On and after July 1, 2000, it is unprofessional conduct for a physician and surgeon to perform procedures in any outpatient setting except in compliance with Section 2216, unless the setting has a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care.

§ 2216.2. Failure to provide adequate security by liability insurance

(a) It is unprofessional conduct for a physician and surgeon to fail to provide adequate security by liability insurance, or by participation in an interindemnity trust, for claims by patients arising out of surgical procedures performed outside of a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

(b) For purposes of this section, the board shall determine what constitutes adequate security.

(c) Nothing in this section shall require an insurer admitted to transact liability insurance in this state to provide coverage to a physician and surgeon.

(d) The security required by this section shall be acceptable only if provided by any one of the following:

- (1) An insurer admitted pursuant to Section 700 of the Insurance Code to transact liability insurance in this state.
- (2) An insurer that is eligible pursuant to Section 1765.1 of the Insurance Code.
- (3) A cooperative corporation authorized by Section 1280.7 of the Insurance Code.
- (4) An insurer licensed to transact liability insurance in at least one state of the United States.

§ 2217. Adoption of regulations

The Division of Licensing of the Medical Board of California may adopt regulations to implement this article and Chapter 1.3 (commencing with Section 1248) of Division 2 of the Health and Safety Code.

West's Ann.Cal.Bus. & Prof.Code § 2240

§ 2240. Scheduled medical procedure outside general acute care hospital resulting in death or transfer to emergency center; written report; contents

(a) Any physician and surgeon who performs a scheduled medical procedure outside of a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, that results in the death of any patient on whom that medical treatment was performed by the physician and surgeon, or by a person acting under the physician and surgeon's orders or supervision, shall report, in writing on a form prescribed by the board, that occurrence to the board within 15 days after the occurrence.

(b) Any physician and surgeon who performs a scheduled medical procedure outside of a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, that results in the transfer to a hospital or emergency center for medical treatment for a period exceeding 24 hours, of any patient on whom that medical treatment was performed by the physician and surgeon, or by a person acting under the physician and surgeon's orders or supervision, shall report, in writing, on a form prescribed by the board that occurrence, within 15 days after the occurrence. The form shall contain all of the following information:

- (1) Name of the patient's physician in the outpatient setting.
- (2) Name of the physician with hospital privileges.
- (3) Name of the patient and patient identifying information.
- (4) Name of the hospital or emergency center where the patient was transferred.
- (5) Type of outpatient procedures being performed.
- (6) Events triggering the transfer.
- (7) Duration of the hospital stay.
- (8) Final disposition or status, if not released from the hospital, of the patient.
- (9) Physician's practice specialty and ABMS certification, if applicable.

(c) The form described in subdivision (b) shall be constructed in a format to enable the physician and surgeon to transmit the information in paragraphs (5) to (9), inclusive, to the board in a manner that the physician and surgeon and the patient are anonymous and their identifying information is not transmitted to the board. The entire form containing information described in paragraphs (1) to (9), inclusive, shall be placed in the patient's medical record.

(d) The board shall aggregate the data and publish an annual report on the information collected pursuant to subdivisions (a) and (b).

(e) On and after January 1, 2002, the data required in subdivision (b) shall be sent to the Office of Statewide Health Planning and Development (OSHPD) instead of the board. OSHPD may revise the reporting requirements to fit state and national standards, as applicable. The board shall work with OSHPD in developing the reporting mechanism to satisfy the data collection requirements of this section.

(f) The failure to comply with this section constitutes unprofessional conduct.

CA Hlth & S D. 2, Ch. 1.3 Outpatient Settings

§ 1248. Definitions

For purposes of this chapter, the following definitions shall apply:

(a) "Division" means the Medical Board of California. All references in this chapter to the division, the Division of Licensing of the Medical Board of California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.

(b)(1) "Outpatient setting" means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.

(2) "Outpatient setting" also means facilities that offer in vitro fertilization, as defined in subdivision (b) of Section 1374.55.

(3) "Outpatient setting" does not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.

(c) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the board pursuant to Sections 1248.15 and 1248.4.

§ 1248.1. Operation and maintenance of outpatient setting; restrictions

No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:

(a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.

(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.

(c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.

(d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.

(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).

(f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.

(g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.

(h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable.

§ 1248.15. Standards for accreditation; approval of accreditation agencies; certification programs; minimum standards; additional standards; adoption of regulations for specific procedures preformed; investigation of prior history

(a) The board shall adopt standards for accreditation and, in approving accreditation agencies to perform accreditation of outpatient settings, shall ensure that the certification program shall, at a minimum, include standards for the following aspects of the settings' operations:

(1) Outpatient setting allied health staff shall be licensed or certified to the extent required by state or federal law.

- (2)(A) Outpatient settings shall have a system for facility safety and emergency training requirements.
- (B) There shall be onsite equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate handling of any medical emergency that may arise in connection with services sought or provided.
- (C) In order for procedures to be performed in an outpatient setting as defined in Section 1248, the outpatient setting shall do one of the following:
- (i) Have a written transfer agreement with a local accredited or licensed acute care hospital, approved by the facility's medical staff.
 - (ii) Permit surgery only by a licensee who has admitting privileges at a local accredited or licensed acute care hospital, with the exception that licensees who may be precluded from having admitting privileges by their professional classification or other administrative limitations, shall have a written transfer agreement with licensees who have admitting privileges at local accredited or licensed acute care hospitals.
 - (iii) Submit for approval by an accrediting agency a detailed procedural plan for handling medical emergencies that shall be reviewed at the time of accreditation. No reasonable plan shall be disapproved by the accrediting agency.
- (D) In addition to the requirements imposed in subparagraph (C), the outpatient setting shall submit for approval by an accreditation agency at the time of accreditation a detailed plan, standardized procedures, and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm or to govern emergency and urgent care situations. The plan shall include, at a minimum, that if a patient is being transferred to a local accredited or licensed acute care hospital, the outpatient setting shall do all of the following:
- (i) Notify the individual designated by the patient to be notified in case of an emergency.
 - (ii) Ensure that the mode of transfer is consistent with the patient's medical condition.
 - (iii) Ensure that all relevant clinical information is documented and accompanies the patient at the time of transfer.
 - (iv) Continue to provide appropriate care to the patient until the transfer is effectuated.
- (E) All physicians and surgeons transferring patients from an outpatient setting shall agree to cooperate with the medical staff peer review process on the transferred case, the results of which shall be referred back to the outpatient setting, if deemed appropriate by the medical staff peer review committee. If the medical staff of the acute care facility determines that inappropriate care was delivered at the outpatient setting, the acute care facility's peer review outcome shall be reported, as appropriate, to the accrediting body or in accordance with existing law.
- (3) The outpatient setting shall permit surgery by a dentist acting within his or her scope of practice under Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code or physician and surgeon, osteopathic physician and surgeon, or podiatrist acting within his or her scope of practice under Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or the Osteopathic Initiative Act. The outpatient setting may, in its discretion, permit anesthesia service by a certified registered nurse anesthetist acting within his or her scope of practice under Article 7 (commencing with Section 2825) of Chapter 6 of Division 2 of the Business and Professions Code.
- (4) Outpatient settings shall have a system for maintaining clinical records.
- (5) Outpatient settings shall have a system for patient care and monitoring procedures.
- (6)(A) Outpatient settings shall have a system for quality assessment and improvement.
- (B) Members of the medical staff and other practitioners who are granted clinical privileges shall be professionally qualified and appropriately credentialed for the performance of privileges granted. The outpatient setting shall grant privileges in accordance with recommendations from qualified health professionals, and credentialing standards established by the outpatient setting.
- (C) Clinical privileges shall be periodically reappraised by the outpatient setting. The scope of procedures performed in the outpatient setting shall be periodically reviewed and amended as appropriate.
- (7) Outpatient settings regulated by this chapter that have multiple service locations shall have all of the sites inspected.

- (8) Outpatient settings shall post the certificate of accreditation in a location readily visible to patients and staff.
- (9) Outpatient settings shall post the name and telephone number of the accrediting agency with instructions on the submission of complaints in a location readily visible to patients and staff.
- (10) Outpatient settings shall have a written discharge criteria.
- (b) Outpatient settings shall have a minimum of two staff persons on the premises, one of whom shall either be a licensed physician and surgeon or a licensed health care professional with current certification in advanced cardiac life support (ACLS), as long as a patient is present who has not been discharged from supervised care. Transfer to an unlicensed setting of a patient who does not meet the discharge criteria adopted pursuant to paragraph (10) of subdivision (a) shall constitute unprofessional conduct.
- (c) An accreditation agency may include additional standards in its determination to accredit outpatient settings if these are approved by the board to protect the public health and safety.
- (d) No accreditation standard adopted or approved by the board, and no standard included in any certification program of any accreditation agency approved by the board, shall serve to limit the ability of any allied health care practitioner to provide services within his or her full scope of practice. Notwithstanding this or any other provision of law, each outpatient setting may limit the privileges, or determine the privileges, within the appropriate scope of practice, that will be afforded to physicians and allied health care practitioners who practice at the facility, in accordance with credentialing standards established by the outpatient setting in compliance with this chapter. Privileges may not be arbitrarily restricted based on category of licensure.
- (e) The board shall adopt standards that it deems necessary for outpatient settings that offer in vitro fertilization.
- (f) The board may adopt regulations it deems necessary to specify procedures that should be performed in an accredited outpatient setting for facilities or clinics that are outside the definition of outpatient setting as specified in Section 1248.
- (g) As part of the accreditation process, the accrediting agency shall conduct a reasonable investigation of the prior history of the outpatient setting, including all licensed physicians and surgeons who have an ownership interest therein, to determine whether there have been any adverse accreditation decisions rendered against them. For the purposes of this section, "conducting a reasonable investigation" means querying the Medical Board of California and the Osteopathic Medical Board of California to ascertain if either the outpatient setting has, or, if its owners are licensed physicians and surgeons, if those physicians and surgeons have, been subject to an adverse accreditation decision.
- (h) An outpatient setting shall be subject to the reporting requirements in Section 1279.1 and the penalties for failure to report specified in Section 1280.4.

§ 1248.2. Certificate of accreditation; application; issuance; list of accredited, certified, and licensed outpatient settings; notification to public by placing on Internet Web site; inclusion; notification

- (a) Any outpatient setting may apply to an accreditation agency for a certificate of accreditation. Accreditation shall be issued by the accreditation agency solely on the basis of compliance with its standards as approved by the board under this chapter.
- (b) The board shall obtain and maintain a list of accredited outpatient settings from the information provided by the accreditation agencies approved by the board, and shall notify the public, by placing the information on its Internet Web site, whether an outpatient setting is accredited or the setting's accreditation has been revoked, suspended, or placed on probation, or the setting has received a reprimand by the accreditation agency.
- (c) The list of outpatient settings shall include all of the following:
- (1) Name, address, and telephone number of any owners, and their medical license numbers.
 - (2) Name and address of the facility.
 - (3) The name and telephone number of the accreditation agency.
 - (4) The effective and expiration dates of the accreditation.

(d) Accrediting agencies approved by the board shall notify the board and update the board on all outpatient settings that are accredited.

§ 1248.25. Denial of accreditation; reapplication

If an outpatient setting does not meet the standards approved by the board, accreditation shall be denied by the accreditation agency, which shall provide the outpatient setting notification of the reasons for the denial. An outpatient setting may reapply for accreditation at any time after receiving notification of the denial. The accreditation agency shall report within three business days to the board if the outpatient setting's certificate for accreditation has been denied.

§ 1248.3. Validity of certificates of accreditation; change in ownership; notification; disclosure of information obtained in performance of accreditation activities

(a) Certificates of accreditation issued to outpatient settings by an accreditation agency shall be valid for not more than three years.

(b) The outpatient setting shall notify the accreditation agency within 30 days of any significant change in ownership, including, but not limited to, a merger, change in majority interest, consolidation, name change, change in scope of services, additional services, or change in locations.

(c) Except for disclosures to the division or to the Division of Medical Quality under this chapter, an accreditation agency shall not disclose information obtained in the performance of accreditation activities under this chapter that individually identifies patients, individual medical practitioners, or outpatient settings. Neither the proceedings nor the records of an accreditation agency or the proceedings and records of an outpatient setting related to performance of quality assurance or accreditation activities under this chapter shall be subject to discovery, nor shall the records or proceedings be admissible in a court of law. The prohibition relating to discovery and admissibility of records and proceedings does not apply to any outpatient setting requesting accreditation in the event that denial or revocation of that outpatient setting's accreditation is being contested. Nothing in this section shall prohibit the accreditation agency from making discretionary disclosures of information to an outpatient setting pertaining to the accreditation of that outpatient setting.

§ 1248.35. Inspection of outpatient settings; requirements; noncompliance with standards; reprimand, probation, suspension or revocation; notice; reporting on results of inspection

Currentness

(a) Every outpatient setting which is accredited shall be inspected by the accreditation agency and may also be inspected by the Medical Board of California. The Medical Board of California shall ensure that accreditation agencies inspect outpatient settings.

(b) Unless otherwise specified, the following requirements apply to inspections described in subdivision (a).

(1) The frequency of inspection shall depend upon the type and complexity of the outpatient setting to be inspected.

(2) Inspections shall be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board of California to ensure the quality of care provided.

(3) The Medical Board of California or the accreditation agency may enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to ensure compliance with, or investigate an alleged violation of, any standard of the accreditation agency or any provision of this chapter.

(c) If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance with the standards under which it was approved, the accreditation agency may do any of the following:

(1) Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the outpatient setting's accreditation.

(2) Issue a reprimand.

(3) Place the outpatient setting on probation, during which time the setting shall successfully institute and complete a plan of correction, approved by the board or the accreditation agency, to correct the deficiencies.

(4) Suspend or revoke the outpatient setting's certification of accreditation.

(d)(1) Except as is otherwise provided in this subdivision, before suspending or revoking a certificate of accreditation under this chapter, the accreditation agency shall provide the outpatient setting with notice of any deficiencies and the outpatient setting shall agree with the accreditation agency on a plan of correction that shall give the outpatient setting reasonable time to supply information demonstrating compliance with the standards of the accreditation agency in compliance with this chapter, as well as the opportunity for a hearing on the matter upon the request of the outpatient setting. During the allotted time to correct the deficiencies, the plan of correction, which includes the deficiencies, shall be conspicuously posted by the outpatient setting in a location accessible to public view. Within 10 days after the adoption of the plan of correction, the accrediting agency shall send a list of deficiencies and the corrective action to be taken to the board. The accreditation agency may immediately suspend the certificate of accreditation before providing notice and an opportunity to be heard, but only when failure to take the action may result in imminent danger to the health of an individual. In such cases, the accreditation agency shall provide subsequent notice and an opportunity to be heard.

(2) If an outpatient setting does not comply with a corrective action within a timeframe specified by the accrediting agency, the accrediting agency shall issue a reprimand, and may either place the outpatient setting on probation or suspend or revoke the accreditation of the outpatient setting, and shall notify the board of its action. This section shall not be deemed to prohibit an outpatient setting that is unable to correct the deficiencies, as specified in the plan of correction, for reasons beyond its control, from voluntarily surrendering its accreditation prior to initiation of any suspension or revocation proceeding.

(e) The accreditation agency shall, within 24 hours, report to the board if the outpatient setting has been issued a reprimand or if the outpatient setting's certification of accreditation has been suspended or revoked or if the outpatient setting has been placed on probation.

(f) The accreditation agency, upon receipt of a complaint from the board that an outpatient setting poses an immediate risk to public safety, shall inspect the outpatient setting and report its findings of inspection to the board within five business days. If an accreditation agency receives any other complaint from the board, it shall investigate the outpatient setting and report its findings of investigation to the board within 30 days.

(g) Reports on the results of any inspection shall be kept on file with the board and the accreditation agency along with the plan of correction and the comments of the outpatient setting. The inspection report may include a recommendation for reinspection. All final inspection reports, which include the lists of deficiencies, plans of correction or requirements for improvements and correction, and corrective action completed, shall be public records open to public inspection.

(h) If one accrediting agency denies accreditation, or revokes or suspends the accreditation of an outpatient setting, this action shall apply to all other accrediting agencies. An outpatient setting that is denied accreditation is permitted to reapply for accreditation with the same accrediting agency. The outpatient setting also may apply for accreditation from another accrediting agency, but only if it discloses the full accreditation report of the accrediting agency that denied accreditation. Any outpatient setting that has been denied accreditation shall disclose the accreditation report to any other accrediting agency to which it submits an application. The new accrediting agency shall ensure that all deficiencies have been corrected and conduct a new onsite inspection consistent with the standards specified in this chapter.

(i) If an outpatient setting's certification of accreditation has been suspended or revoked, or if the accreditation has been denied, the accreditation agency shall do all of the following:

(1) Notify the board of the action.

(2) Send a notification letter to the outpatient setting of the action. The notification letter shall state that the setting is no longer allowed to perform procedures that require outpatient setting accreditation.

(3) Require the outpatient setting to remove its accreditation certification and to post the notification letter in a conspicuous location, accessible to public view.

(j) The board may take any appropriate action it deems necessary pursuant to Section 1248.7 if an outpatient setting's certification of accreditation has been suspended or revoked, or if accreditation has been denied.

