Document No. 3079
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BOARD OF MEDICAL EXAMINERS
Chapter 81
Statutory Authority: 1976 Code Sections 40-1-70, 40-47-10(I)(3)

Synopsis:

The Board of Medical Examiners is adding Regulation 81-96 regarding office-based surgery.

Instructions:

Add regulation 81-96 as printed below.

Text:

81-96 Office-based Surgery
A. Statement of Intent and Goals
The purpose of this regulation is to promote patient safety in the non-hospital office-based setting during procedures that require the administration of local anesthesia, sedation/analgesia, or general anesthesia, or minor or major conduction block. Moreover, this regulation has been developed to provide physicians performing office-based surgery (including cryosurgery and laser surgery), that requires anesthesia (including tumescent anesthesia), analgesia or sedation, the benefit of uniform professional standards regarding qualification of practitioners and staff, equipment, facilities and policies and procedures for patient assessment and monitoring. Level I procedures as defined in (B)(13) are excluded from this regulation.

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

1. “Advanced resuscitative technique” means current certification in Advanced Trauma Life Support (ATLS), Advanced Cardiac Life Support (ACLS), or Pediatrics Advanced Life Support (PALS) as appropriate for the individual patient and surgical situation involved. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) is appropriate.
2. “Anesthesiologist” means a physician who has successfully completed a residency program in anesthesiology approved by the Accreditation Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who is currently a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.
3. “Anesthesiologist's assistant (AA)” means a person licensed by the Board as an anesthesiologist’s assistant who is an allied health graduate of an accredited anesthesiologist's assistant program who is currently certified by the National Commission for Certification of Anesthesiologist's Assistants and who works under the direct supervision of an anesthesiologist who is immediately available in the operating suite and is physically present during the most demanding portions of the anesthetic including, but not limited to, induction and emergence.
4. “Board” means the South Carolina State Board of Medical Examiners.
5. “Certified registered nurse anesthetist (CRNA)” means a person licensed by the South Carolina State Board of Nursing as an Advanced Practice Registered Nurse in the category of Certified Registered Nurse Anesthetist.
6. “Complications” means untoward events occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia in an office setting including, but not limited to, any

of the following: paralysis, malignant hypothermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, unintended hospitalization for more than 24 hours, or death.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Office Administration

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

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

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

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

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

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

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

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

4. Performance Improvement:

a. A performance improvement program must be implemented to provide a mechanism to periodically review (minimum of every six months) the current practice activities and quality of care provided to patients, including peer review by members not affiliated with the same practice. Performance improvement (PI) can be established by:

(1) Establishment of a PI program by the practice; or

(2) A cooperative agreement with a hospital-based performance or quality improvement program; or

(3) A cooperative agreement with another practice to jointly conduct PI activities; or

(4) A cooperative agreement with a peer review organization, a managed care organization, specialty society, or other appropriate organization dedicated to performance improvement approved by the Board.

b. PI activities must include, but not be limited to review of mortalities, review of the appropriateness and necessity of procedures performed, emergency transfers, surgical and anesthetic complications, and resultant outcomes (including all postoperative infections), analysis of patient satisfaction surveys and complaints, and identification of undesirable trends, such as diagnostic errors,

unacceptable results, follow-up of abnormal test results, and medication errors and system problems. Findings of the PI program must be incorporated into the practice's educational activity.

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

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

a. Non-Discrimination (see Civil Rights statutes and the Americans with Disabilities Act)
b. Personal Safety (see Occupational Safety and Health Administration information)
c. Controlled Substance Safeguards
d. Laboratory Operations and Performance (CLIA)
e. Personnel Licensure Scope of Practice and Limitations.

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

D. Credentialing

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

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

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

2. Practitioners:

a. The specific office-based surgical procedures and anesthesia services that each respective practitioner involved is qualified and competent to perform must be commensurate with each

practitioner's level of training and experience. Criteria to be considered to demonstrate competence include:

(1) State licensure.

(2) Procedure-specific education, training, experience and successful evaluation appropriate for the patient population being treated (e.g. pediatrics).

(3)(a) For physicians, staff privileges in a hospital to perform the same procedure or service as that being performed in the office setting or board certification, board eligibility or completion of a training program in a field of specialization recognized by the ACGME for expertise and proficiency in that field, or comparable background, formal training, or experience as approved by the Board. Board certification is understood as American Board of Medical Specialists (ABMS), American Osteopathic Association (AOA), or equivalent board certification as determined by the Board.

(b) For non-physician practitioners, certification that is appropriate and applicable for the practitioner, as recognized by the practitioner's licensing board or this Board.

(4) Professional misconduct and malpractice history.

(5) Participation in peer and quality review proceedings.

(6) Participation in continuing competency activities consistent with the statutory requirements and requirements of the practitioner's professional organization.

(7) Malpractice insurance coverage adequate for the specialty.

(8) Procedure-specific competence (and competence in the use of new procedures/technology), which encompasses education, training, experience and evaluation, and which includes:

(a) Adherence to professional society standards;

(b) Hospital and/or ambulatory surgical privileges for the scope of services performed in the office-based setting at Levels II and III or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties, American Osteopathic Association, or comparable background, formal training, or experience as approved by the Board;

(c) Credentials approved by a nationally recognized accrediting/credentialing organization;

(d) For physicians, didactic course complemented by hands-on, observed experience. Training is to be followed by a specified number of cases supervised by a practitioner already competent in the respective procedure, in accordance with professional society standards and guidelines.

