# NOTICE OF INTENTNotice of Intent

**Department of Health and Hospitals**

**Board of Medical Examiners**

**Office-Based Surgery**

(LAC 46:XLV.7301*, et seq*.)

Notice is hereby given that pursuant to the authority vested in it by the Louisiana Medical Practice Act, R.S. 37:1261-1292, and in accordance with the applicable provisions of the Louisiana Administrative Procedure Act, R.S. 49:950 *et seq*., the Louisiana State Board of Medical Examiners (Board) intends to amend its rules governing Office-Based Surgery.

The proposed rule changes revise definitions, increase physician reporting requirements, clarify conditions necessary to preform office-based surgery, enact regulations for Level I, II, and III office-based surgeries, and correct typographical errors.

The proposed amendments are set forth below.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions

Subpart 3. Practice

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~~ by individuals licensed to practice medicine, including podiatry, 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~~context clearly states otherwise, the following terms and phrases shall have the meanings specified.

*A~~nesthesia~~*~~―moderate sedation or deep sedation, as such terms are defined in this Section.~~

***Anesthesia***―a medical intervention that causes a temporary loss of sensation or awareness, usually for medical or veterinary purposes. It prevents patients from feeling pain during procedures like surgery, dental work, and tissue sample removal. Anesthesia works by stopping nerves from sending signals to the brain.

*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~~postgraduate 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 t~~he~~ this 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.

***Equipment***--implicit within the use of the term “equipment” in this Chapter is the requirement that the specific item named must meet generally accepted current performance standards.

*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,~~ *et seq.,* as may be amended from time to time.

*Major Conduction Anesthesia*—a drug or combination of drugs to interrupt nerve impulses without loss of consciousness.

*Medical Records*—as required by this Chapter, a complete record maintained by the physician or podiatric physician performing office-based surgery to include patient history and physical, diagnostic evaluations, consultations, laboratory and diagnostic reports, informed consents, preoperative, intraoperative, and postoperative anesthesia assessments, course of anesthesia (including monitoring modalities), drug administration, and discharge and follow-up care.

*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 currently certified in advanced cardiac life support or pediatric advanced life support for pediatric patients who is lawfully entitled to engage in the practice of medicine or podiatry in this state as evidenced by a current license or permit ~~duly~~ issued by the board.

***Podiatrist***—a person lawfully allowed to engage in the practice of podiatry as evidence by current license or permit issued by the board.

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

Reasonable Proximity―for patients 13 years of age and older, a location not more than 30 miles away or which may be reached within 30 minutes. For patients 12 years of age and under, a location not more than 15 miles away or which can be reached within 15 minutes.

*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~~ any operative procedure, including ~~but not limited to~~ the use of lasers~~, pulsed light, radio frequency, or medical microwave devices, that is not exempted by these rules~~ preformed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life~~,~~ or relieving suffering, and/or any elective procedure for aesthetic, reconstructive or cosmetic purposes~~. Surgery shall have the same meaning as "operate."~~ , to include, but not be limited to: incision or curettage of tissue or organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure.

***Office-based Surgery***-- surgery which is performed outside a hospital, an ambulatory surgical center, abortion clinic, or other medical facility licensed by the Louisiana Department of Health or a successor agency.

***“Surgical Event”*** --a potentially harmful or life-threatening episode related to either the anesthetic or the surgery. Any surgical event in the immediate perioperative period that must be reported are those which are life-threatening, or require special treatment, or require hospitalization, including, but not limited to: (1) serious cardiopulmonary or anesthetic events; (2) major anesthetic or surgical complications; (3) temporary or permanent disability; (4) coma; or (5) death.

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), LR 51

§7307. Prohibitions

A. ~~On and after January 1, 2005, no~~ 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~~used 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), LR 51 (

§7308. Required ~~Information~~Reporting and Registration

A. Each physician or podiatric physician shall report to the board annually as a condition ~~to~~of 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.~~ the physician performs or intends to perform office-based surgery.

~~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.~~ Each physician or podiatric physician who performs or intends to perform office-based surgery must provide the following information in a format designated by the board:

 1. the medical specialty and types of procedures for which the physician has completed surgical training as required in this Chapter. Alternative credentialling for procedures outside the physician’s core competency must be separately applied for.

