

**TEXAS MEDICAL BOARD
BOARD RULES**

Texas Administrative Code, Title 22, Part 9

**Chapter 192. Office Based Anesthesia Services
§§192.1-192.6**

§192.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents indicate otherwise.

(1) ACLS--Advanced Cardiac Life Support, as defined by the AHA.

(2) AED--Automatic External Defibrillator.

(3) AHA--American Heart Association.

(4) Analgesics--Dangerous or scheduled drugs that alleviate pain.

(5) Anesthesia--The loss of feeling or sensation resulting from the use of dangerous or scheduled drugs to depress nerve function. Anesthetics are scheduled or dangerous drugs used to induce anesthesia.

(6) Anesthesia Services--The use of dangerous and scheduled drugs, including anesthetics, analgesics, and anxiolytics, to permit the performance of surgery or other painful medical procedures.

(7) Anxiolytics--Dangerous or scheduled drugs used to treat episodes of anxiety.

(8) Anesthesiologist assistant--A graduate of an approved anesthesiologist assistant training program.

(9) Anesthesiology resident--A physician who is presently in an approved Texas anesthesiology residency program who is either licensed as a physician in Texas or holds a postgraduate resident permit issued by the Texas Medical Board.

(10) BCLS--Basic Cardiac Life Support, as defined by the AHA.

(11) Certified registered nurse anesthetist--A person licensed by the Board of Nurse Examiners for the State of Texas (BNE) as a registered professional nurse, authorized by the BNE as an advanced practice nurse in the role of nurse anesthetist, and certified by a national certifying body recognized by the BNE.

(12) Dangerous drugs--medications defined by the Texas Dangerous Drug Act, Chapter 483, Texas Health and Safety Code. Dangerous drugs require a prescription, but are not included in the list of scheduled drugs. A dangerous drug bears the legend "Caution: federal law prohibits dispensing without a prescription" or "Prescription Only."

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

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

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

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

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

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

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

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

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

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

(19) Board--The Texas Medical Board.

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

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

(22) Scheduled Drugs--medications defined by the Texas Controlled Substances Act, Chapter 481, Texas Health and Safety Code. This Act establishes five categories, or schedules of drugs, based on risk of

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abuse and addiction. (Schedule I includes drugs that carry an extremely high risk of abuse and addiction and have no legitimate medical use. Schedule V includes drugs that have the lowest abuse/addiction risk).

Source Note: The provisions of this §192.1 adopted to be effective May 21, 2000, 25 TexReg 4350; amended to be effective June 29, 2006, 31 TexReg 5107.

§192.2. Provision of Anesthesia Services in Outpatient Settings.

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

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

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

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

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

(4) a licensed ambulatory surgical center;

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

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

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

(8) an outpatient setting accredited by:

(A) the Joint Commission on Accreditation of Healthcare Organizations relating to ambulatory surgical centers;

(B) the American Association for the Accreditation of Ambulatory Surgery Facilities; or

(C) the Accreditation Association for Ambulatory Health Care.

(c) Standards for Anesthesia Services. The following standards are required for outpatient settings providing anesthesia services that are administered within two hours before an out patient procedure. If personnel and equipment meet the requirements of a higher level, lower level anesthesia services may also be provided.

(1) Level I services:

(A) at least two personnel must be present, including the physician who must be currently certified at least in AHA approved BCLS; and

(B) the following age-appropriate equipment must be present:

(i) bag mask valve;

(ii) oxygen;

(iii) AED or other defibrillator; and

(iv) pre-measured doses of epinephrine, atropine, adreno-corticoids, and antihistamines.

(2) Level II services:

(A) at least two personnel must be present, including the physician who must be currently certified at least in AHA approved ACLS or PALS, as appropriate;

(i) another person must be currently certified at least in AHA approved BCLS; and

(ii) a licensed health care provider, who may be one of the two required personnel, must attend the patient, until the patient is ready for discharge; and

(B) a crash cart must be present containing drugs and equipment necessary to carry out ACLS protocols, including, but not limited to, the following age-appropriate equipment:

(i) bag mask valve and appropriate airway maintenance devices;

(ii) oxygen;

(iii) AED or other defibrillator;

(iv) pre-measured doses of first line cardiac medications, including epinephrine, atropine, adreno-corticoids, and antihistamines;

(v) IV equipment;

(vi) pulse oximeter; and

(vii) EKG Monitor.

(3) Level III services:

(A) at least two personnel must be present, including the physician who must be currently certified at least in AHA approved ACLS or PALS, as appropriate;

(i) another person must be currently certified at least in AHA approved BCLS;

(ii) a licensed health care provider, which may be either of the two required personnel, must attend the patient, until the patient is ready for discharge; and

(iii) a person, who may be either of the two required personnel, must be responsible for monitoring the patient during the procedure; and

(B) the same equipment required for Level II;

(4) Level IV services: Physicians who practice medicine in this state and who administer anesthesia or perform a procedure for which anesthesia services are provided in outpatient settings at Level IV shall follow

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current, applicable standards and guidelines as put forth by the American Society of Anesthesiologists (ASA) including, but not limited to, the following listed in paragraphs (1)-(8) of this subsection:

- (A) Basic Standards for Preanesthesia Care;
- (B) Standards for Basic Anesthetic Monitoring;
- (C) Standards for Postanesthesia Care;
- (D) Position on Monitored Anesthesia Care;
- (E) The ASA Physical Status Classification System;
- (F) Guidelines for Nonoperating Room Anesthetizing Locations;
- (G) Guidelines for Ambulatory Anesthesia and Surgery; and
- (H) Guidelines for Office-Based Anesthesia.

