

NOTICE OF INTENT
Department of Health and Hospitals
Board of Medical Examiners

Physician Practice; Marijuana for Therapeutic
Use by Patients Suffering From a Debilitating
Medical Condition—
(LAC 46:XLV Chapter 77)

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 *et. seq.*, and pursuant to the authority vested in the Louisiana State Board of Medical Examiners (Board) by the Louisiana Medical Practice Act, R.S. 37:1270, the Board intends to amend its Rules governing physicians who utilize therapeutic marijuana in the treatment of their patients who are suffering from a debilitating medical condition, LAC 46:XLV Chapter 77. The proposed amendments are needed to conform the Board's rules to Act 96 of the 2016 Regular Session of the Louisiana Legislature. Among other items, the proposed changes: incorporate changes in definitions made to the law e.g., changing a *prescription* to a *recommendation* (7705) and a *qualified medical condition* to a *debilitating medical condition* (7701, 7705); expand the conditions for which therapeutic marijuana may be recommended from three to ten (7705); provide for instances where the United States Food and Drug Administration may subsequently approve therapeutic marijuana for a debilitating medical condition in the same or a different form (7709A.2); consistent with the law, provide that physicians who recommend therapeutic marijuana must be domiciled in this state (7711A.3); incorporate certain changes to provisions on medical diagnoses and independent medical judgment consistent with guidance by the Federation of State Medical Boards and update provisions relative to the treatment plan and patient informed consent (7717); remove the delay in rule implementation so that the rules will be effective upon promulgation (7725); and update the suggested form for physician recommendation for therapeutic marijuana consistent with the changes to the law (7729).

**Chapter 77. Marijuana for
Therapeutic Use by Patients
Suffering from a Debilitating
Medical Condition**

**Subchapter A. General
Provisions**

**§7701. Preamble, Warning, and Suggested
Consultation**

A. Preamble—State Law. Pursuant to Act 261, R.S. 40:1046, of the 2015 Session of the Louisiana Legislature, as amended and supplemented by Act 96 of the 2016 Session of the Louisiana Legislature, the Louisiana State Board of Medical Examiners was directed to:

1. promulgate rules and regulations authorizing physicians licensed to practice in this state to recommend marijuana for therapeutic use by patients clinically diagnosed as suffering from a debilitating medical condition; and

2.-C. . . .

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2631 (December 2015), amended, LR

§7703. Scope of Chapter

A. This Chapter is being adopted in order to comply with the obligations imposed upon the board by Act 261, R.S. 40:1046, of the 2015 Session of the Louisiana Legislature, as amended and supplemented by Act 96 of the 2016 Session of the Louisiana Legislature, and govern a physician's recommendation for the therapeutic use of marijuana for a patient suffering from a debilitating medical condition with whom the physician has established a bona-fide physician-patient relationship.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292 and R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015), amended, LR.

§7705. Definitions

A. As used in this Chapter, the following terms and phrases shall have the meanings specified.

* * *

Conventional Treatment or Conventional Medicine—therapeutic modalities and medications offered or employed by a physician in the treatment of a debilitating medical condition which are generally accepted and recognized as falling within the standard of care in the course of medical practice based upon medical training, experience and peer reviewed scientific literature.

Debilitating Medical Condition (also referred to in this Chapter as a *Qualifying Medical Condition*)—cancer, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy, spasticity, Crohn's disease, muscular dystrophy, or multiple sclerosis, and/or such other diseases or conditions that may subsequently be identified as a debilitating medical condition by amendment of R.S. 40:1046 or other state law.

Qualifying Medical Condition—a debilitating medical condition, as defined in this Section.

Recommend or Recommendation (also referred to in this Chapter as a *Written Request or Recommendation*)—a physician's written direction transmitted in a form and manner specified in §7721 of this Chapter, to a licensed therapeutic marijuana pharmacy. The issuance of a recommendation must be in good faith and in the usual course of the physician's professional practice.

Step Therapy or Fail First Protocols—as used in this Chapter means that if the USFDA approves the use of therapeutic marijuana for a debilitating medication condition, in a form or derivative that is different than provided for in this Chapter, the USFDA form or derivative shall be used first. If the physician determines that such USFDA approved form or derivative has been ineffective in the treatment of the patient's debilitating medical condition, the physician may then recommend a form of therapeutic marijuana provided in this Chapter for use by the patient as medically necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015), amended, LR.

Subchapter B. Prohibitions and Exceptions

§7709. Exceptions

A. This Chapter is subject to the following exceptions:

1. The rules of this Chapter shall not apply to a physician's prescription of cannabinoid derived pharmaceuticals that are approved by the USFDA for administration to patients.

2. If the USFDA approves the use of therapeutic marijuana:

a. in the same form provided for in this Chapter for a debilitating medical condition, identified in §7705A, that medical condition shall no longer be covered by this Chapter;

b. in a form or derivative different than provided for in this Chapter for a debilitating medical condition, identified in §7705A, that disease state shall remain covered by this Chapter. However, the patient shall first be treated through utilization of step therapy or fail first protocols.

