NOTICE OF INTENT

Department of Health

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 proposes pursuant to R.S. 40:1046, to repeal the Board’s Rules, LAC 46.XLV.Chapter 77, governing physicians who recommend therapeutic marijuana, legal warning with regard to recommending marijuana, definitions and prohibitions with regard to the conditions for which it may be recommended, registration of physicians, form for recommendation, requirements for treatment and keeping of records, and discipline pertaining to such rules, to conform to Act 286 of the 2020 Regular Session of the Louisiana Legislature. The repeal will be effective upon final promulgation.

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

§7701. Preamble, Warning, and Suggested Consultation

Repealed.

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

B. Warning—Federal Law. Irrespective of Louisiana law, which as an agency of this state the board is obliged to adhere, marijuana is classified as a schedule I controlled substance under federal law and regulation and has not been approved by the United States Food and Drug Administration (USFDA) for the treatment of any medical condition. Prescribing marijuana is illegal under federal law and physicians who do so may be subject to criminal, civil and administrative consequences that include, among others, federal criminal prosecution, civil fines, forfeitures, penalties, revocation of controlled dangerous substance registration issued by the United States Drug Enforcement Administration, exclusion from Medicare and other federal payer programs, etc. Patients who possess marijuana, on the written request or recommendation of a physician or otherwise, may also be exposed to federal criminal prosecution, civil fines, forfeitures and penalties. Neither Louisiana nor the board’s rules preempt federal law, which may also impact the methods of payment to physicians for visits when therapeutic marijuana is requested or recommended and inhibit the deposit of proceeds from such visits into banks and other federally insured institutions.

C. Consultation. For the foregoing reasons, physicians may wish to consult with their own legal counsel, as well as any health care facility, private or governmental payor with which the physician is affiliated, medical malpractice insurers and financial institutions before suggesting marijuana for the treatment of a qualifying medical condition in their patients.

§7703. Scope of Chapter
Repealed.

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.


HISTORICAL NOTE: Promulgated by the Department of Health Hospitals, Board of Medical Examiners, LR 41:2632 (December 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:318 (February 2017); LR 47: (2021).

§7705. Definitions
Repealed.

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

Board— the Louisiana State Board of Medical Examiners, as established in R.S. 37:1261-1292.

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. maintains a medical record in accordance with professional standards; and
   c. is responsible for the ongoing assessment, care and treatment of a patient’s qualifying medical condition, or a symptom of the patient’s qualifying medical condition.

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.

Controlled Substance—any medication or other substance which is designated as a controlled substance and regulated as such under Louisiana or federal law or regulations.

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)—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:
  i. repetitive or self-stimulatory behavior of such severity that the physical health of the person with autism is jeopardized;
  ii. avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized;
  iii. self-injuring behavior;
  iv. 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.

Licensed Therapeutic Marijuana Pharmacy—a pharmacy located in this state that is licensed by and in good standing with the Louisiana Board of Pharmacy to provide therapeutic marijuana to a patient on the written request or recommendation of the patient's physician.

Marijuana—tetrahydrocannabinols, or a chemical derivative of tetrahydrocannabinols in any form, except for inhalation, raw or crude marijuana, as permitted by the rules and regulations of the Louisiana Board of Pharmacy (LBP). For purposes of this definition inhalation shall not exclude a form of medical marijuana administered by metered-dose inhaler to the extent permitted by LBP rules.

Medical Practice Act or the Act—R.S. 37:1261-92, as may from time-to-time be amended.

Patient—an individual who:
  a. is a resident of this state;
  b. has a current clinical diagnoses of a qualifying medical condition; and
  c. with whom the physician has a bona-fide physician-patient relationship.

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

Physical Practice Location in this State—a clinic or office physically located in this state where the physician spends the majority of his or her time practicing medicine.

Physician—an individual lawfully entitled to practice medicine in this state, as evidenced by a current license duly issued by the board.

Prescription Monitoring Program or PMP—the prescription monitoring program established by R.S. 40:1001 et seq., as may from time-to-time be amended.

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.

Registrant—a physician who is registered with the board to issue a written request or recommendation for the use of marijuana for therapeutic purposes.

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 45:1471 (October 2019), LR 46:342 (March 2020); LR 47: ( 2021).

