

STATE OF LOUISIANA

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To: Dr. Vincent A. Culotta, Jr.

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Louisiana State Board of Medical Examiners

From: Jessica Weimer

Louisiana Department of Justice

Occupational Licensing Review Program

Date: May 6, 2025

Subject: Louisiana State Board of Medical Examiners

Proposed Amendments to LAC 46:XLV.7301 et seq.

Regarding Office Based Surgery

I. <u>SUMMARY</u>

The Louisiana State Board of Medical Examiners (the "*Board*") proposes amending LAC 46: XLV.7301, *et seq.* (the "*Proposed Amendments*"), regarding office-based surgery regulations.¹

The Board published a Notice of Intent to promulgate the Proposed Amendments on December 20, 2024.² The Notice invited written comments on these Proposed Amendments until January 9, 2025 and received none³.

Pursuant to La. R.S. 49:260, the Board submitted the Proposed Amendments to the Louisiana Department of Justice's Occupational Licensing Review Program ("*OLRP*") on February 18, 2025. The OLRP invited public comments on the Proposed Amendments February 21, 2025 through February 28, 2025 and received no comments.

The OLRP has the statutory authority to review the substance of each proposed occupational regulation submitted to ensure compliance with clearly articulated state policy and adherence to applicable state law.⁴ An Occupational Regulation is a "rule defined in the Administrative Procedure Act that has reasonably foreseeable anti-competitive effects. Any license, permit, or regulation established by a ... Board not composed of a controlling number of active market participants is excluded." The Louisiana Administrative Procedure Act ("APA") defines a rule as an agency (Board) requirement for conduct or action prescribing the procedure or

¹ Louisiana Register, Vol. 50, No. 12, at pgs. 1921-1926

² Id.

³ Id. at pg. 1926

⁴ LSA-R.S. 49:260 (D) (2)

⁵ LSA-R.S. 49:260 (G) (4)

practice requirements of the agency (Board).⁶ Anti-Competitive behavior is an act, or series of acts, that have the effect of harming the market or the process of competition among businesses, or a tendency to reduce or eliminate competition, with no legitimate business purpose.⁷

As set forth below, the OLRP has determined the Board's Proposed Amendments to LAC 46: XLV §7301 *et seq.* adhere to clearly articulated state policy and are within the Board's statutory authority. Therefore, these amendments are approved for promulgation as drafted in accordance with the Louisiana APA.

II. <u>ANALYSIS</u>

The Louisiana Legislature has deemed it the policy of the State of Louisiana in the interest of public health, safety, and welfare to provide laws and provisions covering the practice of medicine and its subsequent use, control, and regulation to protect the public against unprofessional, improper, unauthorized, and unqualified practice of medicine and from unprofessional conduct of persons licensed to practice medicine. The Board of Medical Examiners was created to control and regulate the practice of medicine in this state. The Board is authorized to take appropriate administrative actions to regulate the practice of medicine in Louisiana in order to promote the established policy of the State. The Board may also adopt rules, regulations and standards necessary to carry out the Board's duties, powers and functions as provided for in LSA R.S. 37:1261 et seq. 11

A. Proposed LAC 46:XLV.7301 Scope of Chapter (Office Based Surgery)

Louisiana Administrative Code 46:XLV.7301 currently states, "The rules of this Chapter govern the performance of office-based surgery by physicians in this state." The Board proposes amending this section to clarify the rules govern individuals licensed to practice medicine, including podiatry, in this state. Podiatry is the health science profession focused on the prevention, diagnosis, and treatment (medical and surgical) of conditions affecting the human foot and adjacent connective tissue to the proximal end of the talus¹². No one shall practice podiatry unless duly licensed to do so by the Louisiana State Board of Medical Examiners.¹³

The proposed amendment clarifies that podiatrists are included in the definition of physicians and are subject to the provisions of LAC 46:XLV.7301 et seq. This rule is not an occupational regulation with reasonably foreseeable anti-competitive effects, and thus does not require input

⁶ LSA-R.S. 49:951 (8)

⁷ Black's Law Dictionary, 12th Edition 2024

⁸ LSA-R.S. 37:1261

⁹ LSA-R.S. 37:1263

¹⁰LSA-R.S. 37:1270 (A)(1)

¹¹LSA-R.S. 37:1270 (B)(6)

¹² LSA-R.S. 37:611(3)(a)(i)

¹³ LSA-R.S. 37:712; LSA-R.S.37:611(A)(1)

from the OLRP. Therefore, the Board may proceed with promulgation of this amendment in accordance with the Louisiana APA.

