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, and Louisiana law governing therapeutic marijuana, R.S. 40:1046, the Board intends to amend its Rules governing physicians who diagnose their patients with a debilitating medical condition for which therapeutic marijuana may be recommended, LAC 46:XLV Chapter 77. The proposed amendments are needed to conform the Board’s rules to Acts 496 and 708 of the 2018 Regular Session of the Louisiana Legislature. Among other items, the proposed changes: (i) add various conditions to the definition of a debilitating medical condition(s) (DMC or DMCs) for which therapeutic marijuana (TM) may be recommended (glaucoma, Parkinson’s disease, severe muscle spasm, intractable pain, post-traumatic stress disorder, autism spectrum disorder); (ii) add definitions for “intractable pain,” “consult or consultant” and “pediatric subspecialists,” to accommodate the revised list of DMCs; (iii) eliminate the 100 patient limit on the number of patients for whom a physician registered with the Board may recommend TM; (iv) remove the requirement that the physician re-examine the patient at intervals not to exceed 90 days, leaving the frequency of follow up exams to the physician’s judgment. The proposed changes also: (v) clarify that the existing prohibition against ownership or investment interest in a TM pharmacy or producer applies only to physicians registered to recommend TM; (vi) clarify that physicians recommending TM must also comply with the rules on treatment of non-cancer related chronic or intractable pain if TM is utilized for this condition; (vii) amend the definition of “Bona-Fide Physician-Patient Relationship,” to eliminate unintended consequences (Definition of Bona-Fide Physician-Patient Relationship); and (viii) clarify the mode of transmission of a recommendation to a TM pharmacy. The proposed amendments which amend §§7705A (definitions), 7707A.5, 7717A.4.d, 7717A.6, 7721C and 7729C and delete 7707A.2 and 7709B, are set forth below.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XLV. Medical Professions
Subpart 3. Practice
Chapter 77. Marijuana for Therapeutic Use by Patients Suffering from a Debilitating Condition
Subchapter A. General Provisions

§7705. Definitions

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

* * *

Bona-Fide Physician-Patient Relationship—a relationship in which a physician:

a. has conducted at least one in-person examination at a physical practice location, or another location identified in his or her registration under this Chapter, in this state;

b.-c. . . .

Consult or Consultation—as used in this Chapter, means advice or opinions provided to a physician registered with the board to recommend therapeutic marijuana, by a pediatric subspecialist regarding a patient’s diagnosis of ASD and treatment with therapeutic marijuana. The consultation may be obtained in person or by telephone, telemedicine or electronic mail, provided it affords for medical/health information privacy and security. The request for and report of the consultant must be documented in the patient record of the requesting physician, who shall remain personally responsible to the patient for the primary diagnosis and any treatment provided. If the consultant’s advice or opinions are not accepted by the requesting physician, the medical record should document the consultation and the reason(s) why it was not accepted.

* * *

Debilitating Medical Condition (also referred to in this Chapter as a Qualifying Medical Condition)—means any of the following:

a. cancer;
b. glaucoma;c. Parkinson’s disease;d. positive status for human immunodeficiency virus;
e. acquired immune deficiency syndrome;f. cachexia or wasting syndrome;g. seizure disorders;h. epilepsy;
i. spasticity;
j. severe muscle spasms;
k. intractable pain;
l. Crohn’s disease;
m. muscular dystrophy;
n. multiple sclerosis;
o. post-traumatic stress disorder;
p. any of the following conditions associated with autism spectrum disorder (ASD); provided, however, that prior to recommending therapeutic marijuana for any condition associated with ASD to a patient under eighteen years of age, the physician shall consult with a pediatric subspecialist:
1. repetitive or self-stimulatory behavior of such severity that the physical health of the person with autism is jeopardized;
2. avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized;
3. self-injuring behavior;
4. physically aggressive or destructive behavior;
q. and 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.

