

THE LOUISIANA STATE
BOARD OF MEDICAL EXAMINERS

Therapeutic Marijuana Guidance
(April 2019)

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I. Introduction

As the administrative agency constituted under and charged with implementation and enforcement of the laws and rules governing the practice of physicians and a number of allied health care practitioners in this state, the Louisiana State Board of Medical Examiners (the “Board”) is accorded the responsibility and primary jurisdiction to construe the meaning of the practice acts and other laws we are responsible for enforcing. To aid in compliance by affected persons we issue, from time-to-time, advisory opinions, rulings, and, on occasion, guidance on a particular area of practice. Into this category falls the guidance we are providing concerning therapeutic marijuana.

In so doing, we note that the information provided does not replace or alter the force or effect of Louisiana law (La. R.S. 40:1046) or the Board’s Rules governing therapeutic marijuana (LAC 46:XLV. 7701-7729). Physicians who wish to recommend it for their patients must adhere to both. We strongly encourage any physician considering recommending therapeutic marijuana to visit our webpage www.lsbme.la.gov and carefully review the law and Rules.

II. Louisiana History

In 2015, the legislature amended the existing law and put in place the mechanisms and statutory framework for growing, distributing and recommending therapeutic marijuana (TM). The Board was tasked with promulgating rules authorizing physicians to prescribe TM and annually report to the legislature any additional diseases or conditions that should be added (Act 261, La. Leg. 2015). In 2016, the legislature expanded the medical conditions (which are identified as *debilitating medical conditions*) from 3 to 10, for which TM could be *recommended*, rather than *prescribed* (Act 96, La. Leg. 2016). In 2018, the list of debilitating medical conditions (DMCs) was expanded again from 10 to 16 (Act 496, La. Leg. 2018).

III. Preamble-Warning; Recommend v. Prescribe; Consultation

Warning—Federal Law. Neither Louisiana law nor the Board’s rules preempt federal law. As noted in the Board’s Rules (7701), marijuana is classified as a Schedule I CDS under federal law (21 U.S.C. 821). As such, federal regulators view it as having a high potential for dependency or addiction with no accepted medical use. Because of its classification, *prescribing* marijuana remains illegal under federal law. Physicians who do so, and patients who possess it, may be subject to federal criminal prosecution, civil fines, forfeitures and penalties.

Recommend v. Prescribe. As with other states, Louisiana law authorizes physicians to *recommend* TM for DMCs. Despite the attempt to distinguish the physician’s role of *recommending* vs. *prescribing*, and the implementation of various statutory and regulatory protections for patient safety established in this state, it is important to understand that TM remains subject to oversight by federal authorities in the exercise of their discretionary authority to enforce federal criminal, civil and administrative law and regulations.¹

Consultation. Physicians who choose to recommend TM should consult in advance 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.

IV. List of Current Debilitating Medical Conditions (DMCs)

As of August 2018, the following are designated as DMCs: cancer, glaucoma, Parkinson’s disease, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy, spasticity, severe muscle spasms, intractable pain, crohn’s disease, muscular dystrophy, multiple sclerosis, post-traumatic stress disorder, and certain conditions associated with autism spectrum disorder *e.g.*: behavior of such severity that the physical health of the person with autism is jeopardized; avoidance of others or inability to communicate of such severity that the physical health of the person with autism is jeopardized; self-injuring behavior; and physically aggressive or destructive behavior (La. R.S. 40:1046).

¹Every year since 2015, Congress has annually extended an amendment (Rohrabacher-Farr amendment) in the Justice Department’s appropriation bill that prohibits the U.S. Department of Justice from using federal funds to impede the implementation of state medical marijuana law. However, the Rohrabacher-Farr amendment does not change the legal status of marijuana and must be renewed annually to remain in effect. H. Amdt.332 to H.R. 2578-Commerce, Justice, Science, and Related Agencies Appropriations Act, 2016 – 114th Congress (2015-2016).

V. Points to Consider

- The Science.* By virtue of the limited amount of marijuana legally available for clinical studies, there are few peer reviewed studies on its therapeutic use for the DMCs allowed by Louisiana law. As with any substance that has not been approved by the U.S. Food and Drug Administration, physicians who recommend TM should seek out scientific literature, on-line and other educational courses and resources to assist them and their patients to make informed decisions on side-effects, safety, drug-interactions and dosing.