B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015), amended LR.

Subchapter C. Registration

§7711. Registration, Physician Eligibility

A. To be eligible for registration under this Chapter a physician shall, as of the date of the application:

1.-2. ...

3. be domiciled in and practice at a physical practice location in this state; and

4.-D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015), amended, LR.

Subchapter D. Marijuana for Therapeutic Purposes, Limitations, Access to Records

§7717. Use of Marijuana for Therapeutic Purposes, Limitations

A. . . .

1. **Medical Diagnosis.** A medical diagnosis of a debilitating medical condition shall be clinically established and clearly documented in the patient's medical record, based on an in-person physical examination. The diagnosis shall be supported by an assessment of the patient which, at a minimum, shall include a review of the patient's present illness, medical and surgical history, social history, alcohol and substance use history (including addiction, mental illness and psychotic disorders), prescription history, and an assessment of current coexisting illnesses, diseases, or conditions.

2. . . .

3. **Independent Medical Judgment.** A physician's decision to utilize marijuana in the treatment of a patient must be based on the physician's independent medical judgment. The indication, appropriateness, and safety of the recommendation shall be evaluated in accordance with current standards of practice and in compliance with the laws of this state and the rules of this Chapter.

4. **Treatment Plan.** An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for the use of marijuana. In addition, the plan shall include documentation:

a. that conventional treatment for the patient's debilitating medical condition have been considered, are being undertaken or have been attempted without adequate or reasonable success or a statement that the patient has refused such methods;

b. whether therapeutic marijuana could interfere with any ongoing conventional treatment; and

c. the intended role of therapeutic marijuana within the overall plan.

5. **Informed Consent.** A physician shall explain the potential risks and benefits of both the therapeutic use of marijuana and any alternative

conventional treatment to the patient. Among other items, informed consent should caution against driving, operating machinery or performing any task that requires the patient to be alert or react when under the influence of the drug and the need for secure storage to reduce the risk of exposure to children or diversion by others. Unless approved by the USFDA for treatment of the patient's debilitating medical condition, a physician shall also advise patients that therapeutic marijuana is experimental, unconventional, and has not been approved by the USFDA for the treatment of the patient's debilitating medical condition, and that possession may be viewed as illegal under federal law and subject to federal (and workplace) enforcement action. Discussion of the risks and benefits should be clearly noted in the patient's record. If the patient is a minor a custodial parent or legal guardian shall be fully informed of the risks and benefits and consent to such use.

6.-B.3. . . .

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015), amended, LR.

§7721. Form of Written Request or Recommendation

A. **Required Contents.** A written request or recommendation for therapeutic marijuana shall include:

1.-3. . . .

4. the form, amount, dosage and instructions for use of therapeutic marijuana in an amount which is not greater than that necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amounts for topical treatment; and

5.-C. . . .

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2634 (December 2015), amended, LR.

**Subchapter E. Sanctions,
Severability**

§7725. [Reserved]
[Repealed].

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, 1270, and 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2635 (December 2015), repealed, LR.

§7729. Appendix—Form For Recommendation for Therapeutic Marijuana

**—THIS IS NOT A PRESCRIPTION—
PHYSICIAN RECOMMENDATION FORM**

Section A.-B. . . .

Section C. Patient's Debilitating Medical Condition(s) (Required)

This patient has been diagnosed with the following debilitating medical condition: (A minimum of one condition must be checked)
<input type="checkbox"/> Acquired Immune Deficiency Syndrome <input type="checkbox"/> Cachexia or Wasting Syndrome <input type="checkbox"/> Cancer <input type="checkbox"/> Crohn's Disease <input type="checkbox"/> Epilepsy <input type="checkbox"/> Multiple Sclerosis <input type="checkbox"/> Muscular Dystrophy <input type="checkbox"/> Positive Status for Human Immunodeficiency Virus <input type="checkbox"/> Spasticity <input type="checkbox"/> Seizure Disorders

Section D. . . .

Section E. Certification, Signature and Date (Required)

<p>By signing below, I attest that the information entered on this recommendation is true and accurate. I further attest that the above-named individual is my patient, who suffers from a debilitating medical condition and that this recommendation is submitted by and in conformity with Louisiana Law, R.S. 40:1046, and administrative rules promulgated by the Louisiana State Board of Medical Examiners, LAC 46:XLV.Chapter 77.</p> <p>Signature of Physician: X _____ Date: _____</p>
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AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1261-1292, and R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2635 (December 2015), amended, 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.

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.

Poverty Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the

Provider 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 developmental 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, Louisiana, 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4:00 p.m., November 21, 2016.

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 November 28, 2016 at 11:30 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.

Eric D. Torres
Executive Director