Subchapter B. Prohibitions and Exceptions
§7707. Prohibitions
Repealed.
A.—No physician shall:
  1. issue a written request or recommendation for therapeutic marijuana unless he or she is registered with the board and complies with Louisiana law and the rules of this Chapter;
2. Reserved.
3. delegate to any other healthcare professional or other person the authority to diagnose the patient as having a qualifying medical condition;
4. examine a patient at any location where marijuana is provided; or
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 45:1472 (October 2019); LR 47: (2021).

§7709. Exceptions
Repealed.
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.

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 45:1472 (October 2019), LR 46:342 (March 2020); LR 47: (2021).

Subchapter C. Registration
§7711. Registration, Physician Eligibility
Repealed.
A. To be eligible for registration under this Chapter a physician shall, as of the date of the application:
1. hold a current, unrestricted license to practice medicine issued by the board;
2. hold current schedule I authority or such other authority as may be designated for therapeutic marijuana by the Louisiana Board of Pharmacy;
3. complete an on-line educational activity available at no cost on the board's web page.
B. A physician shall be deemed ineligible for registration who has:
1. has been convicted, whether upon verdict, judgment, or plea of guilty or nolo contendere, of a felony or any crime an element of which is the manufacture, production, possession, use, distribution, sale or exchange of any controlled substance or who has entered into a diversion program, a deferred prosecution or other agreement in lieu of the institution of criminal charges or prosecution for such crime;
2. has within the 10 years preceding application for registration, abused or excessively used any medication, alcohol, or other substance which can produce physiological or psychological dependence or tolerance or which acts as a central nervous system stimulant or depressant; or
3. is the subject of a pending formal investigation or administrative proceeding before the board.
C. The board may deny registration to an otherwise eligible physician for any of the causes enumerated by R.S. 37:1285 or any other violation of the provisions of the Act.
D. The burden of satisfying the board as to the qualifications and eligibility of the physician-applicant for registration shall be upon the applicant. An applicant shall not be deemed to possess such qualifications unless the applicant demonstrates and evidences such qualifications in the manner prescribed by and to the satisfaction of the board.

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 46:342 (March 2020); LR 47: (2021).

§7713. Application
Repealed.
A. Application for registration shall be made in a format approved by the board and shall include:
1. the applicant's full name, contact information, and such other information and documentation as the board may require;
2. criminal history record information; and
3. an application fee of $75.

B. The board may refuse any application that is not complete and may require a more detailed or complete response to any request for information in the application.

C. Applications and instructions may be obtained from the board's webpage, www.lsbe.la.gov, or by contacting the board.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015); LR 47: (2021).

§7715. Registration Issuance, Expiration, Renewal
Repealed.

A. If the qualifications, requirements, and procedures set forth in this Chapter are met to the satisfaction of the board, registration shall be issued to the applicant.

B. Registration shall expire and become null, void, and to no effect the following year after issuance on the last day of the month in which the registrant was born.

C. Registration shall be renewed annually on or before its date of expiration by submitting to the board a renewal application and a renewal fee of $50.

D. Registration which has expired as a result of nonrenewal may be reinstated upon the applicant's satisfaction of the qualifications, requirements and procedures prescribed for original application for registration.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 41:2633 (December 2015); LR 47: (2021).

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

§7717. Use of Marijuana for Therapeutic Purposes, Limitations
Repealed.

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 alleviate symptoms of a patient's qualifying medical condition the physician shall comply with the following rules.

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. Prescription Monitoring Program. The physician shall review the patient's information in the Prescription Monitoring Program database prior to issuing any written request or recommendation for marijuana.

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.

   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. 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. 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. Medical Records. A physician shall document and maintain in the patient’s medical record, accurate and complete records of the medical diagnoses of a qualifying medical condition, PMP inquiries, consultations, treatment plans, informed consents, periodic assessments, and the results of all other attempts which the physician has employed alternative to marijuana. A physician shall also document the date, type, quantity, dosage, route, and frequency of each written request or recommendation for marijuana which the physician has made for the patient. A copy of a written request or recommendation shall suffice for this purpose.

B. Termination of Use. A physician shall refuse to initiate or re-initiate or shall terminate the use of marijuana with respect to a patient on any date that the physician determines, becomes aware, knows, or should know that:

1. the patient is not a qualifying candidate for the use of marijuana under the conditions and limitations prescribed by this Section;
2. the patient has failed to demonstrate clinical benefit from the use of marijuana; or
3. the patient has engaged in diversion, excessive use, misuse, or abuse of marijuana or has otherwise consumed or disposed of the drug other than in compliance with the directions and indications for use given by the physician.