§ 1248.4. Accreditation agencies operating on or before Jan. 1, 1995; temporary certificates of approval; list of certificated settings; approval for accreditation; criteria; notification of revocation of certificate; expiration of certification; renewal

(a) It is the intent of the Legislature that an accreditation agency operating on or before January 1, 1995, or a successor thereof, or an accreditation agency thereafter operating as part of a joint program granted temporary certification as an accreditation agency by the division, whether operating as part of a joint program or independently, and meeting the standards set forth in this chapter, as determined by the division, not be required to go through the entire application process with the division. Therefore, the division may grant a temporary certificate of approval to such an accreditation agency. The temporary approval issued to an accreditation agency under this subdivision shall expire on January 1, 1998. In order to continue its status as an accreditation agency, an accreditation agency approved by the division under this subdivision shall apply for renewal of approval by the division on or before January 1, 1998, and shall establish that it is in compliance with the standards set forth in this chapter and any regulations adopted pursuant thereto.

(b) Each accreditation agency approved by the division shall, on and after January 1, 1995, promptly forward to the division a list of each outpatient setting to which it has granted a certificate of accreditation, as well as settings that have lost accreditation or were denied accreditation.

(c) The division shall approve an accreditation agency that applies for approval on a form prescribed by the division, accompanied by payment of the fee prescribed by this chapter and evidence that the accreditation agency meets the following criteria:

(1) Includes within its accreditation program, at a minimum, the standards for accreditation of outpatient settings approved by the division as well as standards for patient care and safety at the setting.

(2) Submits its current accreditation standards to the division every three years, or upon request for continuing approval by the division.

(3) Maintains internal quality management programs to ensure quality of the accreditation process.

(4) Has a process by which accreditation standards can be reviewed and revised no less than every three years.

(5) Maintains an available pool of allied health care practitioners to serve on accreditation review teams as appropriate.

(6) Has accreditation review teams that shall do all of the following:

(A) Consist of at least one physician and surgeon who practices in an outpatient setting; any other members shall be practicing actively in these settings.

(B) Participate in formal educational training programs provided by the accreditation agency in evaluation of the certification standards at least every three years.

(7) The accreditation agency shall demonstrate that professional members of its review team have experience in conducting review activities of freestanding outpatient settings.

(8) Standards for accreditation shall be developed with the input of the medical community and the ambulatory surgery industry.

(9) Accreditation reviewers shall be credentialed and screened by the accreditation agency.

(10) The accreditation agency shall not have an ownership interest in nor be involved in the operation of a freestanding outpatient setting, nor in the delivery of health care services to patients.

(d) Accreditation agencies approved by the division shall forward to the division copies of all certificates of accreditation and shall notify the division promptly whenever the agency denies or revokes a certificate of accreditation.

(e) A certification of an accreditation agency by the division shall expire at midnight on the last day of a three-year term if not renewed. The division shall establish by regulation the procedure for renewal. To renew an unexpired approval, the accreditation agency shall, on or before the date upon which the certification would otherwise expire, apply for renewal on a form, and pay the renewal fee, as prescribed by the division.

§ 1248.5. Performance evaluations

The board shall evaluate the performance of an approved accreditation agency no less than every three years, or in response to complaints against an agency, or complaints against one or more outpatient settings accreditation by an agency that indicates noncompliance by the agency with the standards approved by the board.

§ 1248.55. Failure to meet criteria; termination of approval

(a) If the accreditation agency is not meeting the criteria set by the division, the division may terminate approval of the agency.

(b) Before terminating approval of an accreditation agency, the division shall provide the accreditation agency with notice of any deficiencies and reasonable time to supply information demonstrating compliance with the requirements of this chapter, as well as the opportunity for a hearing on the matter in compliance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(c)(1) If approval of the accreditation agency is terminated by the division, outpatient settings accredited by that agency shall be notified by the division and, except as provided in paragraph (2), shall be authorized to continue to operate for a period of 12 months in order to seek accreditation through an approved accreditation agency, unless the time is extended by the division for good cause.

(2) The division may require that an outpatient setting, that has been accredited by an accreditation agency whose approval has been terminated by the division, cease operations immediately in the event that the division is in possession of information indicating that continued operation poses an imminent risk of harm to the health of an individual. In such cases, the division shall provide the outpatient setting with notice of its action, the reason underlying it, and a subsequent opportunity for a hearing on the matter. An outpatient setting that is ordered to cease operations under this paragraph may reapply for a certificate of accreditation after six months and shall notify the division promptly of its reapplication.

§ 1248.6. Fees

(a) The Division of Licensing shall establish by regulation a reasonable fee for an application for approval as an accreditation agency in an amount that is reasonably necessary to recover the cost of implementing and administering this chapter, and not to exceed five thousand dollars (\$5,000). The division shall establish by regulation a reasonable fee for a temporary certificate of approval, as outlined in subdivision (a) of Section 1248.4, not to exceed two thousand dollars (\$2,000). The division shall also establish a reasonable fee for renewal. The renewal fee shall be proportionate to the number of outpatient settings accredited by the approved accrediting body seeking renewal, and shall not exceed one hundred dollars (\$100) per outpatient setting accreditation reviewed.

(b) All fees paid to and received by the division or the Medical Board of California under this chapter shall be paid into the State Treasury and shall be credited to a special fund that is hereby created as the Outpatient Setting Fund of the Medical Board of California. Funds in the Outpatient Setting Fund of the Medical Board of California shall be expended by the board for the purpose of implementing and administering this chapter upon appropriation by the Legislature. No surplus in the fund shall be deposited in or transferred to the General Fund or any other fund.

§ 1248.65. Violations; unprofessional conduct

It shall constitute unprofessional conduct for a physician and surgeon to willfully and knowingly violate this chapter.

§ 1248.7. Injunctions; requirements for proceedings

(a) The board shall investigate all complaints concerning a violation of this chapter. With respect to any complaints relating to a violation of Section 1248.1, or upon discovery that an outpatient setting is not in compliance with Section 1248.1, the board shall investigate and, where appropriate, the board, through or in conjunction with the local district attorney, shall bring an action to enjoin the outpatient setting's operation. The board or the local district attorney may bring an action to enjoin a violation or threatened violation of any other provision of this chapter in the superior court in and for the county in which the violation

occurred or is about to occur. Any proceeding under this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure, except that the Division of Medical Quality shall not be required to allege facts necessary to show or tending to show lack of adequate remedy at law or irreparable damage or loss.

(b) With respect to any and all actions brought pursuant to this section alleging an actual or threatened violation of any requirement of this chapter, the court shall, if it finds the allegations to be true, issue an order enjoining the person or facility from continuing the violation. For purposes of Section 1248.1, if an outpatient setting is operating without a certificate of accreditation, this shall be prima facie evidence that a violation of Section 1248.1 has occurred and additional proof shall not be necessary to enjoin the outpatient setting's operation.

§ 1248.75. Injunctions; notification of deficiencies in compliance and of regulations; plan of correction; inspection; corrective action

(a) Except as may otherwise be provided in this section, before the Division of Medical Quality may seek an injunction as provided under Section 1248.7, the Division of Medical Quality shall notify the outpatient setting of all deficiencies in its compliance with this chapter, and any rules and regulations adopted pursuant to this chapter, and the Division of Medical Quality and the outpatient setting shall reach an agreement upon a plan of correction that shall give the outpatient setting reasonable time to correct the deficiencies. The Division of Medical Quality shall also inform the outpatient setting that failure to reach an agreement or to correct deficiencies may lead to corrective action by the Division of Medical Quality, which may include imposition of fines under Section 1248.8. If at the end of the allotted time the division and the outpatient setting have failed to reach an agreement or the outpatient setting has failed to correct the deficiencies, as revealed by inspection, the Division of Medical Quality may take corrective action to include, as appropriate, seeking an injunction under Section 1248.7, revoking or requesting that the accreditation agency revoke accreditation, or communicating with any agency that has oversight authority over the outpatient setting, such as the Department of Health Services or other appropriate licensing authority, to request that the agency take corrective action against the outpatient setting.

(b) For purposes of this section, and at the sole discretion of the Division of Medical Quality, any notifications, inspections, and corrective action plans of the Division of Medical Quality relating to outpatient settings that have been accredited by an accreditation agency may be performed or coordinated by the accreditation agency rather than by the Division of Medical Quality.

(c) If the Division of Medical Quality determines that an outpatient setting poses an immediate and substantial hazard to the health or safety of the patient, that may not reasonably be corrected through a plan of correction, the Division of Medical Quality may immediately institute injunction proceedings pursuant to Section 1248.7.

§ 1248.8. Willful violations; punishment; considerations

(a) Any person or entity that willfully violates this chapter or any rule or regulation adopted under this chapter shall be guilty of a misdemeanor and subject to a fine not to exceed one thousand dollars (\$1,000) per day of violation.

(b) In determining the punishment to be imposed under this section, the court shall consider all relevant facts, including, but not limited to, the following:

(1) Whether the violation exposed a patient or other individual to the risk of death or serious physical harm.

(2) Whether the violation had a direct or immediate relationship to health, safety, or security of a patient or other individual.

(3) Evidence, if any, of willfulness in the violation.

(4) The presence or absence of good faith efforts by the outpatient setting to prevent the violation.

(c) For purposes of this section, "willfully" or "willful" means that the person doing an act or omitting to do an act intends the act or omission, and knows the relevant circumstances connected with the act or omission.

(d) The district attorney of every county shall, upon application by the Division of Medical Quality or its authorized representative, institute and conduct the prosecution of any action or violation within the county of any provisions of this chapter.

§ 1248.85. Additional standards, procedures, and fees established by accreditation agency

This chapter shall not preclude an approved accreditation agency from adopting additional standards consistent with Section 1248.15, establishing procedures for the conduct of onsite inspections, selecting onsite inspectors to perform accreditation onsite inspections, or establishing and collecting reasonable fees for the conduct of accreditation onsite inspections.

California – Osteopathic

None

Colorado

Policy Statement

Office-Based Surgery and Anesthesia

<http://www.dora.state.co.us/medical/policies/40-12.pdf>

Connecticut

§ 19a-490m. Development of surgery protocols by hospitals and outpatient surgical facilities

(a) Each hospital and outpatient surgical facility shall develop protocols for accurate identification procedures that shall be used by such hospital or outpatient surgical facility prior to surgery.

Such protocols shall include, but need not be limited to, (1) procedures to be followed to identify the (A) patient, (B) surgical procedure to be performed, and (C) body part on which the surgical procedure is to be performed, and (2) alternative identification procedures in urgent or emergency circumstances or where the patient is nonspeaking, comatose or incompetent or is a child. After January 1, 2006, no hospital or outpatient surgical facility may anesthetize a patient or perform surgery unless the protocols have been followed. Each hospital and outpatient surgical facility shall make a copy of the protocols available to the Commissioner of Public Health upon request.

(b) Not later than October 1, 2006, the Department of Public Health shall report, in accordance with section 11-4a, to the joint standing committee of the General Assembly having cognizance of matters relating to public health describing the protocols developed pursuant to subsection (a) of this section.

C.G.S.A. § 19a-493b. Definition of outpatient surgical facility. Licensure and exceptions. Compliance with certificate of need requirements. Dental clinics not subject to section. Waiver of certain licensure regulation requirements

(a) As used in this section and subsection (a) of section 19a-490, “outpatient surgical facility” means any entity, individual, firm, partnership, corporation, limited liability company or association, other than a hospital, engaged in providing surgical services or diagnostic procedures for human health conditions that include the use of moderate or deep sedation, moderate or deep analgesia or general anesthesia, as such levels of anesthesia are defined from time to time by the American Society of Anesthesiologists, or by such other professional or accrediting entity recognized by the Department of Public Health.

An outpatient surgical facility shall not include a medical office owned and operated exclusively by a person or persons licensed pursuant to section 20-13, provided such medical office: (1) Has no operating room or designated surgical area; (2) bills no facility fees to third party payers; (3) administers no deep sedation or general anesthesia; (4) performs only minor surgical procedures incidental to the work performed in said

medical office of the physician or physicians that own and operate such medical office; and (5) uses only light or moderate sedation or analgesia in connection with such incidental minor surgical procedures. Nothing in this subsection shall be construed to affect any obligation to comply with the provisions of section 19a-691.

(b) No entity, individual, firm, partnership, corporation, limited liability company or association, other than a hospital, shall individually or jointly establish or operate an outpatient surgical facility in this state without complying with chapter 368z,¹ except as otherwise provided by this section, and obtaining a license within the time specified in this subsection from the Department of Public Health for such facility pursuant to the provisions of this chapter, unless such entity, individual, firm, partnership, corporation, limited liability company or association: (1) Provides to the Office of Health Care Access division of the Department of Public Health satisfactory evidence that it was in operation on or before July 1, 2003, or (2) obtained, on or before July 1, 2003, from the Office of Health Care Access, a determination that a certificate of need is not required. An entity, individual, firm, partnership, corporation, limited liability company or association otherwise in compliance with this section may operate an outpatient surgical facility without a license through March 30, 2007, and shall have until March 30, 2007, to obtain a license from the Department of Public Health.

(c) Notwithstanding the provisions of this section, no outpatient surgical facility shall be required to comply with section 19a-631, 19a-632, 19a-644, 19a-645, 19a-646, 19a-649, 19a-654 to 19a-660, inclusive, 19a-664 to 19a-666, inclusive, 19a-673 to 19a-676, inclusive, 19a-678, 19a-681 or 19a-683.

Each outpatient surgical facility shall continue to be subject to the obligations and requirements applicable to such facility, including, but not limited to, any applicable provision of this chapter and those provisions of chapter 368z not specified in this subsection, except that a request for permission to undertake a transfer or change of ownership or control shall not be required pursuant to subsection (a) of section 19a-638 if the Office of Health Care Access division of the Department of Public Health determines that the following conditions are satisfied: (1) Prior to any such transfer or change of ownership or control, the outpatient surgical facility shall be owned and controlled exclusively by persons licensed pursuant to section 20-13 or chapter 375, either directly or through a limited liability company, formed pursuant to chapter 613,² a corporation, formed pursuant to chapters 601³ and 602,⁴ or a limited liability partnership, formed pursuant to chapter 614,⁵ that is exclusively owned by persons licensed pursuant to section 20-13 or chapter 375, or is under the interim control of an estate executor or conservator pending transfer of an ownership interest or control to a person licensed under section 20-13 or chapter 375, and (2) after any such transfer or change of ownership or control, persons licensed pursuant to section 20-13 or chapter 375, a limited liability company, formed pursuant to chapter 613, a corporation, formed pursuant to chapters 601 and 602, or a limited liability partnership, formed pursuant to chapter 614, that is exclusively owned by persons licensed pursuant to section 20-13 or chapter 375, shall own and control no less than a sixty per cent interest in the outpatient surgical facility.

(d) The provisions of this section shall not apply to persons licensed to practice dentistry or dental medicine pursuant to chapter 379⁶ or to outpatient clinics licensed pursuant to this chapter.

(e) Any outpatient surgical facility that is accredited as provided in section 19a-691 shall continue to be subject to the requirements of section 19a-691.

(f) The Commissioner of Public Health may provide a waiver for outpatient surgical facilities from the physical plant and staffing requirements of the licensing regulations adopted pursuant to this chapter, provided no waiver may be granted unless the health, safety and welfare of patients is ensured.

C.G.S.A. § 19a-691 Anesthesia accreditation

a) Any office or unlicensed facility operated by a licensed health care practitioner or practitioner group at which moderate sedation/analgesia, deep sedation/analgesia or general anesthesia, as such levels of anesthesia are defined from time to time by the American Society of Anesthesiology, is administered shall be accredited by at least one of the following entities: (1) The Medicare program; (2) the Accreditation Association for Ambulatory Health Care; (3) the American Association for Accreditation of Ambulatory Surgery Facilities, Inc.; or (4) the Joint Commission on Accreditation of Healthcare Organizations. Such

accreditation shall be obtained not later than eighteen months after July 1, 2001, or eighteen months after the date on which moderate sedation/analgesia, deep sedation/analgesia or general anesthesia is first administered at such office or facility, whichever is later. Upon the expiration of the applicable eighteen-month period, no moderate sedation/analgesia, deep sedation/analgesia or general anesthesia may be administered at any such office or facility that does not receive accreditation as required by this section. Evidence of such accreditation shall be maintained at any such office or facility at which moderate sedation/analgesia, deep sedation/analgesia or general anesthesia is administered and shall be made available for inspection upon request of the Department of Public Health. The provisions of this section shall not apply to any such office or facility operated by a practitioner holding a permit issued under section 20-123b. (b) Notwithstanding the provisions of subsection (a) of this section, any office or unlicensed facility that is accredited as provided in subsection (a) of this section shall continue to be subject to the obligations and requirements applicable to such office or facility, including, but not limited to, any applicable certificate of need requirements as provided in chapter 368z¹ and any applicable licensure requirements as provided in chapter 368v².

Delaware

None

District of Columbia

None

Florida – Medical

Chapter 64B8–9. Standards of Practice for Medical Doctors

Standard of Care for Office Surgery.