2. the location(s) where the physician performs or intends to perform office-based surgery.

3. such other information as the board may request.

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), LR:51

§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 telephones 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.~~

A. For all office-based surgical procedures, the level of sterilization shall meet current OSHA requirements.

B. Complete medical records and documentation must be maintained for each surgical procedure including anesthesia records when applicable. For Level I, Level II, and Level III cases, the medical record must include written informed consent from the patient reflecting the patient’s knowledge of identified risks, consent to the procedure, type of anesthesia, and anesthesia provider.

C. The physician must maintain a log of all Level II and Level III surgical procedures performed, which must include a confidential patient identifier, the type of procedure performed. the type of anesthesia used, the duration of the procedure, the type of postoperative care, and any surgical events. The log and all surgical records shall be provided to investigators of the Louisiana State Board of Medical Examiners upon request.

D. In any liposuction procedure, the physician is responsible for determining the appropriate amount of supernatant fat to be removed from the patient. Using the tumescent method of liposuction, the physician must fully document the anticipated amount of material to be removed in a manner consistent with recognized standards of care. Post-operatively, any deviation from the anticipated amount, and the reason for deviation, must be fully documented in the operative report. Morbidly obese patients should have liposuction performed in a hospital setting unless the physician can document significant advantage to an alternative setting.

E. A policy and procedure manual must be maintained in the office and updated annually. The policy and procedure manual must contain provisions for:

1. duties and responsibilities of all personnel;
2. cleaning and infection control,;
3. a written response plan for emergencies within the facility;
4. personnel training in emergency procedures; and
5. transfer agreements.

F. The performing physician shall report to the board any surgical event that occurs within the office-based surgical setting. This report shall be made within 15 days after the occurrence of a surgical event on a form designated by the board. The filing of a report of surgical event as required by this rule does not, in and of itself, constitute an acknowledgment or admission of malpractice, error, or omission. Upon receipt of the report, the Board may, in its discretion, obtain patient and other records pursuant to authority granted by the Medical Practice Act and pertinent administrative rules.

G. In offices where Level II and Level III office-based surgery is performed, a sign must be prominently posted in the office which states that the office is a doctor’s office regulated pursuant to the rules of the Louisianan State Board of Medical Examniers. This notice must also appear prominently within the required patient informed consent.

H. Office surgery facilities should adhere to recognized standards such as those promulgated by the American Society of Anesthesiologists’ *Guidelines for Office-Based Anesthesia* or theAmerican Association of Nurse Anesthetists’ *Standards for Office Based Anesthesia*.

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).

**§7309.1 Level I Office-based Surgery**

A. Level I office-based surgery includes, but is not limited to:

1. minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas, Loop Electrosurgical Excision Procedures (LEEP), laser cone of cervix, laser/cautery ablation of warts or other lesions, and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness;
2. Incision and drainage of superficial abscesses, skin biopsies, arthrocentesis, paracentesis, dilation of urethra, cystoscopy procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints) performed under topical or local anesthesia not involving drug-induced alteration of consciousness;
3. other procedures requiring only topical, local, or no anesthesia with no drug-induced alteration of respiratory effort or consciousness. Only minimal or no preoperative sedation should be required or used. Level 1 office-based surgery shall only be performed on patients rated ASA class 1 or 2.

B. Requirements for Level I Office-based Surgery

1. Required Training

The physician’s continuing medical education must include management of toxicity or hypersensitivity to local anesthetic drugs and Advanced Life Support Certification.

1. Required Equipment and Supplies

The facility where office-based surgery is to be performed must contain oral airway and positive pressure ventilation device, epinephrine (or other vasopressor), corticosteroids, antihistamines, oxygen, atropine, adequate resuscitative equipment to manage the adverse effects of the anesthesia used, if any type of anesthesia is used. The equipment and skills to establish intravenous access must be available if any other medications are administered. The equipment and supplies must be suitable for and consistent with the potential patient population, i.e., pediatrics, etc.