Intractable pain—for purposes of this Chapter, means a pain state in which the course of the pain cannot be removed or otherwise treated with the consent of the patient and which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. It is pain so chronic and severe as to otherwise warrant an opiate prescription.

Pediatric Subspecialist—an individual licensed to practice medicine in any state in the United States who provides care to patients with ASD.

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 by the Department of Health, Board of Medical Examiners, LR 43:319 (February 2017), LR

Subchapter B. Prohibitions and Exceptions

§7707. Prohibitions

A. No physician shall:

1. ...

2. [Reserved].

3.-4. ...

5. if registered with the board under this Chapter, have an ownership or investment interest established through debt, equity, or other means, whether held directly or indirectly by a physician or a member of a physician's immediate family, nor any contract or other arrangement to provide goods or services, in or with a licensed therapeutic marijuana pharmacy or a producer licensed by the Louisiana Department of Agriculture and Forestry to produce marijuana.

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 by the Department of Health, Board of Medical Examiners, LR

§7709. Exceptions

A. This Chapter is subject to the following exceptions.

1.-2.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 by the Department of Health, Board of Medical Examiners, LR 43:319 (February 2017), LR

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

§7717. Use of Marijuana for Therapeutic Purposes, Limitations

A. Required Prior Conditions. Nothing in this Chapter requires that a physician issue a written request or recommendation for marijuana. However, if a physician determines it medically appropriate to do so to treat or relieve symptoms of a patient’s qualifying medical condition the physician shall comply with the following rules.

1.-3. ...

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.-c. ;

d. of compliance with the board’s rules on chronic or intractable pain, set forth in 6915-6923 of this Part, if therapeutic marijuana is utilized for the treatment of non-cancer-related chronic or intractable pain.

5. ...

6. Continued Use of Marijuana. The physician shall monitor the patient's progress at such intervals as the physician determines appropriate to assess the benefits of treatment, assure the therapeutic use of marijuana remains indicated, and evaluate the patient's progress toward treatment objectives. During each visit, attention shall be given to the possibility that marijuana use is not masking an acute or treatable progressive condition or that such use will lead to a worsening of the patient's condition. Indications of substance abuse or diversion should also be evaluated.

7.-B.3. ...
§7721. Form of Written Request or Recommendation

A.-B. . . .

C. Manner of Transmission. A written request or recommendation for therapeutic marijuana shall be transmitted by the physician or physician's designee to a licensed therapeutic marijuana pharmacy by facsimile or in another electronic manner that provides for medical/health information privacy and security and is in compliance with rules promulgated by the Louisiana Board of Pharmacy. The pharmacy shall be selected by the patient from a list of licensed therapeutic marijuana pharmacies.

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 by the Department of Health, Board of Medical Examiners, LR 43:319 (February 2017), 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) |
| --- | --- |
| ___ Acquired Immune Deficiency Syndrome | ___ Severe Muscle Spasms |
| ___ Cachexia or Wasting Syndrome | ___ Intractable Pain |
| ___ Cancer | ___ Post-Traumatic Stress Disorder |
| ___ Crohn’s Disease | --- Any of the following conditions associated with autism spectrum disorder: |
| ___ Epilepsy | | (i) repetitive or self-stimulatory behavior of such severity that the health |
| ___ Multiple Sclerosis | | of the person with autism is jeopardized; |
| ___ Muscular Dystrophy | | (ii) avoidance of others or inability to communicate of such severity |
| ___ Positive Status for Human Immunodeficiency Virus | | that the physical health of the person with autism is jeopardized; |
| ___ Spasticity | | (iii) self-injuring behavior; |
| ___ Seizure Disorders | | (iv) physically aggressive or destructive behavior. |
| ___ Glaucoma | |
| ___ Parkinson’s Disease | |

Section D.-E. ...

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2635 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:320 (February 2017), 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 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 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.

Small Business Statement

It is not anticipated that the proposed rule 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 amendments 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., May 21, 2019.

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 Thursday, May 30, 2019 at 10:00 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.

Vincent A. Culotta, Jr., M.D.,
Executive Director