NOTHING IN THIS RULE RELIEVES THE SURGEON OF THE RESPONSIBILITY FOR MAKING THE MEDICAL DETERMINATION THAT THE OFFICE IS AN APPROPRIATE FORUM FOR THE PARTICULAR PROCEDURE(S) TO BE PERFORMED ON THE PARTICULAR PATIENT.

(1) Definitions.

(a) Surgery. For the purpose of this rule, surgery is defined as any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(b) Surgeon. For the purpose of this rule, surgeon is defined as a licensed physician performing any procedure included within the definition of surgery.

(c) Equipment. For the purpose of this rule, implicit within the use of the term of equipment is the requirement that the specific item named must meet current performance standards.

(d) Office surgery. For the purpose of this rule office surgery is defined as surgery which is performed outside of any facility licensed under Chapter 390 or 395, F.S. Office surgical procedures shall not be of a type that generally result in blood loss of more than ten percent of estimated blood volume in a patient with

a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; directly involve major blood vessels; or are generally emergent or life threatening in nature.

(e) Pediatric patients are defined as those patients who are 13 years of age or under.

(2) General Requirements for Office Surgery.

(a) The surgeon must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. The surgeon must maintain complete records of each surgical procedure, as set forth in Rule 64B8-9.003, F.A.C., including anesthesia records, when applicable and the records shall contain written informed consent from the patient reflecting the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists, i.e., anesthesiologist, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C.

(b) The requirement set forth in paragraph (2)(a) above for written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.

(c) The surgeon must maintain a log of all Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, the name of the physician who provided medical clearances, the surgeon's name, diagnosis, CPT Codes, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, the type of post-operative care, duration of recovery, disposition of the patient upon discharge, list of medications used during surgery and recovery, and any adverse incidents, as identified in Section 458.351, F.S. The log and all surgical records shall be provided to investigators of the Department of Health upon request and must be maintained for six (6) years from the last patient contact.

(d) In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.

(e) Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operation, only in the following circumstances:

1. When combined with abdominoplasty, liposuction may not exceed 1000cc of supernatant fat;
2. When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000 cc of supernatant fat;
3. Major liposuction in excess of 1000cc supernatant fat may not be performed in a remote location from any other procedure.

(f) For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined must not exceed 8 hours. Except for elective cosmetic and plastic surgery, the surgeon shall not keep patients past midnight in a physician's office. For elective cosmetic and plastic surgical procedures, the patient must be discharged within 24 hours of presenting to the office for surgery; an overnight stay is permitted in the office provided the total time the patient is at the office does not exceed 23 hours and 59 minutes including the surgery time. An overnight stay in a physician's office for elective cosmetic and plastic surgery shall be strictly limited to the physician's office. If the patient has not recovered sufficiently to be safely discharged within the timeframes set forth, the patient must be transferred to a hospital for continued post-operative care.

(g) The Board of Medicine adopts the "Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring," approved by House Delegates on October 21, 1986, and last amended on October 21, 1998, as the standards for anesthetic monitoring by any qualified anesthesia provider.

1. These standards apply to general anesthetics, regional anesthetics, and monitored anesthesia care (Level II and III as defined by this rule) although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible supervising physician or anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as

warranted by the evolution of technology and practice. This set of standards address only the issue of basic anesthesia monitoring, which is one component of anesthesia care.

2. In certain rare or unusual circumstances some of these methods of monitoring may be clinically impractical, and appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. For purpose of this rule, “continual” is defined as “repeated regularly and frequently in steady rapid succession” whereas “continuous” means “prolonged without any interruption at any time.”

3. Under extenuating circumstances, the responsible supervising physician or anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record. These standards are not intended for the application to the care of the obstetrical patient in labor or in the conduct of pain management.

a. Standard I.

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

II. OBJECTIVE. Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the supervising physician or anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

b. Standard II.

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

II. OXYGENATION.

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

(B) METHODS.

(I) Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*

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

III. VENTILATION.

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

(B) METHODS.

(I) Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*

(II) When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/ removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.*

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

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

IV. CIRCULATION.

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

(B) METHODS.

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

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

(III) Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

V. BODY TEMPERATURE.

(A) OBJECTIVE. To aid in the maintenance of appropriate body temperature during all anesthetics.

(B) METHODS. Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

(h) The surgeon must assure that the post-operative care arrangements made for the patient are adequate to the procedure being performed as set forth in Rule 64B8-9.007, F.A.C. Management of post surgical care is the responsibility of the operating surgeon and may be delegated only as set forth in subsection 64B8-9.007(3), F.A.C. If there is an overnight stay at the office in relation to any surgical procedure:

1. The office must provide at least two (2) monitors, one of these monitors must be certified in Advanced Cardiac Life Support (ACLS), and maintain a monitor to patient ratio of at least 1 monitor to 2 patients. Once the surgeon has signed a timed and dated discharge order, the office may provide only one monitor to monitor the patient. The monitor must be qualified by licensure and training to administer all of the medications required on the crash cart and must be certified in Advanced Cardiac Life Support. The full and current crash cart required below must be present in the office and immediately accessible for the monitors.

2. The surgeon must be reachable by telephone and readily available to return to the office if needed. For purposes of this subsection, "readily available" means capable of returning to the office within 15 minutes of receiving a call.

(i) A policy and procedure manual must be maintained in the office, updated annually, and implemented. The policy and procedure manual must contain the following: duties and responsibilities of all personnel, quality assessment and improvement systems comparable to those required by Rule 59A-5.019, F.A.C.; cleaning, sterilization and infection control, and emergency procedures. This applies only to physician offices at which Level II and Level III procedures are performed.

(j) The surgeon shall establish a risk management program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,

2. The identification of trends or patterns of incidents,

3. The development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients, and

4. The documentation of these functions and periodic review no less than quarterly of such information by the surgeon.

(k) The surgeon shall report to the Department of Health any adverse incidents that occur within the office surgical setting. This report shall be made within 15 days after the occurrence of an incident as required by Section 197, Chapter 99-397, Laws of Florida.

(l) A sign must be prominently posted in the office which states that the office is a doctor's office regulated pursuant to the rules of the Board of Medicine as set forth in Rule Chapter 64B8, F.A.C. This notice must also appear prominently within the required patient informed consent.

(m) All physicians performing office surgery must be qualified by education, training, and experience to perform any procedure the physician performs in the office surgery setting.

(3) Level I Office Surgery.

(a) Scope. Level I office surgery includes the following:

1. Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient.
2. Liposuction involving the removal of less than 4000cc supernatant fat is permitted.
3. Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).
4. Pre-operative medications not required or used other than minimal pre-operative tranquilization of the patient; anesthesia is local, topical, or none. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted in level I Office Surgery.
5. Chances of complication requiring hospitalization are remote.

(b) Standards for Level I Office Surgery.

1. Training Required. Surgeon's continuing medical education should include: proper dosages; management of toxicity or hypersensitivity to regional anesthetic drugs. Basic Life Support Certification is recommended but not required.
2. Equipment and Supplies Required. Oxygen, positive pressure ventilation device, Epinephrine (or other vasopressor), Corticoids, Antihistamine and Atropine if any anesthesia is used.
3. Assistance of Other Personnel Required. No other assistance is required, unless the specific surgical procedure being performed requires an assistant.

(4) Level II Office Surgery.

(a) Scope.

1. Level II Office Surgery is that in which peri-operative medication and sedation are used by any means altering the level of consciousness, thus making intra and post-operative monitoring necessary. Such procedures shall include, but not be limited to: hemorrhoidectomy, hernia repair, reduction of simple fractures, large joint dislocations, breast biopsies, colonoscopy, and liposuction involving the removal of up to 4000cc supernatant fat.
2. Level II Office surgery includes any surgery in which the patient is placed in a state which allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by this definition.

(b) Standards for Level II Office Surgery.

1. Transfer Agreement Required. The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity. "Reasonable proximity" is defined as not to exceed thirty (30) minutes transport time to the hospital.
2. Training Required.
 - a. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board eligibility by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to establish comparable background, training, and experience. Such Board certification or comparable background, training and experience must also be directly related to and include the procedure(s) being performed by the physician in the office surgery facility.
 - b. One (1) assistant must be currently certified in Basic Life Support and the surgeon must be currently certified in Advanced Cardiac Life Support.
3. Equipment and Supplies Required.
 - a. Full and current crash cart at the location the anesthetizing is being carried out. The crash cart must include, at a minimum, the following resuscitative medications:
 - I. Adenosine 6 mg/2 ml x 3

- II. Albuterol Inhaler
- III. Amiodarone 150 mg x 2
- IV. Atropine 0.4 mg/ml; 3 ml
- V. Calcium chloride 10%; 10 ml
- VI. Dextrose 50%; 50 ml
- VII. Diphenhydramine 50 mg
- VIII. Dopamine 200 mg minimum
- IX. Epinephrine 1:10,000 dilution; 10 ml
- X. Epinephrine 1:1000 dilution; 1 ml x 3
- XI. Flumazenil 0.1 mg/ml; 5 ml x 2
- XII. Furosemide 40 mg
- XIII. Hydrocortisone or Methylprednisolone or Dexamethasone
- XIV. Lidocaine 100 mg
- XV. Magnesium sulfate 1 gm x 2
- XVI. Naloxone 0.4 mg/ml; 3 ml
- XVII. Propranolol 1 mg x 1
- XVIII. Sodium bicarbonate 50 mEq/50 ml
- XIX. Succinylcholine 1 vial
- XX. Vasopressin 20 units x 2
- XXI. Verapamil 5 mg x 2

b. A Benzodiazepine must be stocked, but not on the crash cart.

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

d. Positive pressure ventilation device (e.g. Ambu) plus oxygen supply.

e. Double tourniquet for the Bier block procedure.

f. Monitors for blood pressure/EKG/Oxygen saturation.

g. Emergency intubation equipment.

h. Defibrillator or an Automated External Defibrillator unit (AED).

i. Adequate operating room lighting.

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

k. Appropriate sterilization equipment.

l. IV solution and IV equipment.

4. Assistance of Other Personnel Required. The surgeon must be assisted by a qualified anesthesia provider as follows: An Anesthesiologist, Certified Registered Nurse Anesthetist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C., or a registered nurse may be utilized to assist with the anesthesia, if the surgeon is ACLS certified. An assisting anesthesia provider cannot function in any other capacity during the procedure. If additional assistance is required by the specific procedure or patient circumstances, such assistance must be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, a licensed registered nurse with post-anesthesia care unit experience or the equivalent, credentialed in Advanced Cardiac Life Support or, in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.

(5) Level IIA Office Surgery.

(a) Scope. Level IIA office surgeries are those Level II office surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote.

(b) Standards for Level IIA Office Surgery.

1. The standards set forth in subsection 64B8-9.009(4), F.A.C., must be met except for the requirements set forth in subparagraph 64B8-9.009(4)(b)4., F.A.C., regarding assistance of other personnel.

2. Assistance of Other Personnel Required. During the procedure, the surgeon must be assisted by a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or by a licensed

registered nurse or a licensed practical nurse. Additional assistance may be required by specific procedure or patient circumstances. Following the procedure, a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or a licensed registered nurse must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitor must be certified in Advanced Cardiac Life Support, or, in the case of pediatric patients, Pediatric Advanced Life Support.

(6) Level III Office Surgery.

(a) Scope.

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

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

2. Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery.

a. All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center.

b. For all ASA II patients above the age of 40, the surgeon must obtain, at a minimum, an EKG and a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient is deemed to be a complicated medical patient, the patient must be referred to an appropriate consultant for an independent medical clearance. This requirement may be waived after evaluation by the patient's anesthesiologist.

(b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:

1. Training Required.

a. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. Such Board certification or comparable background, training and experience must also be directly related to and include the procedure(s) being performed by the physician in the office surgery facility. In addition, the surgeon must have knowledge of the principles of general anesthesia.

b. One assistant must be currently certified in Basic Life Support and the surgeon must be currently certified in Advanced Cardiac Life Support.

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

3. Equipment and Supplies Required.

a. Equipment, medication, including at least 36 ampules of dantrolene on site, and monitored post-anesthesia recovery must be available in the office.

b. The office, in terms of general preparation, equipment, and supplies, must be comparable to a free standing ambulatory surgical center, including, but not limited to, recovery capability, and must have provisions for proper recordkeeping.

c. Blood pressure monitoring equipment; EKG; end tidal CO₂ monitor; pulse oximeter, precordial or esophageal stethoscope, emergency intubation equipment and a temperature monitoring device.

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

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

f. IV solutions and IV equipment.

4. Assistance of Other Personnel Required. An Anesthesiologist, Certified Registered Nurse Anesthetist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(c)6., F.A.C., must administer the general or regional anesthesia and an M.D., D.O., Registered Nurse, Licensed Practical Nurse, Physician

Assistant, or Operating Room Technician must assist with the surgery. The anesthesia provider cannot function in any other capacity during the procedure. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, or a licensed registered nurse with post-anesthesia care unit experience or the equivalent, and credentialed in Advanced Cardiac Life Support, or in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient has recovered from anesthesia.

64B8-9.0091. Requirement for Physician Office Registration; Inspection or Accreditation.

Currentness

(1) Registration.

(a) Every licensed physician who holds an active Florida license and performs Level II surgical procedures in Florida with a maximum planned duration of more than five minutes or any Level III office surgery, as fully defined in Rule 64B8-9.009, F.A.C., shall register the office with the Department of Health. It is the physician's responsibility to ensure that every office in which he or she performs Levels II or III surgical procedures as described above is registered, regardless of whether other physicians are practicing in the same office or whether the office is non-physician owned. Physicians participating in post-graduate training programs, and registered pursuant to Section 458.345, F.S., may provide services under the direct supervision of a Florida physician, licensed pursuant to Section 458.311 or 458.313, F.S., in an office surgery facility and under the auspices of their training program for a period of time not to exceed three months without registering pursuant to this rule.

(b) In order to register an office for surgical procedures, the physician must comply with the Department's Rule 64B-4.003, F.A.C., and provide documentation to support compliance with Rule 64B8-9.009, F.A.C.

(c) The physician must immediately notify the Department, in writing, of any changes to the registration information.

(d) The registration shall be posted in the office.

(2) Inspection.

(a) Unless the physician has previously provided written notification of current accreditation by a nationally recognized accrediting agency or an accrediting organization approved by the Board the physician shall submit to an annual inspection by the Department. Nationally recognized accrediting agencies are the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). All nationally recognized and Board-approved accrediting organizations shall be held to the same Board-determined surgery and anesthesia standards for accrediting Florida office surgery sites.

(b) The office surgery inspection fee set forth in the Department's Rule 64B-4.002, F.A.C., shall be remitted for each practice location.

(c) The inspection conducted pursuant to this rule shall be announced at least one week in advance of the arrival of the inspector(s).

(d) The Department shall determine compliance with the requirements of Rule 64B8-9.009, F.A.C.

(e) If the office is determined to be in noncompliance, the physician shall be notified and shall be given a written statement at the time of inspection. Such written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and imminent danger to the public, the physician shall be given 30 days from the date of inspection to correct any documented deficiencies and notify the Department of corrective action. Upon written notification from the physician that all deficiencies have been corrected, the Department is authorized to re-inspect for compliance. If the physician fails to submit a corrective action plan within 30 days of the inspection, the Department is authorized to re-inspect the office to ensure that the deficiencies have been corrected.

(f) The deficiency notice and any subsequent documentation shall be reviewed for consideration of disciplinary action under any of the following circumstances:

1. When the initial notice of deficiencies contain deficiencies that constitute immediate and imminent danger to the public;
2. The physician fails to provide the Department with documentation of correction of all deficiencies within 30 days from the date of inspection;
3. Upon a finding of noncompliance after a reinspection has been conducted pursuant to paragraph (2)(e) of this rule.

(g) Documentation of corrective action shall be considered in mitigation of any offense.

(h) Nothing herein shall limit the authority of the Department to investigate a complaint without prior notice.

(3) Accreditation.

(a) The physician shall submit written notification of the current accreditation survey of his or her office(s) from a nationally recognized accrediting agency or an accrediting organization approved by the Board in lieu of undergoing an inspection by the Department.

(b) A physician shall submit, within 30 days of accreditation, a copy of the current accreditation survey of his or her office(s) and shall immediately notify the Board of Medicine of any accreditation changes that occur. For purposes of initial registration, a physician shall submit a copy of the most recent accreditation survey of his or her office(s) in lieu of undergoing an inspection by the Department.

(c) If a provisional or conditional accreditation is received, the physician shall notify the Board of Medicine in writing and shall include a plan of correction.

64B8-9.0092. Approval of Physician Office Accrediting Organizations.

Currentness

(1) Definitions.

(a) "Accredited" means full accreditation granted by a Board approved accrediting agency or organization. "Accredited" shall also mean provisional accreditation provided that the office is in substantial compliance with the accrediting agency or organization's standards; any deficiencies cited by the accrediting agency or organization do not affect the quality of patient care, and the deficiencies will be corrected within thirty days of the date on which the office was granted provisional accreditation.

(b) "Approved accrediting agency or organization" means nationally recognized accrediting agencies: American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Approved organizations also include those approved by the Board after submission of an application for approval pursuant to this rule.

(c) "Department" means the Department of Health.