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 by the Department of Health, Board of Medical Examiners, LR 43:319 (February 2017), LR 45:1472 (October 2019); LR 47: (2021).

§7719. Board Access to Records
Repealed.

A. The records required by this Subchapter shall be available for examination, inspection and copying by the board or its designated employee or agent at any reasonable time, but without the necessity of prior notice by the board. The failure or refusal of a registrant to make such records available pursuant to this Section shall constitute a violation of these rules.

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); LR 47: (2021).

§7721. Form of Written Request or Recommendation
Repealed.

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

1. the physician’s name, address, telephone number, e-mail address, registration number issued under this Chapter, and Louisiana schedule I or other license number for therapeutic marijuana issued by the Louisiana Board of Pharmacy;
2. the name, address and date of birth of the patient;
3. the date, name and address of the licensed therapeutic marijuana pharmacy to whom the written request or recommendation is being transmitted;
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. confirmation that the written request or recommendation for therapeutic marijuana is being submitted for the physician's patient as defined by and in conformity with the rules of this chapter.

B. Approved Form. Direction provided to a pharmacist substantially in the form of the written request or recommendation form prescribed in the Appendix to these rules (§7729) shall be presumptively deemed to satisfy the requirements of this section.

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 Hospitals, Board of Medical Examiners, LR 41:2634 (December 2015), amended by the Department of Health, Board of Medical Examiners LR 43:320 (February 2017), LR 45:1472 (October 2019); LR 47: (2021).

Subchapter E. Sanctions, Severability

§7723. Sanctions Against Medical License or Registration

Repealed.

A. For noncompliance with any of the provisions of this chapter the board may suspend, revoke, refuse to issue or impose probationary or other terms, conditions and restrictions on any license or permit to practice medicine in the state of Louisiana, or any registration issued under this chapter, held or applied for by a physician culpable of such violation under R.S. 37:1285(A)(6), and R.S. 1285(A)(30), respectively.

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 41:2634 (December 2015).

§7727. Severability

Repealed.

A. If any rule, provision, or item of this chapter or the application thereof is held invalid as in excess of or inconsistent with statutory or constitutional authority, such invalidity shall not affect other rules, provisions, items, or applications, and to this end the rules and provisions of this chapter are hereby declared to be severable.

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); LR 47: (2021).

§7729. Appendix—Form for Recommendation for Therapeutic Marijuana

Repealed.

---THIS IS NOT A PRESCRIPTION---

PHYSICIAN RECOMMENDATION FORM

Section A. Patient’s Physician Information (Required)

1. Legal First Name 2. Middle Initial 3a. Legal Last Name 3b. Suffix (Jr., Sr., III, etc.)

4a. Full Professional Address (street, city (in LA), zip code) 4b. e-mail address 4c. fax number


9a. LSBME Registration No. for Therapeutic Marijuana 9b. Schedule I No. (Board of Pharmacy) for Therapeutic Marijuana

---No.________________________________________ No.________________________________________---

Section B. Patient Information (Required)

10. Legal First Name 11. Middle Initial 12a. Legal Last Name 12b. Suffix (Jr., Sr., III, etc.)
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
___ Cachexia or Wasting Syndrome
___ Cancer
___ Crohn’s Disease
___ Epilepsy
___ Multiple Sclerosis
___ Muscular Dystrophy
___ Positive Status for Human Immunodeficiency Virus
___ Spasticity
___ Seizure Disorders
___ Glaucoma
___ Parkinson’s Disease
___ Severe Muscle Spasms
___ Intractable Pain
___ Post-Traumatic Stress Disorder
___ Any of the following conditions associated with autism spectrum disorder:
   ___ (i) repetitive or self-stimulatory behavior of such severity that the health of the person with autism is jeopardized;
   ___ (ii) avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized;
   ___ (iii) self-injuring behavior;
   ___ (iv) physically aggressive or destructive behavior.

Section D. Form, Amount, Dose, and Instructions for Use of Therapeutic Marijuana (Required)

Section E. Certification, Signature and Date (Required)
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:XIV.Chapter 77.
Signature of Physician: X______________________________
Date:____________________________

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HISTORICAL NOTE: Promulgated by the Department of Health 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 45:1472 (October 2019); LR 47: (2021).