

## Chapter 73. Office-Based Surgery

### Subchapter A. General Provisions

#### §7301. Scope of Chapter

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

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

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:424 (March 2004).

#### §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*—moderate sedation or deep sedation, as such terms are defined in this Section.

*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.

*Deep Sedation/Analgesia*—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. Monitoring of patients undergoing deep sedation shall only be performed by an anesthesia provider.

*General Anesthesia*—a drug-induced loss of consciousness, by use of any anesthetic induction agent or otherwise, 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. General anesthesia shall only be performed by an anesthesia provider.

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

*Moderate Sedation/Analgesia (conscious sedation)*—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. Monitoring of the patients undergoing moderate sedation shall be performed by qualified monitoring personnel or an anesthesia provider.

*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.

*Qualified Monitoring Personnel*—an appropriately trained, qualified and licensed health care provider in this state, who is currently certified in advanced cardiac life support, or pediatric advanced life support for pediatric patients, and designated to monitor and attend to the patient during the pre-operative, intra-operative and post-operative periods.

*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.

*Single Oral Dose*—one dosage unit of a medication in an amount recommended by the manufacturer of the drug for oral administration to the patient.

*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).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:424 (March 2004), amended LR 40:2246 (November 2014).

### **§7305. Exemptions**

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

1. exempt surgical procedures include those:

a. that do not involve a drug induced alteration of consciousness and do not require the use of anesthesia or an anesthetic agent, those using only local, topical or regional anesthesia or those using a single oral dose of a sedative or analgesic which is appropriate for the unsupervised treatment of anxiety or pain; 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. exempt 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.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:425 (March 2004), amended LR 40:2246 (November 2014).

### **§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.

B. The level of sedation utilized for office-based surgery shall be appropriate to the procedure. Under no circumstances shall a physician withhold appropriate sedation or under-sedate a patient for the purpose of avoiding compliance with the requirements of this Chapter.

C. General anesthesia shall not be utilized in office-based surgery. Any surgery or surgical procedure that employs general anesthesia shall only be performed in an exempted clinical setting as described in Section 7305 of this Chapter.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:425 (March 2004), amended LR 40:2246 (November 2014).

### **§7308. Required Information**

A. Each physician shall report to the board annually as a condition to the issuance or renewal of medical licensure, whether or not and the location(s) where the physician performs office-based surgery, along with such other information as the board may request.

B. The information shall be reported in a format prepared by the board, which shall be made a part of or accompany each physician's renewal application for medical licensure.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 40:2247 (November 2014).

### **§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. have completed residency training in a specialty that encompasses the procedure performed in an office-based surgery setting;

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. 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.

### 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. A physician performing office-based surgery shall remain physically present throughout surgery and be immediately available for diagnosis, treatment and management of complications or emergencies. The physician shall also insure the provision of indicated post-anesthesia care.

b. The anesthesia provider or qualified monitoring personnel shall be physically present throughout the surgery.

c. The anesthesia provider or qualified monitoring personnel shall remain in the facility until all patients have been released from anesthesia care by a CRNA or a physician.

d. Discharge of a patient shall be properly documented in the medical record and include:

- i. confirmation of stable vital signs;
- ii. return to pre-surgical mental status;
- iii. adequate pain control;
- iv. minimal bleeding, nausea and vomiting;
- v. confirmation that the patient has been discharged in the company of a competent adult; and
- vi. time of discharge.

### 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. 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 by the physician performing office-based surgery 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. A written policy and procedure manual for the orderly conduct of the facility shall be prepared, maintained on-site and updated annually, as evidenced

by the dated signature of a physician performing office-based surgery at the facility 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. The policy and procedure manual shall specify the duties and responsibilities of all facility personnel.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:425 (March 2004), amended LR 40:2247 (November 2014).

### **§7311. Administration of Anesthesia**

A. Evaluation of the Patient. All patients shall have a pre-surgical evaluation (history and physical) to screen for and identify any medical condition that could adversely affect the patient's response to the medications utilized for moderate or deep sedation.

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. Deep sedation/analgesia 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. Qualified monitoring personnel assigned to monitor a patient shall not participate in the surgery.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:427 (March 2004), amended LR 40:2247 (November 2014).

### **§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.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:427 (March 2004).

### **§7314. Creation of Log; Board Access to Log and Facilities**

A. A physician shall create and maintain a continuous log by calendar date of all office-based surgical procedures. The log shall include patient identifiers and the type and duration of each procedure and remain at the physician's office-based surgery facility. The log shall be provided to the board's staff or its agents upon request.

B. A physician who performs office-based surgery shall respond to the inquiries and requests of, and make his or her office-based surgery facility available for inspection by, the board's staff or its agents at any reasonable time without the necessity of prior notice. The failure or refusal to respond or comply with such inquiries or requests, or make an office-based surgery facility available for inspection, shall be deemed a violation of this Chapter.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 40:2247 (November 2014).

**§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.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 30:427 (March 2004).