(2) Application. An application for approval as an accrediting organization shall be filed with the Board office at 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399-3253, and shall include the following information and documents:

(a) Name and address of applicant;

(b) Date applicant began to operate as an accrediting organization;

(c) Copy of applicant's current accreditation standards;

(d) Description of accreditation process, including composition and qualifications of accreditation surveyors; accreditation activities; criteria for determination of compliance; and deficiency follow-up activities.

Accreditation surveyors shall meet the following qualifications:

1. The surveyor must be an ABMS board certified physician with two (2) years experience performing office surgery; or

2. A Florida Health Care Risk Manager licensed through AHCA with two (2) years experience serving as a risk manager in a surgical facility; or

3. An ABMS board certified anesthesiologist with two (2) years experience administering anesthesia in a surgical facility.

4. In addition to the above-outlined qualification, accreditation surveyors may not have any discipline imposed on his or her license within the preceding seven (7) years, may not be in direct competition with the

subject of the review or have any direct or indirect contractual relationship with the inspected facility or any of its physicians.

(e) A list of all physician offices located in Florida that are accredited by the applicant, if any. If there are no accredited Florida physician offices, but there are accredited offices outside Florida, a list of the accredited offices outside of Florida is required.

(f) Copies of all adverse incident reports filed with the state by any of the applicants accredited offices pursuant to Section 458.331, F.S.

(g) Statement of compliance with all requirements as specified in this rule.

(3) Standards. The standards adopted by an accrediting organization for surgical and anesthetic procedures performed in a physician office shall meet or exceed provisions of Chapters 456 and 458, F.S., and rules promulgated thereunder. Standards shall require that all health care practitioners be licensed or certified to the extent required by law.

(4) Requirements. In order to be approved by the Board, an accrediting organization must demonstrate compliance with the following requirements:

(a) The accrediting agency must implement, administer and monitor a mandatory quality assurance program approved by the Board of Medicine that meets the following minimum standards:

1. General Provisions. Each office surgery facility surgical center shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the Medical Director to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public.

a. Such a system shall be based on the mission and plans of the organization, the needs and expectations of the patients and staff, up-to-date sources of information, and the performance of the processes and their outcomes.

b. Each system for quality assurance, which shall include utilization review, must be defined in writing, approved by the accrediting agencies governing body, enforced, and shall include:

I. A written delineation of responsibilities for key staff;

II. A policy for all members of the organized medical staff, whereby staff members do not initially review their own cases for quality assessment and improvement program purposes;

III. A confidentiality policy that complies with all applicable federal and state confidentiality laws;

IV. Written, measurable criteria and norms;

V. A description of the methods used for identifying problems;

VI. A description of the methods used for assessing problems, determining priorities for investigation, and resolving problems;

VII. A description of the methods for monitoring activities to assure that the desired results are achieved and sustained; and

VIII. Documentation of the activities and results of the program.

c. Each quality assurance program shall include a peer review system that entails the following:

I. Peer review is performed at least every six months and includes reviews of both random cases and unanticipated adverse office incidents as defined in Section 458.351, F.S., and as set forth in sub-subparagraph (4)(a)1.d. of this rule;

II. If the peer review sources external to the facility are employed to evaluate delivery of medical care, the patient consent form is so written as to waive confidentiality of the medical records or in the alternative medical records reviewed by such external peer review sources must use confidential patient identifiers rather than patient names; and

III. Peer review must be conducted by a recognized peer review organization or a licensed medical doctor or osteopathic physician other than the operating surgeon.

d. Each quality assurance program shall include a system where all adverse incidents as defined in Section 458.351, F.S., are reviewed. In addition to those incidents set forth in Section 458.351, F.S., the following incidents shall also be reviewed:

- I. Unplanned hospital admissions that occurred within seven (7) days from the date the patient left the facility;
 - II. Unscheduled return to the operating room for complication of a previous procedure;
 - III. Untoward result of procedure such as infection, bleeding, wound dehiscence or inadvertent injury to other body structure;
 - IV. Cardiac or respiratory problems during stay at facility or within 48 hours of discharge;
 - V. Allergic reaction of medication;
 - VI. Incorrect needle or sponge count;
 - VII. Patient or family complaint;
 - VIII. Equipment malfunction leading to injury or potential injury to patient.
- e. Each quality assurance program shall include an adverse incident chart review program which shall include the following information, in addition to the operative procedure performed:
- I. Identification of the problem;
 - II. Immediate treatment or disposition of the case;
 - III. Outcome;
 - IV. Analysis of reason for problem; and
 - V. Assessment of efficacy of treatment.
2. Each office surgery facility shall have in place a systematic process to collect data on process outcomes, priority issues chosen for improvement, and the satisfaction of the patient. Processes measured shall include:
- a. Appropriate surgical procedures;
 - b. Preparation of patient for the procedure;
 - c. Performance of the procedure and monitoring of the patient;
 - d. Provision of post-operative care;
 - e. Use of medications including administration and monitoring of effects;
 - f. Risk management activities;
 - g. Quality assurance activities including at least clinical laboratory services and radiology services;
 - h. Results of autopsies if needed.
3. Each center shall have a process to assess data collected to determine:
- a. The level and performance of existing activities and procedures;
 - b. Priorities for improvement, and
 - c. Actions to improve performance.
4. Each center shall have a process to incorporate quality assurance and improvement activities in existing office surgery facility processes and procedures.
- (b) The accrediting agency must implement, administer and monitor anesthesia-related accreditation standards and quality assurance processes that meet the following minimum standards and are reviewed and approved by the Board of Medicine:
1. Each accredited facility must have an anesthesia provider who participates in an ongoing continuous quality improvement and risk management activities related to the administration of anesthesia in that facility.
 2. Each facility must have a written quality improvement plan that specifies the individuals who are responsible for performing each element of the plan.
 3. The written plan should be in place to continually assess, document and improve the outcome of the anesthesia care provided.
 4. The plan must include a review of quality indicators, to include measures of patient satisfaction.
 5. The plan must include an annual review and check of anesthesia equipment to ensure compliance with current safety standards and the standards for the release of waste anesthetic gases.
 6. The quality assurance plan should include routine review of anesthesia and surgical morbidity and adverse, sentinel or outcome events which include but are not limited to the following:
 - a. Follow-up on post-op day 1 and day 14;
 - b. Cancellation rates and reasons;
 - c. Central nervous system or peripheral nervous system new deficit;
 - d. Need for reversal agents: narcotic, benzodiazepine;

- e. Reintubation;
- f. Unplanned transfusion;
- g. Aspiration pneumonitis;
- h. Pulmonary embolus;
- i. Local anesthetic toxicity;
- j. Anaphylaxis;
- k. Possible Malignant Hyperthermia;
- l. Infection;
- m. Return to operating room;
- n. Unplanned Post-procedural Treatment in physician's office or emergency department within 30 days after discharge;
- o. Unplanned Admission to hospital or acute care facility within 30 days;
- p. Cardiopulmonary Arrest or Death within 30 days;
- q. Continuous Quality Indicators;
- r. Cardiovascular complications in recovery requiring treatment (including: arrhythmias; hypotension, hypertension);
- s. Respiratory complications in recovery requiring treatment (including asthma);
- t. Nausea not controlled within 2 hrs. in recovery;
- u. Pain not controlled within 2 hrs. in recovery;
- v. Postoperative vomiting rate;
- w. Prolonged PACU stay in excess of 2 hrs.;
- x. Medication error;
- y. Injuries, e.g. eye, teeth;
- z. Time to return to light activities of daily living (ADL);
- aa. Common postoperative sequelae, eg sore throat, muscle pain, headache;
- bb. Post-dural puncture headache or transient radicular irritation;
- cc. Discharge without escort or against medical advice (AMA);
- dd. Patient satisfaction;
- ee. Equipment maintenance.

7. Each facility quality improvement plan must require annual reviews conducted by, at a minimum, the medical director, a representative of the anesthesia provider currently providing patient care and a representative of the operating room or recovery nursing staff.

8. The accrediting organization must have at least one anesthesiologist in that organization that implements, administers, and monitors the quality assurance processes set forth above.

(c) Accreditation periods shall not exceed three years.

(d) The accrediting organization shall obtain authorization from the accredited entity to release accreditation reports and corrective action plans to the Board. The accrediting organization shall provide a copy of any accreditation report to the Board office within 30 days of completion of accrediting activities. The accrediting organization shall provide a copy of any corrective action plans to the Board office within 30 days of receipt from the physician office.

(e) If the accrediting agency or organization finds indications at any time during accreditation activities that conditions in the physician office pose a potential threat to patients, the accrediting agency or organization will immediately report the situation to the Department.

(f) An accrediting agency or organization shall send to the Board any change in its accreditation standards within 30 calendar days after making the change.

(g) An accrediting agency or organization shall comply with confidentiality requirements regarding protection of patient records.

(5) Accrediting Organizations shall be approved for a period of time not to exceed three (3) years.

(6) If the Board discovers that an approved accrediting agency has violated or failed to comply with any provision of this rule, the Board shall issue an order to show cause outlining the alleged violation and requiring a representative from the accrediting agency to appear before the Board at its next regularly

scheduled meeting to address the Board's concerns. After such an appearance, if the Board determines that a violation occurred, the accrediting agency's status as an office surgery accrediting agency shall be revoked. Failure to appear before the Board upon receipt of an order to show cause shall not preclude the Board from taking action against an accrediting agency.

(7) **Renewal of Approval of Accrediting Organizations.** Every accrediting organization approved by the Board pursuant to this rule is required to submit to the Board a new complete written application at least three months prior to the end of its term of approval. Upon review of the submission by the Board, written notice shall be provided to the accrediting organization indicating the Board's acceptance of the certification and the next date by which a renewal submission must be filed or of the Board's decision that any identified changes are not acceptable and on that basis denial of renewal of approval as an accrediting organization.

(8) Upon denial of its application, the accrediting organization must wait a minimum of six (6) months prior to reapplying.

(9) Any person interested in obtaining a complete list of approved accrediting organizations may contact the Board of Medicine or Department of Health.

Florida – Osteopathic

64B15-14.007. Standard of Care for Office Surgery.

NOTHING IN THIS RULE RELIEVES THE SURGEON OF THE RESPONSIBILITY FOR MAKING THE MEDICAL DETERMINATION THAT THE OFFICE IS AN APPROPRIATE FORUM FOR THE PARTICULAR PROCEDURE(S) TO BE PERFORMED ON THE PARTICULAR PATIENT.

(1) **Definitions.**

(a) **Surgery.** For the purpose of this rule, surgery is defined as any operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.

(b) **Surgeon.** For the purpose of this rule, surgeon is defined as a licensed osteopathic physician performing any procedure included within the definition of surgery.

(c) **Equipment.** For the purpose of this rule, implicit within the use of the term of equipment is the requirement that the specific item named must meet current performance standards.

(d) **Office surgery.** For the purpose of this rule office surgery is defined as surgery which is performed outside a hospital, an ambulatory surgical center, abortion clinic, or other medical facility licensed by the Department of Health, the Agency for Health Care Administration, or a successor agency. Office surgical procedures shall not be of a type that generally result in blood loss of more than ten percent of estimated blood volume in a patient with a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; directly involve major blood vessels; or are generally emergent or life threatening in nature.

(2) **General Requirements for Office Surgery.**

(a) The surgeon must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. The surgeon must maintain complete records of each surgical procedure, as set forth in Rule 64B15-15.004, F.A.C., including anesthesia records, when applicable and the records shall contain written informed consent from the patient reflecting the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists, i.e., anesthesiologist, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant qualified as set forth in subparagraph 64B15-6.010(2)(b)6., F.A.C.

(b) The requirement set forth in paragraph (2)(a) above for written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.

(c) The surgeon must maintain a log of all Level II and Level III surgical procedures performed, which must include a confidential patient identifier, time of arrival in the operating suite, the surgeon's name, diagnosis, patient ASA classification, the type of procedure, the level of surgery, the anesthesia provider, the type of anesthesia used, the duration of the procedure, the type of post-operative care, duration of recovery, disposition of the patient upon discharge, during surgery, and recovery. The log and all surgical records shall be provided to investigators of the Department of Health upon request.

(d) In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000 cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting.

(e) Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operation, only in the following circumstances:

1. When combined with abdominoplasty, liposuction may not exceed 1000 cc of supernatant fat;
2. When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000cc of supernatant fat;
3. Major liposuction in excess of 1000 cc supernatant fat may not be performed in a remote location from any other procedure.

(f) For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined must not exceed 8 hours. Except for elective cosmetic and plastic surgery, the surgeon shall not keep patients past midnight in a physician's office. For elective cosmetic and plastic surgical procedures, the patient must be discharged within 24 hours of presenting to the office for surgery; an overnight stay is permitted in the office provided the total time the patient is at the office does not exceed 23 hours and 59 minutes including the surgery time. An overnight stay in a physician's office for elective cosmetic and plastic surgery shall be strictly limited to the physician's office. If the patient has not recovered sufficiently to be safely discharged within the timeframes set forth, the patient must be transferred to a hospital for continued post-operative care.

(g) The Board of Osteopathic Medicine adopts the "Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring," approved by House Delegates on October 21, 1986, and last amended on October 21, 1998, as the standards for anesthetic monitoring by any qualified anesthesia provider.

1. These standards apply to general anesthetics, regional anesthetics, and monitored anesthesia care (Level II and III as defined by this rule) although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible supervising physician or anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. This set of standards addresses only the issue of basic anesthesia monitoring, which is one component of anesthesia care.

2. In certain rare or unusual circumstances some of these methods of monitoring may be clinically impractical, and appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. For purpose of this rule, "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time."

3. Under extenuating circumstances, the responsible supervising osteopathic physician or anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record. These standards are not intended for the application to the care of the obstetrical patient in labor or in the conduct of pain management.

a. Standard I.

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

II. OBJECTIVE. Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the supervising physician or anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

b. Standard II.

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

II. OXYGENATION.

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

(B) METHODS:

(I) Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*

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

III. VENTILATION.

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

(B) METHODS:

(I) Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*

(II) When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/ removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.*

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

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

IV. CIRCULATION.

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

(B) METHODS:

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

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

(III) Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

V. BODY TEMPERATURE.

(A) OBJECTIVE - To aid in the maintenance of appropriate body temperature during all anesthetics.

(B) METHODS: Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

(h) The surgeon must assure that the post-operative care arrangements made for the patient are adequate to the procedure being performed as set forth in Rule 64B15-14.006, F.A.C. Management of post-surgical care is the responsibility of the operating surgeon and may be delegated only as set forth in subsection 64B15-14.006(3), F.A.C. If there is an overnight stay at the office in relation to any surgical procedure:

1. The office must provide at least two (2) monitors, one of these monitors must be certified in Advanced Cardiac Life Support (ACLS), and maintain a monitor to patient ratio of at least 1 monitor to 2 patients.

Once the surgeon has signed a timed and dated discharge order, the office may provide only one monitor to monitor the patient. The monitor must be qualified by licensure to administer all of the medications required on the crash cart and must be certified in Advanced Cardiac Life Support¹. The full and current crash cart required below must be present in the office and immediately accessible for the monitors.

2. The surgeon must be reachable by telephone and readily available to return to the office if needed. For purposes of this subsection, "readily available" means capable of returning to the office within 15 minutes of receiving a call.

(i) A policy and procedure manual must be maintained in the office, updated annually, and implemented. The policy and procedure manual must contain the following: duties and responsibilities of all personnel, quality assessment and improvement systems comparable to those required by Rule 59A-5.019, F.A.C.; cleaning, sterilization, and infection control, and emergency procedures. This applies only to physician offices at which Level II and Level III procedures are performed.

(j) The surgeon shall establish a risk management program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,

2. The identification of trends or patterns of incidents,

3. The development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients, and

4. The documentation of these functions and periodic review no less than quarterly of such information by the surgeon.

(k) The surgeon shall report to the Department of Health any adverse incidents that occur within the office surgical setting. This report shall be made within 15 days after the occurrence of an incident as required by Section 497.026, F.S.

(l) A sign must be prominently posted in the office which states that the office is a doctor's office regulated pursuant to the rules of the Board of Osteopathic Medicine as set forth in Rule Chapter 64B15, F.A.C. This notice must also appear prominently within the required patient informed consent.

(m) All physicians performing office surgery must be qualified by education, training, and experience to perform any procedure the physicians perform in the office surgery setting.

(3) Level I Office Surgery.

(a) Scope. Level I office surgery includes the following:

1. Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient.

2. Liposuction involving the removal of less than 4000cc supernatant fat is permitted.

3. Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).

4. Pre-operative medications not required or used other than minimal preoperative tranquilization of the patient; anesthesia is local, topical, or none. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted in Level I Office Surgery.

5. Chances of complication requiring hospitalization are remote.

(b) Standards for Level I Office Surgery.

1. Training Required. Surgeon's continuing medical education should include: proper dosages; management of toxicity or hypersensitivity to regional anesthetic drugs. Basic Life Support Certification is recommended but not required.

2. Equipment and Supplies Required. Oxygen, positive pressure ventilation device, Epinephrine (or other vasopressor), Corticoids, Antihistamine and Atropine if any anesthesia is used.

3. Assistance of Other Personnel Required. No other assistance is required, unless the specific surgical procedure being performed requires an assistant.