B. Proposed LAC 46:XLV.7303 Definitions

The Board proposes adding the following definitions to §7303:

- 1. Equipment
- 2. Major Conduction Anesthesia
- 3. Medical Records
- 4. Podiatrist
- 5. Surgical Event

The Board proposes modification of the following definitions in §7303:

- 1. Anesthesia
- 2. Anesthesiologist
- 3. Certified Registered Nurse Anesthetist (CRNA)
- 4. Medical Practice Act or the Act
- 5. Office-Based Surgery
- 6. Physician
- 7. Qualified Monitoring Personnel
- 8. Regional Proximity
- 9. Regional Anesthesia
- 10. Surgery

The Board proposes removing the following from §7303:

- 1. Office Based Surgery Setting or Facility
- 2. Single Oral Dose

The Board may adopt rules, regulations and standards necessary to properly regulate the practice of medicine in the State of Louisiana in order to protect the public from the unqualified practice of medicine and carry out the board's duties, powers and functions. ¹⁴ While this rule may govern the practice of office-based surgery, it does not have any reasonably foreseeable effects that would be a market barrier into or the continued practice of occupational therapy. Therefore, this rule does not require input from the OLRP pursuant to LA R.S. 49:260 and the Board may proceed with promulgation of this amendment in accordance with the Louisiana APA

C. Proposed LAC 46: XLV.7305 (Exemptions), 7307 (Prohibitions), and 7311 (Administration of Anesthesia)

The Board proposes wording and/or stylistic changes to LAC 46XLV.7303, 7305, and 7311 that do not alter the intent or substantive meaning of the existing regulations. The proposed amendment to §7303 replaces the word "utilized" with "used" and revises the phrase "On or

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¹⁴ LSA R.S. 37:1261, LSA R.S. 37:1270 (B)(6)

after January 1, 2005 no..." to begin simply with "No." The proposed §7305 references the "Louisiana Department of Health" rather than the "Louisiana Department of Health and Hospitals." Lastly, the proposed amendment to §7311 corrects a typographical error in the word nonsurgical and revises "consults" to "consultations." These rules are not Occupational Regulations with reasonably foreseeable anti-competitive effects, and thus do not require input from the OLRP. Therefore, the Board may proceed with promulgation of these amendments in accordance with the Louisiana APA.

D. Proposed LAC 46:XLV.7308 Required Reporting and Registration

The current rule §7308 requires each physician to annually report whether and where they perform office-based surgery, along with any other information requested by the board, using a board prescribed format submitted with the physician's renewal for medical licensure.

The Board proposes increasing physician requirements to include physicians or podiatric physicians, whether or not the physician performs or intends to perform office-based surgery. The Board also proposes requiring the following information in a board prescribed format:

- 1. Medical specialty and types of procedures for which the physician has completed surgical training;
- 2. Location(s) where the physician performs or intends to perform the office-based surgery; and
- 3. Other information as the Board may request.

The Board also adds a specification that alternative credentialing procedures outside the physician's core competency must be separately applied for.

Reporting requirements may be barriers to market entry as they may burden smaller or new providers that lack administrative infrastructure for compliance or by increasing operational costs. In more extreme cases, such requirements could be used to disadvantage competitors under the guise of regulatory compliance. However, the proposed amendment to §7308 appears reasonable, uniformly applied and tailored to serve legitimate regulatory objectives. Oversight by the Board constitutes a valid exercise of its authority to protect the public from unprofessional, improper, unauthorized, and unqualified practice of medicine. The Board shall take appropriate administrative actions to regulation the practice of medicine and may adopt rules, regulations, and standards necessary to carry out its duties, powers and functions. Therefore, this proposed amendment is within the Board's statutory authority and adheres to clearly articulated state policy. Therefore, the Board may proceed with promulgation in accordance with the Louisiana APA.

E. Proposed LAC 46:XLV.7309 Prerequisite Conditions

LSA R.S. 46:LXV.7309 establishes standards for physicians performing office-based surgery, including facility compliance with applicable health, safety and sanitation laws; requirements for sterile equipment, emergency supplies, and medications; and maintenance of appropriate licensure and training for all personnel. It mandates qualifications for performing procedures, including relevant hospital privileges or specialty training, and outlines criteria for patient

¹⁵ LSA R.S. 37:1261

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¹⁶ LSA R.S. 37:1270(A)(1) and (B)(6)

selection, informed consent, and post-anesthesia care. Detailed provisions govern monitoring equipment, emergency preparedness, patient transfer protocols, and medical record keeping. Additionally, the rules requires each facility to maintain an annually updated written policies and procedures manual addressing anesthesia management, infection control, and emergency responses, with all staff trained and familiar with these protocols.

The Board proposes amending \$7309 to clarify the conditions necessary to perform office-based surgery, and enact regulations for Level I, II, and III office-based surgeries. The amendment to \$7309 imposes comprehensive standards for office-based surgical procedures, including compliance with current OSHA sterilization requirements and detailed documentation protocols. Physicians must maintain complete medical records for each procedure, including informed consent and anesthesia documentation for Level I–III surgeries. A procedural log for Level II and III cases must be kept and made available to the Louisiana State Board of Medical Examiners upon request. Specific requirements are established for liposuction, including preoperative documentation, postoperative variance explanations, and recommended hospital setting for morbidly obese patients. Offices must maintain and annually update a policy and procedure manual covering staff roles, infection control, emergency protocols, training, and transfer agreements. Surgical events must be reported to the Board within 15 days, and offices performing Level II or III procedures must prominently display regulatory signage. Facilities are also expected to adhere to nationally recognized anesthesia standards.

