

FINAL REGULATIONS
BOARD OF MEDICINE

PART VIII.

OFFICE-BASED ANESTHESIA.

18 VAC 85-20-310. Definitions.

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

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

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

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

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

“Moderate sedation /conscious sedation” means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are usually required to maintain a patent airway, and spontaneous ventilation is usually adequate. Cardiovascular function is usually maintained.

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

“Office-based” means any setting other than (1) a licensed hospital as defined in § 32.1-123 of the Code of Virginia or state-operated hospitals; or (2) a facility directly maintained or operated by the federal government.

“Physical status classification” means a description used in determining the physical status of a patient as specified by the American Society of Anesthesiologist. Classifications are Class 1 for a normal healthy patient; Class 2 for a patient with mild systemic disease; Class 3 for a patient with

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severe systemic disease limiting activity but not incapacitation; Class 4 for a patient with incapacitating systemic disease that is a constant threat to life; and Class 5 for a moribund patients not expected to live 24 hours with or without surgery.

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

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

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

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

18 VAC 85-20-320. General provisions.

A. Applicability of requirements for office-based anesthesia.

1. The administration of topical anesthesia, local anesthesia, minor conductive blocks, or minimal sedation/anoxiolysis, not involving a drug-induced alteration of consciousness other than minimal pre-operative tranquilization, is not subject to the requirements for office-based anesthesia. A health care practitioner administering such agents shall adhere to an accepted standard of care as appropriate to the level of anesthesia or sedation, including evaluation, drug selection, administration and management of complications.

2. The administration of moderate sedation/ conscious sedation, deep sedation, general anesthesia, or regional anesthesia consisting of a major conductive block are subject to these requirements for office-based anesthesia.

[3. Levels of anesthesia or sedation referred to in this chapter shall relate to the level of anesthesia or sedation intended by the practitioner in the anesthesia plan.]

B. A doctor of medicine, osteopathic medicine, or podiatry administering office-based anesthesia or supervising such administration shall:

1. Perform a pre-anesthetic evaluation and examination or ensure that it has been performed;
2. Develop the anesthesia plan or ensure that it has been developed;
3. Ensure that the anesthesia plan has been discussed and informed consent obtained;
4. Ensure patient assessment and monitoring through the pre-, peri-, and post-procedure phases, addressing not only physical and functional status, but also physiological and cognitive status.
5. Ensure provision of indicated post-anesthesia care;

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6. Remain physically present or immediately available, as appropriate, [for diagnosis, treatment and management of anesthesia-related complications or emergencies to manage complications and emergencies until discharge criteria have been met];

C. All written policies, procedures and protocols required for office-based anesthesia shall be maintained and available for inspection at the facility.

18 VAC 85-20-330. Qualifications of providers.

A. Doctors who utilize office-based anesthesia shall ensure that all medical personnel assisting in providing patient care are appropriately trained, qualified and supervised, are sufficient in numbers to provide adequate care, and maintain training in basic cardiopulmonary resuscitation.

B. All providers of office-based anesthesia shall hold the appropriate license and have the necessary training and skills to deliver the level of anesthesia being provided.

1. Deep sedation, general anesthesia or a major conductive block shall only be administered by an anesthesiologist or by a certified registered nurse anesthetist.

2. Moderate sedation/conscious sedation may be administered by the operating doctor with the assistance of and monitoring by a licensed nurse, a physician assistant or a licensed intern or resident.

C. Additional training.

1. [On or after (six months from the effective date of this regulation),]the doctor who provides office-based anesthesia or who supervises the administration of anesthesia shall maintain current certification in advanced resuscitation techniques.

2. Any doctor who administers office-based anesthesia without the use of an anesthesiologist or certified registered nurse anesthetist shall obtain four hours of continuing education in [topics related to] anesthesia [within the 60 hours required] each biennium [for licensure renewal, which are subject to random audit by the board].

18 VAC 85-20-340. Procedure/anesthesia selection and patient evaluation.

A. A written protocol shall be developed and followed for procedure selection to include but not be limited to:

1. The doctor providing or supervising the anesthesia shall ensure that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.

2. The procedure shall be of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility in less than 24 hours.

3. The level of anesthesia used shall be appropriate for the patient, the surgical procedure, the clinical setting, the education and training of the personnel, and the equipment available. The choice of specific anesthesia agents and techniques shall focus on providing an anesthetic that will be effective,

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appropriate and will address the specific needs of patients while also ensuring rapid recovery to normal function with maximum efforts to control post-operative pain, nausea or other side effects.

B. A written protocol shall be developed for patient evaluation to include but not be limited to:

1. The pre-operative anesthesia evaluation of a patient shall be performed by the health care practitioner administering the anesthesia or supervising the administration of anesthesia. It shall consist of performing an appropriate history and physical examination, determining the patient's physical status classification, developing a plan of anesthesia care, acquainting the patient or the responsible individual with the proposed plan and discussing the risks and benefits.

2. The condition of the patient, specific morbidities that complicate anesthetic management, the specific intrinsic risks involved, and the nature of the planned procedure shall be considered in evaluating a patient for office-based anesthesia.

3. Patients who have pre-existing medical or other conditions that may be of particular risk for complications shall be referred to a facility appropriate for the procedure and administration of anesthesia. Nothing relieves the licensed health care practitioner of the responsibility to make a medical determination of the appropriate surgical facility or setting.

C. Office-based anesthesia shall only be provided for patients in physical status classifications for Classes I, II and III. Patients in Classes IV and V shall not be provided anesthesia in an office-based setting.

18 VAC 85-20-350. Informed consent.

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

18 VAC 85-20-360. Monitoring.

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

1. Monitoring equipment shall be appropriate for the type of anesthesia and the nature of the facility. At a minimum, provisions shall be made for a reliable source of oxygen, suction, resuscitation equipment and emergency drugs.

2. In locations where anesthesia is administered, there shall be adequate anesthesia apparatus and equipment to ensure appropriate monitoring of patients. All equipment shall be maintained, tested and inspected according to manufacturer's specifications, and back-up power shall be sufficient to ensure patient protection in the event of an emergency.

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

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

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

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

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

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

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

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care practitioner administering moderate sedation/conscious sedation shall routinely monitor a patient according to procedures consistent with such administration.

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

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

B. There shall be written protocols for the timely and safe transfer of patients to a pre-specified hospital or hospitals within a reasonable proximity. There shall be a transfer agreement with such hospital or hospitals.

18 VAC 85-20-380. Discharge policies and procedures.

A. There shall be written policies and procedures outlining discharge criteria. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting.

B. Discharge from anesthesia care is the responsibility the health care practitioner providing the anesthesia care and shall only occur when patients have met specific physician-defined criteria.

C. Written instructions and an emergency phone number shall be provided to the patient. Patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

D. At least one person trained in advanced resuscitative techniques shall be immediately available until all patients are discharged.

18 VAC 85-20-390. Reporting requirements.

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

Certification

I certify that this regulation is full, true, and correctly dated.

William L. Harp, M.D.
Executive Director
Virginia Board of Medicine

Date: _____