1. Required Additional Personnel

Unless the specific procedure or conditions dictate otherwise, the presence or assistance of additional personnel is not required for Level I office-based 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 51:

**§7309.2 Level II Office-based Surgery**

A. Level II office-based surgery includes:

 1. any procedure in which perioperative medication and sedation are used orally, intravenously, intramuscularly, or rectally. Such procedures include, but are not limited to: hernia repair, hemorrhoidectomy, reduction of simple fractures, large joint dislocations, breast biopsies, dilatation and curettage, thoracentesis, endoscopies, colonoscopies, hysteroscopies, and cystoscopies and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints). performed using drug-induced alteration of consciousness. If perioperative or intraoperative medication is administered, intraoperative and postoperative monitoring is required.

 2. any procedure in which the patient is sufficiently sedated to allow the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by this definition.

 3.any procedure that has the potential for excessive blood loss.

B. Level of Anesthetic for Level II procedures includes local or peripheral nerve block, including Bier Block, plus intravenous or intramuscular sedation, but with preservation of vital signs.

C. Required Transfer Agreement

1. The physician must have a written transfer agreement from a licensed hospital within reasonable proximity at which the physician has privileges to treat complications.

D. Required Training

1. The physician must document satisfactory completion of surgical training such as board certification or board eligibility for a board approved by the American Board of Medical Specialties or the American Osteopathic Association. Bureau of Osteopathic Specialists. The certification should include training in the procedures performed in the office setting.

E. Required Equipment and Supplies

 1. The location where anesthesia is administered and/or the office-based procedure is being performed must maintain at all times a full and complete crash cart that contains all equipment, medications, and supplies as recommended in current ACLS standards.

F. Required Assistance of Other Personnel

1. In addition to the physician at least one assistant certified in Advanced Life Support must be present during any Level II procedure. Unless an anesthesiologist or certified registered nurse anesthetist is present to manage the anesthetic, there must be at least one person certified in Advanced Cardiac Life Support or pediatric advanced life support, if applicable, present during any Level II procedure.
2. A registered nurse may only administer analgesic doses of medications on the direct order of a physician.
3. An assisting anesthesia provider, including a nurse providing sedation, may not function in any other capacity during the procedure. If additional assistance is required by the specific procedure or patient circumstances, such assistance must be provided by another physician, registered nurse, licensed practical nurse, or operating room technician.

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 51

**§7309.3 Level III Office-based Surgery**.

A. Level III office-based surgery includes:

 1. Surgery that involves, or might foreseeably require, the use of general anesthesia or major conduction anesthesia and perioperative sedation. This includes:

a. Intravenous sedation beyond that defined for Level II office surgery;

b. General Anesthesia: loss of consciousness and loss of vital reflexes with probable requirement of external support of pulmonary or cardiac functions;

c. Major Conduction anesthesia, including epidural, spinal, caudal or any block of a nerve or plexus more proximal than the hip or shoulder joint including visceral nerve blocks.

d. Self-controlled auto-administered nitrous oxide machines, such as Pronox;

B. Only patients classified under the American Society of Anesthesiologists’ (ASA) risk classification criteria as Class I, II, or III are appropriate candidates for Level III office surgery. For ASA Class III patients, the surgeon must document in the patient’s record the justification for an office procedure rather than other surgical venues. The record must also document precautions taken that make the office a preferred venue for the particular procedure to be performed.

C. Required Transfer Agreement

 1. The physician must have a written transfer agreement from a licensed hospital within reasonable proximity at which the physician has privileges to treat complications.

D. Required Training and Personnel

1. To be eligible to perform office-based surgery, the physician must document satisfactory completion of surgical training such as board certification or board eligibility by a board approved by the American Board of Medical Specialties or American Osteopathic Association Bureau of Osteopathic Specialists. The certification should include training in the procedures to be performed in the office setting. Alternative credentialing for procedures outside the physician’s core curriculum and specialty training must be applied for through the Board.

2. In addition to the surgeon, at least one assistant certified in Advanced Life Support must be present during any Level III procedure. At least one person certified in Advanced Cardiac Life Support must be present during any Level III procedure unless there is an anesthesiologist or certified registered nurse anesthetist to manage the anesthetic.

3. Emergency procedures related to anesthesia complications should be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location.