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

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

(f) The anesthesiologist or physician providing anesthesia or anesthesia-related services in an outpatient setting shall perform a pre-anesthetic evaluation, counsel the patient, and prepare the patient for anesthesia per current ASA standards. If the physician has delegated the provision of anesthesia or anesthesia-related services to a CRNA, the CRNA may

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

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

(h) All anesthesia-related equipment and monitors shall be maintained to current operating room standards. All devices shall have regular service/maintenance checks at least annually or per

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

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

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

(1) Management of outpatient anesthesia. At a minimum, these must address:

- (A) patient selection criteria;
- (B) patients/providers with latex allergy;

(C) pediatric drug dosage calculations, where applicable;

(D) ACLS (advanced cardiac life support) or PALS (pediatric advanced life support) algorithms;

(E) infection control;

(F) documentation and tracking use of pharmaceuticals, including controlled substances, expired drugs and wasting of drugs; and

(G) discharge criteria.

(2) Management of emergencies. At a minimum, these must include, but not be limited to:

(A) cardiopulmonary emergencies;

(B) fire;

(C) bomb threat;

(D) chemical spill; and

(E) natural disasters.

(k) Physicians, and anesthesiologists shall maintain current competency in ACLS, PALS, or a course approved by the board. In all settings under these rules, at a minimum, at least two persons, including the surgeon or anesthesiologist, shall maintain current competency in basic life support.

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

Source Note: The provisions of this §192.2 adopted to be effective May 21, 2000, 25 TexReg 4350; amended to be effective November 30, 2003, 28 TexReg 10498; amended to be effective June 29, 2006, 31 TexReg 5107.

§192.3. Compliance with Office-Based Anesthesia Rules.

(a) A physician who provides anesthesia services or performs a procedure for which anesthesia services are provided in an outpatient setting shall comply with the rules adopted under this title.

(b) The board may require a physician to submit and comply with a corrective action plan to remedy or address any current or potential deficiencies with the physician's provision of anesthesia services in an outpatient setting in accordance with the Medical Practice Act, Title 3 Subtitle C §§162.101-.107 of the Texas Occupations Code, or rules of the board.

(c) Any physician who violates these rules shall be subject to disciplinary action and/or termination of the registration issued by the board as authorized by the Medical Practice Act or rules of the board.

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Source Note: The provisions of this §192.3 adopted to be effective May 21, 2000, 25 TexReg 4350; amended to be effective November 30, 2003, 28 TexReg 10498; amended to be effective September 12, 2004, 29 TexReg 8512; amended to be effective June 29, 2006, 31 TexReg 5107.

§192.4. Registration.

(a) Each physician who provides anesthesia services or performs a procedure for which anesthesia services are provided in an outpatient setting shall register with the board on a form prescribed by the board and pay a fee to the board in an amount established by the board.

(b) The board shall coordinate the registration required under this section with the registration required under the Medical Practice Act, Texas Occupations Code Chapter 156, so that the times of registration, payment, notice, and imposition of penalties for late payment are similar and provide a minimum of administrative burden to the board and to physicians.

Source Note: The provisions of this §192.4 adopted to be effective May 21, 2000, 25 TexReg 4350; amended to be effective November 19, 2000, 25 TexReg 11284; amended to be effective November 30, 2003, 28 TexReg 10498; amended to be effective September 12, 2004, 29 TexReg 8512; amended to be effective June 29, 2006, 31 TexReg 5107.

§192.5. Inspections.

(a) The board may conduct inspections to enforce these rules, including inspections of an office site and of documents of a physician's practice that relate to the provision of anesthesia services in an outpatient setting. The board may contract with another state agency or qualified person to conduct these inspections.

(b) Unless it would jeopardize an ongoing investigation, the board shall provide at least five business days' notice before conducting an on-site inspection under this section.

(c) This section does not require the board to make an on-site inspection of a physician's office.

Source Note: The provisions of this §192.5 adopted to be effective May 21, 2000, 25 TexReg 4350; amended to be effective June 29, 2006, 31 TexReg 5107.

§192.6. Requests for Inspection and Advisory Opinion.

(a) The board may consider a request by a physician for an on-site inspection. The board may, in its discretion and on payment of a fee in an amount established by the board, conduct the inspection and issue an advisory opinion.

(b) An advisory opinion issued by the board under this section is not binding on the board, and the board, except as provided by subsection (c) of this section, may take any action under the Medical Practice Act, in relation to the situation addressed by the advisory opinion that the board considers appropriate.

(c) A physician who requests and relies on an advisory opinion of the board may use the opinion as mitigating evidence in an action or proceeding to impose an administrative or civil penalty under the Medical Practice Act. The board or court, as appropriate, shall take proof of reliance on an advisory opinion into consideration and mitigate the imposition of administrative or civil penalties accordingly.

Source Note: The provisions of this §192.6 adopted to be effective May 21, 2000, 25 TexReg 4350; amended to be effective November 30, 2003, 28 TexReg 10498.