(4) Level II Office Surgery.

(a) Scope.

1. Level II Office Surgery is that in which peri-operative medication and sedation are used intravenously, intramuscularly, or rectally, thus making intra and post-operative monitoring necessary. Such procedures shall include, but not be limited to: hemorrhoidectomy, hernia repair, reduction of simple fractures, large joint dislocations, breast biopsies, colonoscopy, and liposuction involving the removal of up to 4000cc supernatant fat.

2. Level II Office Surgery includes any surgery in which the patient is placed in a state which allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by this definition.

(b) Standards for Level II Office Surgery.

1. Transfer Agreement Required. The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity.

“Reasonable proximity” is defined as not to exceed thirty (30) minutes transport time to the hospital.

2. Training Required. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board eligibility by a Board approved by the American Osteopathic Association, the American Board of Medical Specialties, the Accreditation Council on Graduate Medical Education or any other board approved by the Board of Osteopathic Medicine or must be able to establish comparable background, training, and experience. The surgeon and one assistant must be currently certified in Basic Life Support and the surgeon or at least one assistant must be currently certified in Advanced Cardiac Life Support or have a qualified anesthesia provider practicing within the scope of the provider's license manage the anesthesia.

3. Equipment and Supplies Required.

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

I. Adenosine 6 mg/2 ml x 3

II. Albuterol Inhaler

III. Amiodarone 150 mg x 2

IV. Atropine 0.4 mg/ml; 3 ml

V. Calcium chloride 10%; 10 ml

VI. Dextrose 50%; 50 ml

VII. Diphenhydramine 50 mg

VIII. Dopamine 200 mg minimum

IX. Epinephrine 1:10,000 dilution; 10 ml

X. Epinephrine 1:1000 dilution; 1 ml x 3

XI. Flumazenil 0.1 mg/ml; 5 ml x 2

XII. Furosemide 40 mg

XIII. Hydrocortisone or Methylprednisolone or Dexamethasone

XIV. Lidocaine 100 mg

XV. Magnesium sulfate 1 gm x 2

- XVI. Narcan (naloxone) 0.4 mg/ml; 3 ml
- XVII. Propranolol 1 mg x 1
- XVIII. Sodium bicarbonate 50 mEq/50 ml
- XIX. Succinylcholine 1 vial
- XX. Vasopressin 20 units x 2
- XXI. Verapamil 5 mg x 2

- b. A Benzodiazepine must be stocked, but not on the crash cart.
- c. Suction devices, endotracheal tubes, laryngoscopes, etc.
- d. Positive pressure ventilation device (e.g., Ambu) plus oxygen supply.
- e. Double tourniquet for the Bier block procedure.
- f. Monitors for blood pressure/EKG/Oxygen saturation.
- g. Emergency intubation equipment.
- h. Adequate operating room lighting.
- i. Emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours.
- j. Appropriate sterilization equipment.
- k. IV solution and IV equipment.

4. Assistance of Other Personnel Required. The surgeon must be assisted by a qualified anesthesia provider as follows: An Anesthesiologist, Certified Registered Nurse Anesthetist, or Physician Assistant qualified as set forth in subparagraph 64B15-6.010(2)(b)6., F.A.C., or a registered nurse may be utilized to assist with the anesthesia, if the surgeon is ACLS certified. An assisting anesthesia provider cannot function in any other capacity during the procedure. If additional assistance is required by the specific procedure or patient circumstances, such assistance must be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, a licensed registered nurse with post-anesthesia care unit experience or the equivalent, credentialed in Advanced Cardiac Life Support or, in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.

(5) Level IIA Office Surgery.

(a) Scope. Level IIA office surgeries are those Level II office surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote.

(b) Standards for Level IIA Office Surgery.

1. The standards set forth in subsection 64B15-14.006(4), F.A.C., must be met except for the requirements set forth in subparagraph 64B15-14.006(4)(b)4., F.A.C., regarding assistance of other personnel.
2. Assistance of Other Personnel Required. During the procedure, the surgeon must be assisted by a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or by a licensed registered nurse or a licensed practical nurse. Additional assistance may be required by specific procedure or patient circumstances. Following the procedure, a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or a licensed registered nurse must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitor must be certified in Advanced Cardiac Life Support, or, in the case of pediatric patients, Pediatric Advanced Life Support.

(6) Level III Office Surgery.

(a) Scope.

1. Level III Office Surgery is that surgery which involves, or reasonably should require, the use of a general anesthesia or major conduction anesthesia and pre-operative sedation. This includes the use of:
 - a. Intravenous sedation beyond that defined for Level II office surgery;
 - b. General Anesthesia: loss of consciousness and loss of vital reflexes with probable requirement of external support of pulmonary or cardiac functions; or
 - c. Major Conduction anesthesia.
2. Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery.

- a. All Level III surgeries on patient classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center.
 - b. For all ASA II patients above the age of 40, the surgeon must obtain, at a minimum, an EKG and a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient is deemed to be a complicated medical patient, the patient must be referred to an appropriate consultant for an independent medical clearance. This requirement may be waived after evaluation by the patient's anesthesiologist.
- (b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:
1. Training Required.
 - a. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Osteopathic Association, the American Board of Medical Specialties, the Accreditation Council on Graduate Medical Education or any other board approved by the Board of Osteopathic Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. In addition, the surgeon must have knowledge of the principles of general anesthesia.
 - b. The surgeon and one assistant must be currently certified in Basic Life Support and the surgeon or at least one assistant must be currently certified in Advanced Cardiac Life Support.
 2. Emergency procedures related to serious anesthesia complications should be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location.
 3. Equipment and Supplies Required.
 - a. Equipment, medication, including at least 36 ampules of dantrolene on site, and monitored post-anesthesia recovery must be available in the office.
 - b. The office, in terms of general preparation, equipment, and supplies, must be comparable to a free standing ambulatory surgical center, including, but not limited to, recovery capability, and must have provisions for proper recordkeeping.
 - c. Blood pressure monitoring equipment; EKG; end tidal CO₂ monitor; pulse oximeter, precordial or esophageal stethoscope, emergency intubation equipment and a temperature monitoring device.
 - d. Table capable of trendelenburg and other positions necessary to facilitate the surgical procedure.
 - e. IV solutions and IV equipment.
 4. Assistance of Other Personnel Required. An Anesthesiologist, Certified Registered Nurse Anesthetist, or Physician Assistant qualified as set forth in subparagraph 64B15-6.010(2)(c)6., F.A.C., must administer the general or regional anesthesia and an M.D., D.O., Registered Nurse, Licensed Practical Nurse, Physician Assistant, or Operating Room Technician must assist with the surgery. The anesthesia provider cannot function in any other capacity during the procedure. A physician licensed under Chapter 458 or 459 F.S., a licensed physician assistant, or a licensed registered nurse with post-anesthesia care unit experience or the equivalent, and credentialed in Advanced Cardiac Life Support, or in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient has recovered from anesthesia.

Georgia

GEORGIA COMPOSITE MEDICAL BOARD

OFFICE-BASED ANESTHESIA AND SURGERY GUIDELINES

<http://medicalboard.georgia.gov/sites/medicalboard.georgia.gov/files/imported/GCMB/Files/OBS%20Guidelines.pdf>

Purpose

The purpose of these guidelines is to promote and establish consistent standards, continuing competency, and to promote patient safety. The Georgia Composite Medical Board establishes the following guidelines

for physicians who perform surgical procedures and use anesthesia, analgesia or sedation in office-based settings.

Definitions

The following terms used in this subsection apply throughout these guidelines unless the context clearly indicates otherwise:

"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.

"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's protective airway reflexes may be impaired and the patient may be unable to maintain a patent natural airway. Sedation that unintentionally progresses to the point at which the patient's protective airway reflexes are impaired and the patient is unable to maintain a patent natural airway is considered general anesthesia.

"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. 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.

"Tumescent anesthesia" means the technique for delivery of local anesthesia to achieve extensive regional anesthesia of skin and subcutaneous tissue. The subcutaneous infiltration of a large volume of very dilute lidocaine and epinephrine causes the targeted tissue to become swollen and firm, or tumescent, and permits procedures to be performed on patients often without the need for deep sedation or general anesthesia. For the purposes of these guidelines, the maximum safe dose of tumescent lidocaine should not exceed the published standard of 55 mg/kg.

"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.

"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.

"Moderate sedation/ 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.

"Office-based surgery" means any surgery or invasive medical procedure requiring analgesia or sedation, when performed in a location other than a hospital or hospital associated surgical center or an ambulatory surgical facility (licensed as an institution pursuant to *O.C.G.A. T. 31, Ch. 7, Art 1*).

"Physician" means an individual licensed under O.C.G.A. Title 43 Chapter 34.

Exemptions.

These guidelines do not apply to physicians when:

1. Performing surgery and medical procedures that require only infiltration of local anesthetic around peripheral nerves or non-mixed sensory nerves. Infiltration around peripheral nerves or non-mixed sensory nerves does not include infiltration of local anesthetic agents in an amount that exceeds the manufacturer's published recommendations.
2. Performing surgery in a hospital or licensed hospital-associated surgical center or a licensed ambulatory surgical facility.
3. Performing oral and maxillofacial surgery, and the physician:
 - (a) Is licensed both as a physician under chapter Title 43 Chapter-34 and as a dentist under Title 43 Chapter 11; or

(b) Complies with dental quality assurance commission regulations; and

(c) Holds a valid:

(i) Moderate sedation permit; or

(ii) Moderate sedation with parenteral agents permit; or

(iii) General anesthesia and deep sedation permit; and

(iv) Practices within the scope of his or her specialty.

1. Application of guidelines.

These guidelines apply 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; or

(d) Tumescence anesthesia; or

(e) General anesthesia.

2. Accreditation or certification. Physicians who perform any procedures under these guidelines must ensure that the procedure is performed in a facility that is appropriately equipped and maintained to ensure patient safety. Achieving accreditation by an appropriate agency, including any of the following, is one method to demonstrate facility preparedness and staff competency:

(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;

3. Competency. When an anesthesiologist or certified registered nurse anesthetist is not present, the physician performing office-based surgery and using moderate sedation or analgesia must be competent and qualified to oversee the administration of intravenous sedation/ analgesia through one of the following training pathways:

(a) Completion of a continuing medical education course in conscious sedation (moderate sedation/ analgesia);

(b) Relevant training in a residency training program; or

(c) Having privileges for conscious sedation (moderate sedation/ analgesia) granted by a hospital medical staff.

4. 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 (7) of this section.

5. 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.

6. Emergency care and transfer protocols. A physician performing office-based surgery must ensure that in the event of a complication or emergency:

(a) 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.

(b) All office personnel are familiar with a written and documented plan to timely and safely transfer patients to an appropriate hospital.

(c) The plan must include:

(i) a proven accessible route for stretcher transport of the patient out of the office;

(ii) arrangements for emergency medical services and appropriate escort of the patient to the hospital;

(iii) a compliance process to notify the Board of an adverse event as specified in subsection (14) of these guidelines.

(d) Resuscitative equipment should be evaluated for functionality every six months, and records of such evaluations should be maintained by the facility.

7. 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; and

(ii) Drugs (name and dose) and time of administration; and

(iii) The patient's vital signs at regular intervals including, at a minimum, blood pressure, heart rate, respiratory rate, and oxygen saturation; and

(iv) Return to appropriate level of consciousness and readiness for discharge from acute care.

8. Standard of Practice. Any licensed physician engaging in office based surgery must have received appropriate training and education in the safe and effective performance of all surgical procedures performed in the office facility. Such training and education should include:

(a) indications and contraindications for each procedure;

(b) identification of realistic and expected outcomes of each procedure;

(c) selection, maintenance, and utilization of products and equipment;

(d) appropriate technique for each procedure, including infection control and safety precautions;

(e) pharmacological intervention specific to each procedure;

(f) identification of complications and adverse reactions for each procedure;

(g) emergency procedures to be used in the event of:

(i) Complications;

(ii) Adverse reactions;

(iii) Equipment malfunction; or

(iv) Any other interruption of a procedure

9. Adverse events. Any incident within the facility that results in a patient death or transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, shall be reported to the Georgia Composite Medical Board in writing within ten working days of the death or hospitalization, which ever comes first.

10. Truth in advertising. The credentials, education and training received, specialty board certification, and proficiency evaluations of all personnel involved in performing surgical procedures shall be accurately presented in any form of advertising and shall be readily available in writing to all patients.

Guam

None

Hawaii

None

Idaho

None

Illinois

68 Ill. Adm. Code 1285.340 Anesthesia Services in an Office Setting

a) In a physician's office, the operating physician shall have training and experience in the delivery of anesthesia services in order to administer anesthesia or to enter into a practice agreement with a certified registered nurse anesthetist (CRNA) to provide anesthesia services in the office pursuant to Section 54.5 of the Medical Practice Act and Section 15-25 of the Nursing and the Advanced Practice Nursing Act [225 ILCS 65]. When an anesthesiologist is administering anesthesia in a physician's office, the operating physician is not required to have the training and experience set forth in subsection (b). A physician's office is any practice location not regulated by Section 10.7 of the Hospital Licensing Act [210 ILCS 85] or Section 6.5 of the Ambulatory Surgical Treatment Center Act [210 ILCS 5].

b) The training and experience requirements may be met in the manner specified in either subsection (b)(1) or (2):

1) The physician maintains clinical privileges to administer anesthesia services in a hospital licensed in accordance with the Hospital Licensing Act or an ambulatory surgical treatment center licensed in accordance with the Ambulatory Surgical Treatment Center Act; or

2) Completion of continuing medical education:

A) For conscious sedation only, the physician shall complete a minimum of 8 hours of continuing medical education (CME) within each 3 year license renewal period in delivery of anesthesia, including the administration of conscious sedation. The physician will be required to complete 4 of the 8 hours of CME by July 31, 2003. The remaining 4 hours of CME shall be completed by the July 31, 2005 renewal.

B) For deep sedation, regional anesthesia and/or general anesthesia, a physician shall complete a minimum of 34 hours of continuing medical education in the delivery of anesthesia services within each 3 year license renewal period. The physician will be required to complete 16 of the 34 hours of CME by July 31, 2003. The

remaining 18 hours of CME shall be completed by the July 31, 2005 renewal. Fulfillment of this requirement shall satisfy the requirement of subsection (b)(2)(A) for the administration of conscious sedation.

C) A continuing medical education program shall be conducted by a university, professional association, or hospital as a formal CME program under 68 Ill. Adm. Code 1285.110(b)(2).

c) In a physician's office where anesthesia services are being administered, all operating physicians and anesthesiologists shall obtain Advanced Cardiac Life Support (ACLS) certification by December 31, 2002, and shall maintain current ACLS certification. If the physician enters into a practice agreement with the CRNA, the CRNA shall also have a current ACLS certification pursuant to 68 Ill. Adm. Code 1305.45.

d) The ACLS certification and the physician training and experience required by this Section shall be documented in the written practice agreement between the physician and CRNA.

e) The continuing medical education required in subsection (b) and the ACLS training required in subsection (c) may be applied to fulfillment of the 150 hours continuing medical education required for renewal of a license.

f) Definitions of Anesthesia

1) Moderate Sedation Analgesia (Conscious Sedation) is 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 required to maintain a patent airway and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

2) Deep Sedation/Analgesia is 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.

3) Regional Anesthesia is the administration of local anesthetic agents to a patient to interrupt nerve impulses in a major region of the body without loss of consciousness and include epidural, caudal, spinal and brachial plexus anesthesia.

4) General Anesthesia is 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.

g) Physicians who perform procedures in an office setting utilizing anesthesia in the following manner are not required to comply with this Section:

1) The use of local anesthesia in which the total dose of local anesthesia does not exceed 50% of the commonly accepted toxic dose on a weight adjusted basis.

2) The use of topical anesthesia in which the total dose of topical anesthesia does not exceed 50% of the commonly accepted toxic dose on a weight adjusted basis.

3) The use of minimal sedation (anxiolysis). Minimal sedation (anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, respiratory and cardiovascular functions are unaffected.

Indiana

Rule 5. Standards for Procedures Performed in Office-Based Settings that Require Moderate Sedation/Analgesia, Deep Sedation/Analgesia, General Anesthesia, or Regional Anesthesia

Sec. 1. This rule establishes standards for procedures performed in office-based settings that require:

- (1) moderate sedation/analgesia;
- (2) deep sedation/analgesia;
- (3) general anesthesia; or

(4) regional anesthesia.

Sec. 2. Except as provided in section 15 of this rule, this rule does not apply to:

- (1) local anesthesia;
- (2) topical anesthesia;
- (3) superficial nerve blocks; or
- (4) minimal sedation/anxiolysis.

Sec. 3. As used in this rule, “accreditation agency” means a public or private organization that is approved to issue certificates of accreditation to office-based settings by the board under this rule

Sec. 4. As used in this rule, “American Society of Anesthesiologists (ASA) Physical Status Classification System” refers to the following classifications:

- (1) P1 -A normal healthy patient.
- (2) P2 -A patient with mild systemic disease.
- (3) P3 -A patient with severe systemic disease.
- (4) P4 -A patient with severe systemic disease that is a constant threat to life.
- (5) P5 -A moribund patient who is not expected to survive without the operation.
- (6) P6 -A declared brain-dead patient whose organs are being removed for donor purposes.