The Board proposes adding §§7309.1, 7309.2, and 7309.3 to define Level I, II, and III office-based surgery and their requirements. Level I office-based surgery includes minor procedures performed under topical or local anesthesia that do not involve drug-induced alterations in consciousness or respiratory effort. Examples include skin lesion excisions, superficial abscess drainage, and joint reductions, and may only be performed on ASA Class I or II patients. Physicians must have training in managing anesthetic reactions and hold Advanced Life Support Certification. Facilities must be equipped with appropriate emergency and resuscitative supplies, including oxygen, airway devices, and medications. Additional personnel are generally not required unless dictated by the specific procedure or patient condition.

Level II office-based surgery includes procedures involving drug-induced sedation, administered orally, intravenously, intramuscularly, or rectally, sufficient to allow patients to tolerate unpleasant procedures while maintaining vital functions and responsiveness. These procedures may involve local or peripheral nerve blocks combined with sedation and include surgeries such as hernia repairs, endoscopies, and breast biopsies. Physicians must have appropriate surgical training and maintain a written transfer agreement with a nearby hospital where they hold privileges. Facilities must have a crash cart meeting ACLS standards, and at least one assistant certified in Advanced Life Support must be present during procedures. Anesthesia providers must not assume dual roles during procedures, and additional support staff must be provided as needed based on the patient or procedure.

Level III office-based surgery involves procedures requiring, or potentially requiring, general anesthesia, major conduction anesthesia (e.g., epidural, spinal, or nerve plexus blocks), or deep

sedation beyond Level II parameters. Only patients classified as ASA Class I–III may undergo Level III procedures, with additional documentation required for Class III patients justifying the office setting. Physicians must maintain a hospital transfer agreement and demonstrate appropriate board certification or specialty training, with alternative credentialing required for procedures outside their core competencies. An assistant certified in Advanced Life Support must be present, and emergency protocols must be documented and posted. The facility must be equipped comparably to a freestanding ambulatory surgical center, including a full crash cart, post-anesthesia recovery capability, and advanced monitoring and anesthesia equipment suitable to the patient's size and needs.

The proposed amendments may have reasonably foreseeable anticompetitive effects. Specifically, the heightened facility, equipment, staffing, and documentation requirements, particularly for Levels II and III OBS, may create substantial barriers to market entry by creating a burden for new, small, or independent providers. These restrictions could reduce competition and increase costs for physicians. However, it is the policy of the state to protect the health, safety, and public welfare against the improper practice of medicine. The proposed amendments are narrowly tailored to advance the state's legitimate interest in protecting public health and safety by ensuring that office based surgical procedures are performed in environments properly equipped to manage anesthesia related risks and potential surgical complications. By categorizing OBS into levels based on complexity of sedation and the risks to the patient, the rules provide a structured framework in alignment with provider capability and degrees of medical risk. Requirements such as transfer agreements, appropriate monitoring equipment, and delineation of permissible procedures based on ASA classification help safeguard against foreseeable adverse events without banning office-based surgery.

The Board is authorized to take appropriate administrative actions to regulate the practice of medicine in the state of Louisiana and may adopt rules, regulations, and standards as necessary to carry out its duties, powers, and functions.¹⁷ These amendments are consistent with the Board's statutory authority to regulate the practice of medicine in a manner that promotes the health, safety, and welfare of the citizens of Louisiana. The Board may proceed with promulgation in accordance with the Louisiana APA.

III. <u>Determination</u>

The Board is a state regulatory body created "as a matter of policy in the interests of public health, safety, and welfare to provide laws and provisions covering the granting of [the privilege of the practice of medicine] and its subsequent use, control, and regulation to the end that the public shall be properly protected against unprofessional, improper, unauthorized, and unqualified practice of medicine from unprofessional conduct of persons licensed to practice medicine." The Board may adopt rules, regulations, and standards necessary to carry out its duties, powers, and functions as mandated by the legislature. ¹⁹ The Proposed Amendments are within the Board's statutory authority and adhere to clearly articulated state policy of

¹⁷ LSA R.S. 37:1270(A)(1) and (B)(6)

¹⁸ LSA R.S. 37:1261

¹⁹ LSA R.S. 37:1270(B)(6)

protecting the public health, safety, and welfare of the citizens of this state and are approved as submitted by the Attorney General and may be adopted by the Board.

OFFICE OF THE ATTORNEY GENERAL OCCUPATIONAL LICENSING REVIEW PROGRAM

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