E. Required Equipment and Supplies

1. Equipment, medication and monitored post-anesthesia recovery must be available in the office. If anesthetic agents include inhaled agents, other than nitrous oxide, medications must include a stock of no less than 12 vials of Dantrolene.

2. The facility, in terms of general preparation, equipment, and supplies, must be comparable to a free standing ambulatory surgical center, including, but not limited to, recovery capability, and must have provisions for proper record keeping.

3. Blood pressure monitoring equipment; EKG; end tidal CO2 monitor; pulse oximeter, precordial or esophageal stethoscope, emergency intubation equipment and a temperature monitoring device must be available for all phases of perioperative care. This equipment must be sized to the patient whether adult or pediatric.

4. Table capable of Trendelenburg and other positions necessary to facilitate the surgical procedure.

5. IV solutions and IV equipment.

6. A full and complete crash cart that contains all equipment, medications, and supplies as recommended in current ACLS standards.

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 51

**§7309.4 Laser Devices**

A.The use of laser, pulsed light or similar devices, either for invasive or cosmetic procedures, is considered to be the practice of medicine in the state of Louisiana and therefore such use shall be limited to physicians, podiatric physicians, and qualified additional personnel directly supervised by physicians, such that a physician is on the premises and would be directly involved in the treatment if required.

B. These rules shall not apply to any person licensed to practice dentistry if the laser, pulsed light, or similar device is used exclusively for the practice of dentistry.

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 51

§7311. Administration of Anesthesia

A. Evaluation of the Patient. All patients shall have a ~~pre-surgical~~presurgical 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~~consultations 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), LR 51:

§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), LR 51:

§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).

**Family Impact Statement**

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed rules on the family has been considered. It is not anticipated that the proposed rules will have any impact on family, formation, stability or autonomy, as described in R.S. 49:972.

**Poverty Statement**

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed rules on those that may be living at or below one hundred percent of the federal poverty line has been considered. It is not anticipated that the proposed rules will have any impact on child, individual or family poverty in relation to individual or community asset development, as described in R.S. 49:973.

**Provider Statement**

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed rules on organizations that provide services for individuals with developmental disabilities has been considered. It is not anticipated that the proposed rules will have any impact on the staffing, costs or overall ability of such organizations to provide the same level of services, as described in HCR 170.

**Small Business Statement**

It is not anticipated that the proposed rules will have any adverse impact on small businesses as defined in the Regulatory Flexibility Act, R.S. 49:965.2 et. seq.

**Public Comments**

Interested persons may submit written data, views, arguments, information or comments on the proposed rules to Jacintha Duthu, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, Louisiana, 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4:00 p.m., January 9, 2025.

**Public Hearing**

A request pursuant to R.S. 49:953(A)(2) for a public hearing must be made in writing and received by the Board within 20 days of the date of this notice. If a public hearing is requested to provide data, views, arguments, information or comments orally in accordance with the Louisiana Administrative Procedure Act, the hearing will be held on January 28. 2025, **9** a.m., at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, Louisiana 70130. Any person wishing to attend should call to confirm that a hearing is being held.

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Office-Based Surgery

1. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

Aside from the cost of rulemaking, estimated at approximately $1,500 in FY 25 for publishing the proposed and final rules in the *Louisiana Register*, the proposed rule changes are not expected to result in implementation costs or savings for state or local governmental units. The cost of rulemaking will be covered by self-generated funds.
The proposed rule changes revise definitions, increase physician reporting requirements, clarify conditions necessary to perform office-based surgery, enact regulations for Level I, II, and III office-based surgeries, and correct typographical errors.

1. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)
There are no anticipated direct effects on the revenue collections for state or local governmental units.
2. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS (Summary)

There are no anticipated monetary effects on directly affected persons, small businesses, or non-governmental groups. However, there will be significant benefits to public health and safety as physicians adhere to the new regulations when performing office-based surgery.

Physicians should already be conducting their office-based surgeries to meet this standard, so there should not be much financial change. However, offices may have to expend resources to comply if they do not already.

1. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There is not any anticipated effect on competition and employment.

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| Vincent A. Culotta, Jr., M.D. | Patrice Thomas |
| Executive Director  | Deputy Fiscal Officer |
|  | Legislative Fiscal Office |