Sec. 5. As used in this rule, “anesthesia” includes the following:

- (1) Moderate sedation/analgesia.
- (2) Deep sedation/analgesia.
- (3) General anesthesia.
- (4) Regional anesthesia.

Sec. 6. (a) As used in this rule, “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. For purposes of this rule, reflex withdrawal from a painful stimulus is not considered a purposeful response.

(b) The following are conditions that a patient under deep sedation/analgesia may experience:

- (1) The ability to independently maintain ventilatory function may be impaired.
- (2) Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.
- (3) Cardiovascular function is usually maintained.

Sec. 7. (a) As used in this rule, “general anesthesia” means a drug-induced loss of consciousness during which patients are not arousable, even by pain stimulation.

(b) The following are conditions that a patient under general anesthesia may experience:

- (1) The ability to independently maintain ventilatory function is often impaired.
- (2) 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.
- (3) Cardiovascular function may be impaired.

Sec. 8. As used in this rule, “health care provider” means an individual licensed or legally authorized by this state to provide health care services.

Sec. 9. As used in this rule, “immediate presence” means, at a minimum, that the directing practitioner must be:

- (1) physically located within the office-based setting;

- (2) prepared to immediately conduct hands-on intervention if needed; and
- (3) not engaged in activities that could prevent the practitioner from being able to immediately intervene and conduct hands-on interventions if needed.

Sec. 10. As used in this rule, “local anesthesia” means a transient and reversible loss of sensation in a circumscribed portion of the body produced by:

- (1) a local anesthetic agent; or
- (2) cooling a circumscribed area of the skin.

The term includes subcutaneous infiltration of an agent.

Sec. 11. As used in this rule, “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.

Sec. 12. (a) As used in this rule, “moderate sedation/analgesia” (also sometimes called “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.

(b) The following are conditions that a patient under moderate sedation/analgesia may experience:

- (1) No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.
- (2) Cardiovascular function is usually maintained.

Sec. 13. As used in this rule, “office-based setting” means any:

- (1) facility;
- (2) clinic;
- (3) center;
- (4) office; or
- (5) other setting; where procedures are performed that require moderate sedation/analgesia, deep sedation/analgesia, general anesthesia, or regional anesthesia. The term does not include a hospital operated by the federal government or a setting licensed under IC 16-21-2 as a hospital, ambulatory surgical center, abortion clinic, or birthing center.

Sec. 14. As used in this rule, “practitioner” has the meaning set forth in 844 IAC 5-1-1(14).

Sec. 15. (a) As used in this rule, “regional anesthesia” means the administration of anesthetic agents to a patient to interrupt nerve impulses without the loss of consciousness and includes the following:

(1) Major conduction blocks, such as:

- (A) epidural;
- (B) spinal; and
- (C) caudal;

blocks.

(2) Peripheral nerve blocks, such as:

- (A) brachial;
- (B) lumbar plexus;
- (C) peribulbar; and
- (D) retrobulbar;

blocks.

(3) Intravenous regional anesthesia, such as Bier blocks.

(b) Notwithstanding section 2 of this rule, a superficial nerve block or application of a local anesthetic agent in which the total dosage administered exceeds the recommended maximum dosage per body weight described in the manufacturer's package insert shall be considered regional anesthesia for purposes of this rule.

Sec. 16. As used in this rule, “rescue” means an intervention by a practitioner proficient in airway management and advanced life support. In rescuing a patient, the practitioner must:

- (1) correct adverse physiologic consequences of the deeper-than-intended level of sedation, such as:
 - (A) hypoventilation;
 - (B) hypoxia; and
 - (C) hypotension; and
- (2) return the patient to the originally intended level of sedation.

Sec. 17. As used in this rule, “superficial nerve block” means an agent placed in the proximity of any nerve or group of nerves outside of the vertebral canal to produce a loss of sensation in an anatomic or circumscribed area. For purposes of this rule, the term is limited to:

- (1) ankle;
- (2) metacarpal;
- (3) digit; and
- (4) paracervical;
blocks.

Sec. 18. As used in this rule, “topical anesthesia” means a transient and reversible loss of sensation to a circumscribed area produced by an anesthetic agent applied directly or by spray to the skin or mucous membranes.

Sec. 19. (a) Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Practitioners intending to produce a given level of sedation must be able to rescue a patient whose level of sedation becomes deeper than initially intended. Practitioners administering deep sedation/analgesia in an office-based setting, or directing or supervising the administration of deep sedation/analgesia in an office-based setting, must be able to rescue patients who enter a state of general anesthesia. Practitioners administering moderate sedation/analgesia in an office-based setting, or directing or supervising the administration of moderate sedation/analgesia in an office-based setting, must be able to rescue patients who enter a state of deep sedation/analgesia.

(b) Practitioners administering regional anesthesia, or supervising or directing the administration of regional anesthesia, must be knowledgeable about the risks of regional anesthesia and the interventions required to correct any adverse physiological consequences that may occur in the administration of regional anesthesia.

(c) A health care provider may not administer or monitor an anesthetic agent containing alkylphenols in an office-based setting unless the health care provider is:

- (1) trained in the administration of general anesthesia; and
- (2) not involved in the conduct of the procedure.

Sec. 20. After January 1, 2010, a practitioner may not perform or supervise a procedure that requires anesthesia in an office-based setting unless the office-based setting is accredited by an accreditation agency approved by the board under this rule.

Sec. 21. In approving accreditation agencies to perform accreditation of office-based settings, the board shall ensure that the certification program, at a minimum, includes standards for the following aspects of an office-based setting's operations:

- (1) Anesthesia, as follows:
 - (A) The level of anesthesia administered shall be appropriate for the:
 - (i) patient;
 - (ii) procedure;
 - (iii) clinical setting;
 - (iv) education and training of the personnel; and
 - (v) equipment available.

Practitioners shall select patients for procedures in office-based settings using anesthesia by criteria, including the American Society of Anesthesiologists (ASA) Physical Status Classification System, and so document.

(B) The choice of specific anesthetic agents and techniques shall focus on providing anesthesia that will:

(i) be safe, effective, and appropriate; and

(ii) respond to the specific needs of patients while also ensuring rapid recovery to normal function with appropriate efforts to control postoperative pain, nausea, or other side effects.

(C) A health care provider administering anesthesia shall be licensed, qualified, and working within the provider's scope of practice. In those cases in which a nonphysician provider administers the anesthesia, the provider must be:

(i) under the direction and supervision of a practitioner as required by IC 25-22.5-1-2(a)(20); or

(ii) under the direction of and in the immediate presence of a practitioner as required by IC 25-22.5-1-2(a)(13), if the provider is a certified registered nurse anesthetist.

(D) A:

(i) health care provider who administers anesthesia; and

(ii) practitioner who:

(AA) performs a procedure that requires anesthesia; or

(BB) directs or supervises the administration of anesthesia;

in an office-based setting shall maintain current training in advanced resuscitation techniques, such as advanced cardiac life support (ACLS) or pediatric advanced life support (PALS), as applicable. At least one (1) person with ACLS or PALS training should be immediately available until the patient is discharged.

(E) In addition to the health care provider performing the procedure, sufficient numbers of qualified health care providers, each working within the individual provider's scope of practice, must be present to:

(i) evaluate the patient;

(ii) assist with the procedure;

(iii) administer and monitor the anesthesia; and

(iv) recover the patient.

Other health care providers involved in the delivery of procedures in an office-based setting that require anesthesia, at a minimum, shall maintain training in basic cardiopulmonary resuscitation.

(F) Patients who have preexisting medical or other conditions who may be at particular risk for complications shall be referred to:

(i) a hospital;

(ii) an ambulatory surgical center; or

(iii) another office-based setting appropriate for the procedure and the administration of anesthesia.

(G) The practitioner administering the anesthesia, or supervising or directing the administration of anesthesia as required by clause (C), shall do the following:

(i) Perform a preanesthetic examination and evaluation or ensure that it has been appropriately performed by a qualified health care provider.

(ii) Develop the anesthesia plan or personally review and concur with the anesthesia plan if the plan has been developed by a certified registered nurse anesthetist (CRNA).

(iii) Remain physically present during the operative period and be immediately available until the patient is discharged from anesthesia care for diagnosis, treatment, and management of complications or emergencies.

(iv) Assure provision of appropriate postanesthesia care.

(H) Patient assessment shall occur throughout the preprocedure, periprocedure, and postprocedure phases.

The assessment shall:

(i) address not only physical and functional status, but also physiological and cognitive status; and

(ii) be documented in the medical record.

The procedure and anesthesia shall be properly documented in the medical record.

(I) Physiologic monitoring of patients shall be appropriate for the type of anesthesia and individual patient needs, including continuous monitoring or assessment of the following:

(i) Ventilation.

(ii) Cardiovascular status.

- (iii) Body temperature.
 - (iv) Neuromuscular function and status.
 - (v) Patient positioning.
 - (vi) Oxygenation using a quantitative technique such as pulse oximetry.
- When general anesthesia is used, equipment to assess exhaled carbon dioxide must also be available.

(J) Provisions shall be made for a reliable source of the following:

- (i) Oxygen.
- (ii) Suction.
- (iii) Resuscitation equipment.
- (iv) Emergency drugs.

(2) Procedures, as follows:

(A) Procedures shall be provided by qualified health care providers in an environment that promotes patient safety.

(B) Procedures to be undertaken shall be within the:

- (i) scope of practice, training, and expertise of the health care providers; and
- (ii) capabilities of the facilities.

(C) The procedure shall be of a duration and degree of complexity that will permit patients to recover and be discharged from the office-based setting in less than twenty-four (24) hours.

(D) Provisions shall be made for appropriate ancillary services on site or in another predetermined location. Ancillary services shall be provided in a safe and effective manner in accordance with accepted ethical professional practice and statutory requirements. These services include, but are not limited to:

- (i) pharmacy;
- (ii) laboratory;
- (iii) pathology;
- (iv) radiology;
- (v) occupational health; and
- (vi) other associated services.

(3) Facilities and equipment, as follows:

(A) The office-based setting shall:

- (i) be clean and properly maintained and have adequate lighting and ventilation;
- (ii) be equipped with the appropriate medical equipment, supplies, and pharmacological agents that are required in order to provide:

- (AA) anesthesia;
- (BB) recovery services;
- (CC) cardiopulmonary resuscitation; and
- (DD) other emergency services;

(iii) have:

- (AA) appropriate firefighting equipment;
- (BB) signage;
- (CC) emergency power capabilities and lighting; and
- (DD) an evacuation plan;

(iv) have the necessary:

- (AA) personnel;
- (BB) equipment; and
- (CC) procedures;

to handle medical and other emergencies that may arise in connection with services provided; and

(v) comply with:

- (AA) applicable federal, state, and local laws and codes and regulations, and provisions must be made to accommodate disabled individuals in compliance with the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.); and

(BB) federal and state laws and regulations regarding protection of the health and safety of employees.

(B) The space allocated for a particular function or service shall be adequate for the activities performed.

(C) In locations where anesthesia is administered, there shall be appropriate anesthesia apparatus and equipment to allow appropriate monitoring of patients. All equipment shall be maintained, tested, and inspected according to the manufacturer's specifications. Backup power sufficient to ensure patient protection in the event of an emergency shall be available. There shall be sufficient space to:

(i) accommodate all necessary equipment and personnel; and

(ii) allow for expeditious access to patients and all monitoring equipment.

(D) When anesthesia services are provided to infants and children, the required:

(i) equipment;

(ii) medications; and

(iii) resuscitative capabilities;

shall be appropriately sized for children.

(E) All equipment used in patient care, testing, or emergency situations shall be inspected, maintained, and tested:

(i) on a regular basis; and

(ii) according to manufacturers' specifications.

(F) Appropriate emergency equipment and supplies shall be readily accessible to all patient service areas.

(G) Efforts shall be made to eliminate hazards that might lead to:

(i) slipping;

(ii) falling;

(iii) electrical shock;

(iv) burns;

(v) poisoning; or

(vi) other trauma.

(H) Procedures shall be implemented to:

(i) minimize the sources and transmission of infections; and

(ii) maintain a sanitary environment.

(I) A system shall be in place to:

(i) identify;

(ii) manage;

(iii) handle;

(iv) transport;

(v) treat; and

(vi) dispose of;

hazardous materials and wastes, whether solid, liquid, or gas.

(J) Smoking must be prohibited in all patient care areas.

Sec. 22. (a) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, must have:

(1) admitting privileges at a nearby hospital;

(2) a transfer agreement with another practitioner who has admitting privileges at a nearby hospital; or

(3) an emergency transfer agreement with a nearby hospital.

(b) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall ensure that a patient's informed consent for the nature and objectives of the anesthesia planned and procedure to be performed is obtained in writing before the procedure is performed. The informed consent shall be:

(1) obtained after a discussion of the risks, benefits, and alternatives; and

(2) documented in the patient's medical record.

(c) Written procedures for credible peer review to determine the appropriateness of the following shall be established and reviewed at least annually:

- (1) Clinical decision making.
- (2) Overall quality of care.
- (d) 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 re-signed at least annually.
- (e) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall show competency by maintaining privileges at an accredited or licensed hospital or ambulatory surgical center, for the procedures they perform in the office-based setting. Alternatively, the governing body of the office-based setting is responsible for a peer review process for privileging practitioners based on nationally recognized credentialing standards.
- (f) A practitioner who performs a procedure that requires anesthesia in an office-based setting, or who directs or supervises the administration of anesthesia in an office-based setting, shall have appropriate education and training.

Iowa

None

Kansas

K.A.R. 100-25-3 Requirements for office-based surgery and special procedures

A physician shall not perform any office-based surgery or special procedure unless the office meets the requirements of K.A.R. 100-25-2. Except in an emergency, a physician shall not perform any office-based surgery or special procedure on and after January 1, 2006 unless all of the following requirements are met:

(a) Personnel.

- (1) All health care personnel shall be qualified by training, experience, and licensure as required by law.
- (2) At least one person shall have training in advanced resuscitative techniques and shall be in the patient's immediate presence at all times until the patient is discharged from anesthesia care.

(b) Office-based surgery and special procedures.

- (1) Each office-based surgery and special procedure shall be within the scope of practice of the physician.
- (2) Each office-based surgery and special procedure shall be of a duration and complexity that can be undertaken safely and that can reasonably be expected to be completed, with the patient discharged, during normal operational hours.
- (3) Before the office-based surgery or special procedure, the physician shall evaluate and record the condition of the patient, any specific morbidities that complicate operative and anesthesia management, the intrinsic risks involved, and the invasiveness of the planned office-based surgery or special procedure or any combination of these.
- (4) The physician or a registered nurse anesthetist administering anesthesia shall be physically present during the intraoperative period and shall be available until the patient has been discharged from anesthesia care.
- (5) Each patient shall be discharged only after meeting clinically appropriate criteria. These criteria shall include, at a minimum, the patient's vital signs, the patient's responsiveness and orientation, the patient's ability to move voluntarily, and the ability to reasonably control the patient's pain, nausea, or vomiting, or any combination of these.

(c) Equipment.

- (1) All operating equipment and materials shall be sterile, to the extent necessary to meet the applicable standard of care.

(2) Each office at which office-based surgery or special procedures are performed shall have a defibrillator, a positive-pressure ventilation device, a reliable source of oxygen, a suction device, resuscitation equipment, appropriate emergency drugs, appropriate anesthesia devices and equipment for proper monitoring, and emergency airway equipment including appropriately sized oral airways, endotracheal tubes, laryngoscopes, and masks.

(3) Each office shall have sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient, anesthesia machine, and all monitoring equipment.

(4) All equipment shall be maintained and functional to ensure patient safety.

(5) A backup energy source shall be in place to ensure patient protection if an emergency occurs.

(d) Administration of anesthesia. In an emergency, appropriate life-support measures shall take precedence over the requirements of this subsection. If the execution of life-support measures requires the temporary suspension of monitoring otherwise required by this subsection, monitoring shall resume as soon as possible and practical. The physician shall identify the emergency in the patient's medical record and state the time when monitoring resumed. All of the following requirements shall apply:

(1) A preoperative anesthetic risk evaluation shall be performed and documented in the patient's record in each case. In an emergency during which an evaluation cannot be documented preoperatively without endangering the safety of the patient, the anesthetic risk evaluation shall be documented as soon as feasible.

(2) Each patient receiving intravenous anesthesia shall have the blood pressure and heart rate measured and recorded at least every five minutes.

(3) Continuous electrocardiography monitoring shall be used for each patient receiving intravenous anesthesia.

(4) During any anesthesia other than local anesthesia and minimal sedation, patient oxygenation shall be continuously monitored with a pulse oximeter. Whenever an endotracheal tube or laryngeal mask airway is inserted, the correct functioning and positioning in the trachea shall be monitored throughout the duration of placement.

(5) Additional monitoring for ventilation shall include palpation or observation of the reservoir breathing bag and auscultation of breath sounds.

(6) Additional monitoring of blood circulation shall include at least one of the following:

(A) Palpation of the pulse;

(B) auscultation of heart sounds;

(C) monitoring of a tracing of intra-arterial pressure;

(D) pulse plethysmography; or

(E) ultrasound peripheral pulse monitoring.

