

NOTICE OF INTENT

Department of Health and Hospitals Board of Medical Examiners

Physician Practice; Office-Based Surgery
(LAC 46:XLV.Chapter 73)

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 et. seq., and pursuant to the authority of the Louisiana Medical Practice Act, R.S. 37:1270, the Louisiana State Board of Medical Examiners (board) intends to amend its rules governing office-based surgery, LAC 46XLV.7301 et seq. The proposed amendments update definitions and better provide for consistency with current terminology in the application of various levels of sedation and corresponding health care providers involved in the treatment and care of patients undergoing office-based surgery (OBS); redefine exemptions and prohibitions; better provide for quality of care and patient monitoring; add more specificity to documentation requirements and maintenance of medical records and pre-surgical evaluations; provide mechanisms for the board to identify physicians performing OBS procedures; and update the rules generally.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Profession

Subpart 3. Practice

Chapter 73. Office-Based Surgery

Subchapter A. General Provisions

§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.

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.

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.

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.

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.

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:

§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. ...
2. exempt clinical settings include:
 - a. - d.iii. ...

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

§7307. Prohibitions

- A. ...
- 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), 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:

§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), 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR

§7309. Prerequisite Conditions

- A. - A.2.a.i. ...
 - ii. have completed residency training in a specialty that encompasses the procedure performed in an office-based surgery setting;
 - b. ...
 - 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. - 4a. ...

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. - 6.b....

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.

6.d. - 7.c. ...

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. - iii.(c). ...

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), 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:

§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. - C. ...

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), 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:

§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), 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR

Family Impact Statement

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

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed amendments 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 amendments 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 Impact Statement

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed amendments on organizations that provide services for individuals with development disabilities has been considered. It is not anticipated that the proposed amendments 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.

Public Comments

Interested persons may submit written data, views, arguments, information or comments on the proposed amendment to Rita Arceneaux, Confidential Executive Assistant, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA, 70130, (504) 568-6820, ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4 p.m., August 19, 2014.

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 August 26, 2014, at 10 a.m. at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130. Any person wishing to attend should call to confirm that a hearing is being held.

Cecilia Mouton, M.D.
Executive Director

**FISCAL AND ECONOMIC IMPACT
STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Physician Practice;
Office-Based Surgery**

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS)
TO STATE OR LOCAL GOVERNMENT UNITS
(Summary)**

Other than one-time costs for notice and rule publication estimated at a total of \$689 in FY 15, it is not anticipated that the proposed amendments will not result in any additional costs or savings to the Board or other state or local governmental units. The Board anticipates devoting some administrative resources to processing that portion of its annual renewal applications for physicians who perform office-based surgery (OBS). The number of physicians performing OBS is unknown but believed to be relatively small and the information will be included in, and processed with, existing systems for annual renewals of medical licensure. The Board anticipates it can absorb the projected modest increase in administrative workload with existing personnel and resources.

**II. ESTIMATED EFFECT ON REVENUE COLLECTIONS
OF STATE OR LOCAL GOVERNMENTAL UNITS
(Summary)**

There is no anticipated effect on the revenue collections of the Board of Medical Examiners or any state or local governmental unit.

**III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS
TO DIRECTLY AFFECTED PERSONS OR
NONGOVERNMENTAL GROUPS (Summary)**

Any physician who: uses general anesthesia in an OBS setting that is not exempt under Section 7305A.2 of the rules; does not utilize an anesthesia provider to monitor patients undergoing deep sedation; utilizes unlicensed individuals, or licensed individuals who are not certified in advanced life support measures, to monitor and attend to OBS patients; or performs OBS as defined by the rules, would be directly affected by the proposed amendments and may experience an increase in costs and/or decrease in revenue to an extent that is not quantifiable. It is not possible to estimate the proposed rule change's impact in these respects as no information or data is available either as to the number of physicians who perform OBS falling within the purview of the existing rules or the extent to which they may/may not already comply with the proposed changes. Patients undergoing OBS

procedures may realize potential benefits to their health, safety, and welfare.

Pursuant to the proposed amendments, OBS requiring the use of general anesthesia may only be performed in an exempted clinical setting, only anesthesia providers may monitor patients receiving deep sedation, and only licensed health care providers who are properly certified in advanced life support measures may monitor/attend to patients undergoing OBS procedures. Further, the proposed changes to the levels of sedation and exemptions may result in application of the rules to some procedures that were previously exempt under Section 7305A.1. The proposed amendments also require physicians to report whether they perform OBS on their renewal application for medical licensure, maintain a list of OBS and update their OBS policy and procedure manual on an annual basis. The Board does not anticipate that these requirements will have a material effect on paperwork or workload of affected physicians.

**IV. ESTIMATED EFFECT ON COMPETITION AND
EMPLOYMENT (Summary)**

It is not anticipated that the proposed rules will have any significant impact on competition or employment in either the public or private sector.

Cecilia Mouton, M.D.
Executive Director
1407#042

John D. Carpenter
Legislative Fiscal Officer
Legislative Fiscal Office