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

E. Standards for Office Procedures

1. Level II Office Procedures:

a. Training Required:

(1) The physician must have staff privileges in a hospital to perform the same procedure as that being performed in the office setting or must be able to document satisfactory completion of training such as board certification or board eligibility by a specialty board approved by the American Board of Medical Specialties, American Osteopathic Association, or must demonstrate comparable background, formal training, or experience as approved by the Board. The physician must maintain current certification in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

(2) One assistant or other health care personnel that is immediately available (immediately available is defined as being located within the office and not necessarily the person assisting in the procedure) must be certified in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

b. Equipment and Supplies Required:

(1) Emergency resuscitation equipment and a reliable source of oxygen must be current and immediately available.

(2) Monitoring equipment must include a continuous suction device, pulse oximeter, and noninvasive blood pressure apparatus and stethoscope. Electrocardiographic monitoring must be available for patients with a history of cardiac disease. Age-and size-appropriate monitors and resuscitative equipment must be available for patients.

c. Assistance of Other Personnel Required:

(1) Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately available, who possesses sufficient knowledge, and who is qualified in accordance with law supervise the administration of the sedation/analgesia or minor conduction block. The physician providing supervision must:

(a) ensure that an appropriate pre-sedation/analgesia or anesthesia examination and evaluation is performed proximate to the procedure;

(b) order the sedation/analgesia or anesthesia;

(c) ensure that qualified health care personnel participate;

(d) remain immediately available until discharge criteria are met; and

(e) ensure the provision of indicated post-sedation/analgesia or anesthesia care.

(2) Sedation/analgesia or anesthesia must be administered or supervised only by a duly licensed, qualified and competent physician. CRNAs, AAs, or other qualified practitioners who administer sedation/analgesia or anesthesia as part of a medical procedure must have training and experience appropriate to the level of sedation/analgesia or anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented competence to administer sedation/analgesia or anesthesia and to assist in any support or resuscitation measures as required. The individual administering sedation/analgesia or anesthesia and/or monitoring the patient must not play an integral role in performing the surgical procedure. This is not intended to restrict or limit the physician's ability to delegate medical tasks to other qualified practitioners in Level II office procedures.

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

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

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

2. Level III Office Procedures

a. Training Required:

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

(2) One assistant or other health care personnel that is immediately available (immediately available is defined as being located within the office and not necessarily the person assisting in the procedure) must be currently certified in advanced resuscitative techniques as appropriate (e.g. ATLS, ACLS, or PALS).

b. Equipment and Supplies Required:

(1) Emergency resuscitation equipment, a continuous suction device, and a reliable source of oxygen must be current and immediately available. At least 12 ampules of dantrolene sodium must be immediately available. Age-and size-appropriate monitors and resuscitative equipment must be available for patients.

(2) Monitoring equipment must include:

(a) blood pressure apparatus and stethoscope

(b) pulse oximetry

(c) continuous EKG

(d) capnography

(e) temperature monitoring for procedures lasting longer than 30 minutes.

(3) Facility, in terms of general preparation, equipment and supplies, must be comparable to a free standing ambulatory surgical center, have provisions for proper record keeping, and the ability to recover patients after anesthesia.

c. Assistance of Other Personnel Required:

(1) Supervision of the sedation/analgesia component of the medical procedure should be provided by a physician who is immediately available, who possesses sufficient knowledge, and who is qualified in accordance with law to supervise the administration of the sedation/analgesia or minor conduction block. The physician providing supervision must:

(a) ensure that an appropriate pre-sedation/analgesia or anesthesia examination and evaluation is performed proximate to the procedure;

(b) order the sedation/analgesia or anesthesia;

(c) ensure that qualified health care personnel participate;

(d) remain immediately available until discharge criteria are met; and

(e) ensure the provision of indicated post-sedation/analgesia or anesthesia care.

(2) Sedation/analgesia or anesthesia must be administered or supervised only by a duly licensed, qualified and competent physician. CRNAs or AAs who administer sedation/analgesia or anesthesia as part of a medical procedure must have training and experience appropriate to the level of sedation/analgesia or anesthesia administered and function in accordance with their scope of practice. Such personnel must have documented competence to administer sedation/analgesia or anesthesia and to assist in any support or resuscitation measures as required. The individual administering sedation/analgesia or anesthesia and/or monitoring the patient must not play an integral role in performing the surgical procedure.

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

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

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

F. Patient Admission and Discharge

1. Patient Selection. The physician must evaluate the condition of the patient and the potential risks associated with the proposed treatment plan. The physician is also responsible for providing a post-

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

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

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

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

a. confirmation of stable vital signs
b. stable oxygen saturation levels
c. return to pre-procedure mental status
d. adequate pain control
e. minimal bleeding, nausea and vomiting
f. resolving neural block, resolution of the neuraxial block
g. discharged in the company of a competent adult.

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

a. The procedure performed
b. Information about potential complications
c. Telephone numbers to be used by the patient to discuss complications or should questions arise
d. Instructions for medications prescribed and pain management
e. Information regarding the follow-up visit date, time and location
f. Designated treatment facility in the event of emergency.

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

Fiscal Impact Statement:

There will be no additional cost incurred by the State or any political subdivision.

Statement of Rationale:

Standards for office-based surgery are added to promote patient safety in office-based settings requiring anesthesia and to provide uniform professional standards for office-based surgery.