(7) When ventilation is controlled by an automatic mechanical ventilator, the functioning of the ventilator shall be monitored continuously with a device having an audible alarm to warn of disconnection of any component of the breathing system.

(8) During any anesthesia using an anesthesia machine, the concentration of oxygen in the patient's breathing system shall be measured by an oxygen analyzer with an audible alarm to warn of low oxygen concentration.

(e) Administrative policies and procedures.

(1) Each office shall have written protocols in place for the timely and safe transfer of the patients to a prespecified medical care facility within a reasonable proximity if extended or emergency services are needed. The protocols shall include one of the following:

(A) A plan for patient transfer to the specified medical care facility;

(B) a transfer agreement with the specified medical care facility; or

(C) a requirement that all physicians performing any office-based surgery or special procedure at the office have admitting privileges at the specified medical care facility.

(2) Each physician who performs any office-based surgery or special procedure that results in any of the following quality indicators shall notify the board in writing within 15 calendar days following discovery of the event:

(A) The death of a patient during any office-based surgery or special procedure, or within 72 hours thereafter;

- (B) the transport of a patient to a hospital emergency department;
- (C) the unscheduled admission of a patient to a hospital within 72 hours of discharge, if the admission is related to the office-based surgery or special procedure;
- (D) the unplanned extension of the office-based surgery or special procedure more than four hours beyond the planned duration of the surgery or procedure being performed;
- (E) the discovery of a foreign object erroneously remaining in a patient from an office-based surgery or special procedure at that office; or
- (F) the performance of the wrong surgical procedure, surgery on the wrong site, or surgery on the wrong patient.

Kentucky

Guidelines for Office-Based Surgery

<http://kbml.ky.gov/NR/rdonlyres/ABF980E5-DA7C-4B25-986C-6665E2025F58/0/officebasedsurgeryguide.pdf>

Background

The movement of health care services away from traditional inpatient facilities to outpatient settings has escalated the volume of surgery (including invasive procedures) being performed in the private offices of health care practitioners. While the vast majority of these services are provided in a safe and effective manner, the complexity of services and procedures being performed in private practitioners' offices is increasing at unprecedented levels. National reports of liposuction-related morbidity and data from Florida's mandatory reporting of office surgery complications, as well as other reports, suggest that office procedures may be less safe than those performed in hospitals or ambulatory surgery centers.

While surgery performed in Kentucky medical facilities (hospitals and diagnostic and treatment centers, including ambulatory surgery centers) is subject to regulatory standards under the state Cabinet for Health Services Office of Inspector General (including invasive procedures) performed in the private office of a physician, dentist or podiatrist is not subject to the same or similar regulatory standards, regardless of the scope or complexity of the surgical procedure.

A practitioner's authority to perform procedures in an office is established by that practitioner's license to practice his or her profession. The care delivered in such offices is expected to meet prevailing standards of care for the licensed profession. At this time, no such prevailing standards of care for office-based surgery exist.

Summary of Guidelines

The office surgery guidelines document is 21 pages long. The major contents are summarized in Table 1 and a brief summary of each section follows.

Definitions

The first section is definitions. This section defines the common terms used throughout the document.

Facility Requirements

Much of this document deals with the facility requirements for offices in which surgery will be performed. Offices are classified as Level I, II, or III based upon the complexity of anesthesia and surgical procedures performed.

Level I Offices

Level I office surgery includes minor procedures performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal preoperative anti-anxiety medications. These offices should maintain basic emergency equipment as listed in Appendix 1 and have an established emergency transfer plan. It is recommended that the surgeon obtain Advanced Cardiac Life Support certification.

Level II Offices

Level II office surgery includes any procedure which requires administration of minimal or moderate sedation/analgesia making post-operative monitoring necessary. The surgical procedures are limited to those in which there is only a small risk of surgical and anesthetic complications and hospitalization as a result of these complications is unlikely.

In addition to Level I requirements, these offices should maintain full emergency equipment and medications as summarized in Appendix 2. There should be established emergency transfer plans, peer review, and performance improvement programs. Accreditation by one of the agencies listed in Table 2 is required. The surgeon and one assistant should be currently certified in Basic Life Support and the surgeon or at least one assistant should be certified in Advanced Cardiac Life Support or have a qualified anesthetic provider.

Level III Offices

Level III office surgery is a procedure which requires or reasonably should require the use of deep sedation/analgesia, general anesthesia, or major conduction blockade. The known complications of the surgical procedure may be serious or life-threatening.

In addition to Level I and Level II requirements, these offices should maintain full emergency equipment and medications as summarized in Appendix 2. There should be established emergency transfer plans, peer review, and performance improvement programs. Accreditation by one of the agencies listed in Table 2 is *mandatory*. The surgeon and at least one assistant should be currently certified in advanced cardiac life support and recovery should be monitored by an ACLS trained practitioner.

Emergency Transfer and Reporting

In the event of an anesthetic, medical or surgical complication or emergency all office personnel should be familiar with a documented plan for the timely and safe transfer of patients to a nearby hospital. This plan should include

arrangements for emergency medical services, and appropriate escort of the patient to the hospital.

Anesthetic or surgical mishaps requiring resuscitation, emergency transfer, or death should be reported to the medical board within three business days using a specified form.

Credentialing

The guidelines address the qualifications that each practitioner should possess. The practitioner should have an appropriate level of training and experience for the specific surgical procedure performed. Criteria considered should include: 1) procedure-specific education, training, experience and successful evaluation 2) American Board of Medical Specialists or equivalent board certification 3) participation in peer and quality review 4) continuing medical education (5) active hospital and/or ambulatory surgical center privileges and (6) adherence to professional society standards.

Unlicensed personnel may not be assigned duties or responsibilities that require professional licensure.

Duties assigned to unlicensed personnel should be in accordance with their training education and experience and under the direct supervision of a practitioner.

Anesthesia

Anesthesia should be administered only by a licensed, qualified and competent practitioner. Registered nurses who administer analgesic or sedative drugs as part of a medical procedure should have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Registered nurses should have documented competence to administer conscious sedation and to assist in any support or resuscitation measures as required. The individual administering conscious sedation and/or monitoring the patient cannot assist the surgeon in performing the surgical procedure.

As required by statutes and administrative regulations, supervision of the sedation/analgesia component of the medical procedure should be provided by a *physician who is physically present*, who is qualified to supervise the administration of the anesthetic and who has accepted responsibility for supervision. The physician providing supervision should assure that an appropriate pre-anesthetic examination is performed, prescribe the anesthesia, assure that qualified practitioners participate, be available for diagnosis, treatment, and management of anesthesia-related complications or emergencies, and assure the provision of indicated post-anesthesia care.

Liposuction

Tumescent liposuction total lidocaine dosage should not exceed 55 mg/kg in a Level I facility. Total supranatant fat removal should not exceed 4000 cc in any office facility.

A. Statement of Intent and Goals

B. Definitions

Chapter A

Statement of Intent and Goals

The purpose of these guidelines is to promote patient safety in the non-hospital setting during procedures that require the administration of conscious sedation, local, or general anesthesia, or minor or major conduction blockade. Moreover, these guidelines have been developed to provide practitioners 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. *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. Nonetheless, it is expected that any practice performing office-based surgery regardless of anesthesia will have the necessary equipment, protocol, and personnel to handle emergencies resulting from the procedure and/or anesthesia.*

Chapter B

Definitions

For the purpose of these guidelines, the following terms are defined:

1. *“Advanced cardiac life support trained”* means that a licensee has successfully completed and requalified 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 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. *“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. *“Anesthetizing location”* means any location in an office where anesthetic agents are administered to a patient.
4. *“Board”* means the Kentucky Board of Medical Licensure.
5. *Certified registered nurse anesthetist” (CRNA)* means a registered nurse who successfully completed an advanced, organized formal educational program in nurse anesthesia accredited by the national certifying organization of such specialty which is recognized by the Kentucky Board of Nursing; and is certified by a board approved national certifying organization, and who demonstrates advanced knowledge and skill in the delivery of anesthesia services. The Certified Registered Nurse Anesthetist should practice in accordance with approved written guidelines developed under the supervision of a licensed physician or dentist or approved by the medical staff within the facility where the practice privileges have been granted.
6. *“Complications”* means an untoward event occurring at any time within 48 hours of surgery, 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, 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. *“Credentialed”* means that a practitioner or physician has been granted and continues to maintain the privilege by a facility licensed in the jurisdiction in which it is located to provide specified services, such as surgery or the administration or supervision of the administration of one or more types of anesthetic agents or procedures, or can show adequate documentation of training experience in specified services such as surgery that is performed more often in an office or outpatient setting.

8. *“Deep sedation/analgesia”* means the administration of a drug or drugs which produces 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.
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. *“Local anesthesia”* means the administration of an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.
13. *“Major surgery”* means surgery which requires moderate sedation, deep sedation, general anesthesia, or major conduction blockade for patient comfort.
14. *“Major conduction blockade”* 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.
15. *“Minimal sedation” (anxiolysis)* means 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.
16. *“Minor surgery”* means surgery which can be safely and comfortably performed on a patient who has received local or topical anesthesia, without more than minimal pre-operative medication or minimal intraoperative sedation and where the likelihood of complications requiring hospitalization is remote.
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 purposely to verbal commands, either alone or accompanied by a 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.
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 rendered and which is not subject to a jurisdiction and licensing requirements.
21. *“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 patient stay of less than 24 consecutive hours and is performed by a practitioner in a location other than a hospital or a diagnostic treatment center, including free-standing ambulatory surgery centers.
22. *“Operating room”* means that location in the office dedicated to the performance of surgery or special procedures.
23. *“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 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.

24. “*Physician*” means an individual holding an M.D. or D.O. degree licensed pursuant to the Kentucky Medical and Osteopathic Practices Act.

25. “*Practitioner*” means a physician.

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

27. “*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.

28. “*Surgery*” means any operative or manual procedures, including the use of lasers as used under the direction of a physician in certain cases, 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.

29. “*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.

Chapter C

Office Administration

The following summarizes some of the important written document and policies and procedures that office-based practices are encouraged to develop and implement. The policies and procedures should undergo periodic review and updating.

1. Policies and Procedures

Written policies and procedures can assist office-based practices in providing safe and quality surgical care, assure consistent personnel performance, and promote an awareness and understanding of the inherent rights of patients. The following are important aspects of an office-based practice that should benefit from simple policy and procedure statements.

a. Emergency Care and Transfer Plan: A plan should 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.

1. Age appropriate emergency supplies, equipment and medication should be provided in accordance with the scope of surgical and anesthesia services provided at the practitioner’s office.

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

3. A practitioner who is qualified in resuscitation techniques and emergency care should be present and available until all patients having more than local anesthesia or minor conductive block anesthesia have been discharged from the office (Advanced adult or pediatric life support certified).

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

b. **Medical Record Maintenance and Security:** 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. For procedures requiring patient consent, there should be a documented informed written consent. If analgesia/sedation, minor or major conduction blockade or general anesthesia are provided, the record should 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 should also be established to assure patient confidentiality and security of all patient data and information.

c. **Infection Control Policy:** The practice should comply with state and federal regulations regarding infection control. For all surgical procedures, the level of sterilization should meet current OSHA 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.

d. **Performance Improvement:** A performance improvement program should 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. Level I facilities are exempt from Performance Improvement Programs. Performance improvement (PI) can be established by:

1. Establishment of a PI program by the practice; or
2. Cooperative agreement with a hospital-based performance or quality improvement program; or
3. 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.

e. **Reporting of Adverse Incidents:** Anesthetic or surgical mishaps requiring resuscitation, emergency transfer, or death should be reported to the Board within three business days.

f. **Federal and State Laws and Regulations:** Federal and state laws and regulations that affect the practice should be identified and procedures developed to comply with those requirements. The following are some of the key requirements upon which office-based practices should focus:

1. Non-Discrimination (see Civil Rights statutes and the Americans with Disabilities Act)
2. Personal Safety (see Occupational Safety and Health Administration information)
3. Controlled Substance Safeguards
4. Laboratory Operations and Performance (CLIA)
5. Personnel Licensure Scope of Practice and Limitations

g. **Patients' Bill of Rights:** Office personnel should recognize the basic rights of patients and understand the importance of maintaining patients' rights. A patients' rights documents should be readily available upon request.

Chapter D Credentialing

1. **Surgical Facility:** Practices performing office-based surgery or procedures that require the administration of moderate or deep sedation, or general anesthesia (Level II and III facilities as defined below) should be accredited by an accreditation agency, including the American Association of Ambulatory Surgical Facilities (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC) or the Joint Commission of Accreditation of HealthCare Organizations (JCAHO), or any other agency approved by the Board within the first year of operation. The accrediting agency should submit a yearly summary report for each facility to the Board. Any licensee performing Level II or Level III office surgery should register with the Board. Such registration should 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 verbal command (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. Level I Office Surgery:

1. Scope: Level I office surgery includes:

- a. Minor procedures performed under topical or local anesthesia (including digital block) not involving drug-induced alteration of consciousness other than minimal preoperative anti-anxiety medications.
- b. Tumescant liposuction: total lidocaine dosage should not exceed 55 mg/kg in a Level I facility.
- c. Preoperative medications are not required or used other than minimal preoperative perioperative oral or intramuscular anti-anxiety producing drugs; anesthesia is local, topical, or none. No drug-induced alteration of consciousness other than minimal anxiolysis of the patient is permitted in Level I Office Surgery.
- d. Chances of Complications requiring hospitalization are remote.

b. Level II Office Surgery:

2. Scope: Level II office surgery includes the following:

- a. Any procedure which requires the administration of minimal or moderate intravenous, intramuscular, or rectal sedation/analgesia, thus making post-operative monitoring necessary.
- b. Level II office surgery shall 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 blockade, and Bier block.

c. Level III Office Surgery:

3. Scope: Level III office surgery includes the following:

- a. Level III office surgery is any procedure which requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia, or major conduction blockade, and/or in which the known complications of the proposed surgical procedure may be serious or life-threatening.
- b. Tumescant liposuction: supranatant fat removal should not exceed 4000cc.

2. Practitioner:

a. The specific office based surgical procedures and anesthesia services that each practitioner is qualified and competent to perform should be commensurate with practitioner's level of training and should be commensurate with 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 (i.e., pediatrics)
3. For physician practitioners, 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. Board certification is understood as American Board of Medical Specialists (ABMS) or equivalent board certification as determined by the Board for non-physician practitioners, certification that is appropriate and applicable for the practitioner.
4. Professional misconduct and malpractice history.
5. Participation in peer and quality review
6. Participation in continuing education 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 should encompass education, training, experience and evaluation, and which may include the following:
 - a. Adherence to professional society standards
 - b. Hospital and/or ambulatory surgical privileges for the scope of services performed in the office based setting
 - c. Credentials approved by a nationally recognized accrediting/credentialing organization;

d. Didactic course complimented 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 may be acceptable if approved by the Kentucky Board of Medical Licensure.

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

Chapter E

Standards for Office Procedures

1. Level I Office Procedures:

a. Training required: The surgeon is encouraged to pursue continuing medical education in proper drug dosages, management of toxicity or hypersensitivity to local anesthetic and other drugs. It is recommended that the surgeon obtain Advanced Cardiac Life Support certification.

b. Equipment and supplies: Oxygen, positive pressure ventilation device, epinephrine, atropine, antihistamine, and corticosteroids should be available if any anesthesia is used.

c. Assistance of Other Personnel: No other assistance is required, unless dictated by the surgical procedure.

d. Accreditation: No accreditation is necessary for Level I office surgery.

2. Level II Office Procedures:

a. Training Required: The surgeon should have staff privileges to perform the same procedure in that hospital as that being performed in the outpatient setting or should 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, formal training, or experience. The surgeon and one assistant should be currently certified in Basic Life Support and the surgeon or at least one assistant should be currently certified in Advanced Cardiac Life Support or have a qualified anesthetic provider practicing within the scope of the provider's license to manage the anesthetic.

b. Equipment and Supplies Required: Emergency resuscitative equipment and a reliable source of oxygen as outlined in the appendix should be current and readily available. Monitoring equipment should include a continuous suction device, pulse oximeter, and noninvasive blood pressure cuff. Electrocardiographic monitoring should be available for patients with a history of cardiac disease. Age appropriate sized monitors and resuscitative equipment should be available for pediatric patients.

c. Assistance of Other Personnel Required: Anesthesia should be administered only by a licensed, qualified and competent practitioner. Registered professional nurses (RNs) who administer analgesic or sedative drugs as part of a medical, procedure (*including but not limited to Certified Registered Nurse Anesthetists (CRNAs)*) should have training and experience appropriate to the level of anesthesia administered and function in accordance with their scope of practice. Registered professional nurses (RNs) should have documented competence to administer conscious sedation and to assist in any support or resuscitation measures as required. The individual administering conscious sedation and/or monitoring the patient cannot assist the surgeon in performing the surgical procedure. Supervision of the sedation/analgesia component of the medical procedure should be provided by a *physician who is physically present*, who is qualified by *law, regulation, or hospital appointment to perform* and supervise the administration of the sedation/analgesia or minor conduction blockade and who has accepted responsibility for supervision. The *physician* providing supervision should:

i. Assure that an appropriate preanesthetic examination and evaluation is performed proximate to the procedure

ii. Prescribe the anesthesia;

iii. Assure that qualified practitioners participate;

iv. Remain physically present during the entire perioperative period and immediately available for diagnosis, treatment, and *management* of anesthesia-related complications or emergencies; and

v. Assure the provision of indicated post-anesthesia care.

