

GEORGIA COMPOSITE MEDICAL BOARD

OFFICE-BASED ANESTHESIA AND SURGERY GUIDELINES

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, whichever 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.