A registered nurse who is certified in Basic Cardiac Life Support (BCLS) should 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 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. Each patient should meet discharge criteria as established by the practice, prior to leaving the facility.

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

e. Facility Accreditation: The surgeon should obtain Level II accreditation of the office setting by one of the approved agencies.

3. Level III Office Procedures

a. Training Required:

1. The surgeon should have documentation of training to perform the particular surgical procedure(s) and in the event he/she is supervising the administration of anesthesia by a Certified Registered Nurse Anesthetist, he/she should have sufficient knowledge of the anesthetic technique specified by him/her for the procedure to assure compliance with the Kentucky Medical and Osteopathic Practice Act. The CRNA shall practice pursuant to approved written guidelines developed with the supervising licensed physician or dentist or by the medical staff within the facility where practice privileges have been granted. Rule 81-110 requires, among other things, that the surgeon be competent to supervise the specified anesthetic technique. If the surgeon does not possess the requisite knowledge of anesthesia, the anesthesia should be administered by an Anesthesiologist or by a Certified Registered Nurse Anesthetist supervised by an Anesthesiologist.

2. The surgeon and at least one assistant should be currently certified in Basic Cardiac Life Support and the surgeon or at least one assistant should be currently certified in Advanced Cardiac Life Support, and/or if appropriate, Pediatric Advanced Life Support (PALS) (or other profession specific equivalent training).

3. Recovery from general anesthesia or deep sedation should be monitored by an ACLS (PALS or PLS when appropriate) trained practitioner.

b. Equipment and Supplies Required:

1. Emergency resuscitation equipment, suction and a reliable source of oxygen should be readily available (See Appendix). At least 12 ampules of dantrolene sodium should be readily available.

2. Monitoring should include:

a. Blood pressure (apparatus and stethoscope)

b. Pulse oximetry

c. Continuous EKG

d. Capnography

e. Temperature monitoring for procedures lasting longer than thirty minutes

Facility, in terms of general preparation, equipment and supplies, should 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. An Anesthesiologist, or other qualified physician, or a Certified Registered Nurse Anesthetist, directed by a physician, should administer the general, deep sedation or major conduction regional anesthesia. If the anesthetic is administered by a Certified Registered Nurse Anesthetist, the anesthetic component of the procedure should be supervised by a *physician, who is physically present*, and who is qualified to supervise the administration of the anesthetic technique specified by him/her and who has accepted responsibility for such supervision. The anesthesia provider cannot function in any other capacity during the procedure. Recovery from general anesthesia, deep sedation, or major conduction blockade should be monitored by a practitioner with Advanced Cardiac Life Support or Pediatric Advanced Life Support (or other profession specific equivalent training). Recovery from anesthesia should be evaluated by a qualified practitioner for proper anesthesia recovery using criteria that is appropriate for the level of anesthesia.

d. Inspection and Accreditation. The surgeon shall obtain accreditation of the office setting by AAAASF, AAAHC and JCAHO. All expenses related to accreditation or inspection shall be paid by the surgeon.

Chapter E

Patient Admission and Discharge

1. Patient Selection. The physician should evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician is also 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 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, should have the surgery performed in a hospital setting. Patients with a physical status classification of III or greater may be acceptable candidates for moderate sedation/analgesia. ASA Class III patients should be specifically addressed in the operating manual of the surgery center. 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 a deep sedation, general anesthesia, or major conduction blockade 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 should be discussed with the patient and/or, if applicable, the patient's legal guardian prior to the surgical procedure. Written documentation of informed consent should be included in the medical record.

3. Preoperative Assessment. A medical history and physical examination should be performed, and appropriate laboratory studies obtained within 30 days of the planned surgical procedure, by a practitioner qualified to assess the impact of co-existing disease processes on surgery and anesthesia. A preanesthetic examination and evaluation should be conducted immediately prior to surgery by the physician, who will be administering or supervising the anesthesia. *If a certified registered nurse anesthetist will be administering the anesthesia, she/he should collaborate in such examination or evaluation.* The information and data obtained during the course of these evaluations should be documented in the medical record.

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

- 1) Confirmation of stable vital signs
- 2) Stable oxygen saturation levels
- 3) Return to pre-procedure mental status
- 4) Adequate pain control
- 5) Minimal bleeding nausea and vomiting
- 6) Resolving neural blockade, resolution of the neuraxial blockade
- 7) Discharged in the company of a competent adult

5. Patient Instructions. 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:

1. The procedure performed
2. Information about potential complications
3. Telephone numbers to be used by the patient to discuss complications or should questions arise
4. Instructions for medications prescribed and pain management
5. Information regarding the follow-up visit date, time and location
6. Designated treatment facility in the event of emergency

Chapter 73. Office-Based Surgery

§ 7301. Scope of Chapter

A. The rules of this Chapter govern the performance of office-based surgery by physicians in this state.

§ 7303. Definitions

A. As used in this Chapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified.

Anesthesia Provider--an anesthesiologist or certified registered nurse anesthetist who possesses current certification or other evidence of completion of training in advanced cardiac life support training or pediatric advanced life support for pediatric patients.

Anesthesiologist--a physician licensed by the board to practice medicine in this state who has completed post-graduate residency training in anesthesiology and is engaged in the practice of such specialty.

Board--the Louisiana State Board of Medical Examiners.

Certified Registered Nurse Anesthetist (CRNA)--an advanced practice registered nurse certified according to the requirements of a nationally recognized certifying body approved by the Louisiana State Board of Nursing ("Board of Nursing") who possesses a current license or permit duly authorized by the Board of Nursing to select and administer anesthetics or provide ancillary services to patients pursuant to R.S. 37:911 et seq., and who, pursuant to R.S. 37:911 et seq., administers anesthetics and ancillary services under the direction and supervision of a physician who is licensed to practice under the laws of the state of Louisiana.

Conscious Sedation--a drug-induced depression of consciousness during which patients retain the ability to independently maintain an airway, ventilatory and cardiovascular functions and respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation.

Deep Sedation, Monitored Sedation, General Anesthesia (referred to in this Chapter as *anesthesia* unless the context states otherwise)--a drug-induced loss of consciousness that results in the partial or complete loss of ability to independently maintain an airway, ventilatory, neuromuscular or cardiovascular function and during which patients are not arousable, even by painful stimulation.

Medical Practice Act or the Act--R.S. 37:1261-92 as may be amended from time to time.

Office-Based Surgery--any surgery or surgical procedure not exempted by these rules that is performed in an office-based surgery setting or facility.

Office-Based Surgery Setting or Facility--any clinical setting not exempted by these rules where surgery is performed.

Physician--a person lawfully entitled to engage in the practice of medicine in this state as evidenced by a current license or permit duly issued by the board.

Reasonable Proximity--a distance of not more than 30 miles or one which may be reached within 30 minutes for patients 13 years of age and older and a distance of not more than 15 miles or one which can be reached within 15 minutes for patients 12 years of age and under.

Regional Anesthesia/ Blocks (referred to in this Chapter as *regional anesthesia*)--the administration of anesthetic agents that interrupt nerve impulses without loss of consciousness or ability to independently maintain an airway, ventilatory or cardiovascular function that includes but is not limited to the upper or lower extremities. For purposes of this Chapter regional anesthesia of or near the central nervous system by means of epidural or spinal shall be considered general anesthesia.

Surgery or Surgical Procedure--the excision or resection, partial or complete destruction, incision or other structural alteration of human tissue by any means, including but not limited to lasers, pulsed light, radio frequency, or medical microwave devices, that is not exempted by these rules upon the body of a living human being for the purpose of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes. Surgery shall have the same meaning as "operate."

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(A)(1), 1270(B)(6).

§ 7305. Exemptions

A. This Chapter shall not apply to the following surgical procedures or clinical settings:

1. exempt surgical procedures include those:

a. requiring no anesthesia, using only local, oral, topical or intra-muscular anesthesia, those using regional anesthesia as defined by this Chapter or those using conscious sedation either individually or in combination; and/or

b. performed by a physician oral and maxillofacial surgeon under the authority and within the scope of a license to practice dentistry issued by the Louisiana State Board of Dentistry;

2. excepted clinical settings include:

a. a hospital, including an outpatient facility of the hospital that is separated physically from the hospital, an ambulatory surgical center, abortion clinic or other medical facility that is licensed and regulated by the Louisiana Department of Health and Hospitals;

b. a facility maintained or operated by the state of Louisiana or a governmental entity of this state;

c. a clinic maintained or operated by the United States or by any of its departments, offices or agencies; and

d. an outpatient setting currently accredited by one of the following associations or its successor association:

i. the Joint Commission on Accreditation of Healthcare Organizations relating to ambulatory surgical centers;

ii. the American Association for the Accreditation of Ambulatory Surgery Facilities; or

iii. the Accreditation Association for Ambulatory Health Care.

§ 7307. Prohibitions

A. On and after January 1, 2005, no physician shall perform office-based surgery except in compliance with the rules of this Chapter.

§ 7309. Prerequisite Conditions

A. A physician who performs office-based surgery shall adhere to and comply with the following rules.

1. Facility and Safety

a. The facility shall 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, medical waste and hazardous waste, infection control and storage and administration of controlled substances.

b. All premises shall be kept neat and clean. Operating areas shall be sanitized and materials, instruments, accessories and equipment shall be sterilized.

c. Supplies of appropriate sterile linens, gloves and dressings shall be maintained in sufficient quantities for routine and emergency use. All surgical personnel shall wear suitable operative attire.

d. Supplies of appropriate drugs, medications and fluids shall be maintained in sufficient quantities for routine and emergency use.

2. Quality of Care

a. A physician performing office-based surgery shall:

i. possess current staff privileges to perform the same procedure at a hospital located within a reasonable proximity; or

ii. (a) have achieved board certification from a board recognized by the American Board of Medical Specialties in a specialty that encompasses the procedure performed in an office-based surgery setting; and (b) possess current admitting privileges at a hospital located within a reasonable proximity;

b. a physician performing office-based surgery shall possess current certification or other evidence of completion of training in advanced cardiac life support training or pediatric advanced life support for pediatric patients;

c. a physician performing office-based surgery shall ensure that all individuals who provide patient care in the office-based surgery setting are duly qualified, trained and possess a current valid license or certificate to perform their assigned duties. An unlicensed individual otherwise properly trained in the performance of a

given procedure or duty shall participate in a patient's care only under the on-site direction and supervision of a physician who retains responsibility to the patient for the individual's performance.

3. Patient and Procedure Selection

a. Any office-based surgical procedure shall be within the training and experience of the operating physician, the health care practitioners providing clinical care assistance and the capabilities of the facility.

b. The surgical procedure shall be of a duration and degree of complexity that shall permit the patient to recover and be discharged from the facility on the same day. Under no circumstances shall a patient be permitted to remain in an office-based surgery setting overnight.

4. Informed Consent

a. Informed consent for surgery and the planned anesthetic intervention shall be obtained from the patient or legal guardian in accordance with the requirements of law.

5. Patient Care

a. The anesthesia provider shall be physically present throughout the surgery.

b. The anesthesia provider or an individual possessing current certification or other evidence of completion of training in advanced cardiac life support training or pediatric advanced life support for pediatric patients shall remain in the facility until all patients have been released from anesthesia care by a CRNA or a physician.

c. Discharge of a patient shall be properly documented in the medical record.

6. Monitoring and Equipment

a. There shall be sufficient space to accommodate all necessary equipment and personnel and to allow for expeditious access to the patient and all monitoring equipment.

b. All equipment shall be in proper working condition; monitoring equipment shall be available, maintained, tested and inspected according to the manufacturer's specifications.

c. A secondary power source appropriate for equipment in use in the event of a power failure shall be available. In the event of an electrical outage which disrupts the capability to continuously monitor all specified patient parameters, heart rate and breath sounds shall be monitored using a precordial stethoscope or similar device and blood pressure measurements shall be re-established using a non-electrical blood pressure measuring device until power is restored.

d. In an office where anesthesia services are to be provided to infants and children the required equipment, medication, including drug dosage calculations, and resuscitative capabilities shall be appropriately sized for a pediatric population.

e. All facilities shall have an auxiliary source of oxygen, suction, resuscitation equipment and medication for emergency use. A cardiopulmonary resuscitative cart shall be available and shall include, but not be limited to, an Ambu Bag, laryngoscope, emergency intubation equipment, airway management equipment, a defibrillator with pediatric paddles if pediatric patients are treated and a medication kit which shall include appropriate non-expired medication for the treatment of anaphylaxis, cardiac arrhythmia, cardiac arrest and malignant hyperthermia when triggering agents are used or if the patient is at risk for malignant hyperthermia. Resources for determining appropriate drug doses shall be readily available.

7. Emergencies and Transfers

a. Emergency instructions along with the names and telephone numbers to be called in the event of an emergency (i.e., emergency medical services ["EMS"], ambulance, hospital, 911, etc.) shall be posted at each telephone in the facility.

b. Agreements with local EMS or ambulance services shall be in place for the purpose of transferring a patient to a hospital in the event of an emergency.

c. Pre-existing arrangements shall be established for definitive care of patients at a hospital located within a reasonable proximity when extended or emergency services are needed to protect the health or well being of the patient.

8. Medical Records

a. A complete medical record shall be documented and maintained of the patient history, physical and other examinations and diagnostic evaluations, consultations, laboratory and diagnostic reports, informed consents,

preoperative, inter-operative and postoperative anesthesia assessments, the course of anesthesia, including monitoring modalities and drug administration, discharge and any follow-up care.

9. Policies and Procedures

a. Written policies and procedures for the orderly conduct of the facility shall be prepared for the following areas:

i. management of anesthesia including:

(a). patient selection criteria;

(b). drug overdose, cardiovascular and respiratory arrest, and other risks and complications from anesthesia;

(c). the procedures to be followed while a patient is recovering from anesthesia in the office; and

(d). release from anesthesia care and discharge criteria;

ii. infection control (surveillance, sanitation and asepsis, handling and disposal of waste and contaminants, sterilization, disinfection, laundry, etc.); and

iii. management of emergencies, including:

(a). the procedures to be followed in the event that a patient experiences a complication;

(b). the procedures to be followed if the patient requires transportation for emergency services including the identity and telephone numbers of the EMS or ambulance service if one is to be utilized, 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;

(c). fire and bomb threats.

b. All facility personnel providing patient care shall be familiar with, appropriately trained in and annually review the facility's written policies and procedures.

§ 7311. Administration of Anesthesia

A. Evaluation of the Patient. An anesthesia provider shall perform a pre-anesthesia evaluation, counsel the patient and prepare the patient for anesthesia.

B. Diagnostic Testing, Consultations. Appropriate pre-anesthesia diagnostic testing and consults shall be obtained as indicated by the pre-anesthesia evaluation.

C. Anesthesia Plan of Care. A patient-specific plan for anesthesia care shall be formulated based on the assessment of the patient, the surgery to be performed and the capacities of the facility.

D. Administration of Anesthesia. Anesthesia shall be administered by an anesthesia provider who shall not participate in the surgery.

E. Monitoring. Monitoring of the patient shall include continuous monitoring of ventilation, oxygenation and cardiovascular status. Monitors shall include, but not be limited to, pulse oximetry, electrocardiogram continuously, non-invasive blood pressure measured at appropriate intervals, an oxygen analyzer and an end-tidal carbon dioxide analyzer. A means to measure temperature shall be readily available and utilized for continuous monitoring when indicated. 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. Post-operatively, the patient shall be evaluated by continuous monitoring and clinical observation until stable. Monitoring and observations shall be documented in the patient's medical record.

§ 7313. Reports to the Board

A. A physician performing office-based surgery shall notify the board in writing within 15 days of the occurrence or receipt of information that an office-based surgery resulted in:

1. an unanticipated and unplanned transport of the patient from the facility to a hospital emergency department;

2. an unplanned readmission to the office-based surgery setting within 72 hours of discharge from the facility;

3. an unscheduled hospital admission of the patient within 72 hours of discharge from the facility; or

4. the death of the patient within 30 days of surgery in an office-based facility.

§ 7315. Effect of Violation

A. Any violation or failure to comply with the provisions of this Chapter shall be deemed unprofessional conduct and conduct in contravention of the board's rules, in violation of R.S. 37:1285(A)(13) and (30), respectively, as well as violation of any other applicable provision of R.S. 37:1285(A), providing cause for the board to suspend, revoke, refuse to issue or impose probationary or other restrictions on any license held or applied for by a physician culpable of such violation.

Maine

None

Maine -- Osteopathic

None

Maryland

None

Massachusetts

Office Based Surgery Guidelines

<http://www.mass.gov/eohhs/docs/borim/policies-guidelines/surgery-guidelines.pdf>

Michigan – Medical

None

Michigan – Osteopathic

None

Minnesota

None

Mississippi

None

Missouri

None

Montana

None