- Practice Within Scope.* Physicians should constrain TM recommendations to the treatment of DMCs that fall within the scope of their specialty training, education and experience. A good rule of thumb is to practice similar to the manner in which you exercise your privileges at any local hospital.

- Autism Spectrum Disorder (ASD); Consultation Required For Children.* Before recommending TM to a **patient under eighteen years of age** for treatment of the approved conditions associated with ASD, the law requires a physician to consult with a pediatric subspecialist (La. R.S. 40:1046A(2)(xvi)). It has been suggested that the ideal subspecialists for children practice within the specialties of child neurology, child and adolescent psychiatry, and developmental pediatrics. While a consultation need not necessarily be affirmative, the rationale for recommending TM in the absence of an affirmative consultation should be clearly documented in the chart.

- Consultation for Treating Children with Other Conditions.* Consultation is not required for the treatment of children under the age of 18 for any DMC other than ASD. As is the case with adult patients, TM recommendations for children should be confined to the treatment and care of DMCs that fall within the scope of the physician's specialty and routine practice. Such patients should also be closely monitored for adverse effects and the need for potential medication adjustments.

- Shared Decision Making.* As you advise your patients of the risks and benefits of the use of TM, you may consider the information available from the Board's on-line educational activity for your TM registration. Physicians should also advise their TM patients that work-related drug tests may be positive.

- Drug Interactions.* There is little information in the literature regarding the drug-drug interactions of TM and other pharmaceuticals. Physicians should make sure that this is understood by patients and that patient and physician work closely together to recognize and prevent adverse reactions.

- Recommendations of Specialty Organizations.* Make sure that TM is recommended in a manner consistent with recommendations of specialty organizations for patient-specific conditions e.g., pregnancy, breast-feeding mothers, children with Crohn's disease, chronic pain, etc.

- Treatment of Chronic Pain.* Physicians recommending TM for the treatment of chronic pain must adhere to the Board's Chronic Pain Rules, which are available on the Board's website (Rules, 6915-6923).

- Cannabinol/Supplements.* Any form of cannabiniol oil or nutritional supplement containing *any quantity* of tetrahydrocannabinols (THC), including synthetic equivalents and derivatives, is illegal to sell or possess in Louisiana, (La. R.S. 40:964C(27)).

- Dosing.* As with any CDS, when recommending TM physicians should always consider using the lowest effective dose, followed by adjustments as necessary.

The Board is available for consultation should you have any questions.

VI. Summary of The Board's Rules (LAC 46:XLV.7701-7729).

- *Board Registration is Required to Recommend TM; Eligibility.* A physician may not recommend TM unless he or she is registered with the Board (Rules, 7077-7709).
- *Established Physician-Patient Relationship.* TM can only be recommended for *patients* who are residents of this state, have a current clinical diagnoses of a DMC, and with whom the physician has a *bona-fide* physician-patient relationship *e.g.*, the physician has conducted an in-person examination, creates and maintains a medical record, and is responsible for the ongoing assessment, care and treatment of a patient's DMC, or a symptom of it (Rules, 7705).
- *Medical Diagnosis/Assessment.* A medical diagnosis of a DMC must be clinically established and documented in the patient's medical record based on an in-person examination (Rules, 7717A.1).
- *Prescription Monitoring Program (PMP).* The patient's PMP database must always be reviewed before recommending TM (Rules, 7717A.2).
- *Independent Medical Judgment.* The decision to utilize TM for a patient must be based on the physician's independent medical judgment. The recommendation must be evaluated in light of current standards of practice (Rules, 7717A.3).
- *Physicians are not Required to Recommend TM.* Nothing requires a physician to recommend TM, or any other CDS, to a patient. If a physician determines it medically appropriate to do so he or she must comply with the Board's TM Rules
- *Treatment Plan.* An individualized treatment plan must be formulated and documented in the patient chart (Rules, 7717A.4).
- *Informed Consent.* A physician must explain the potential risks and benefits of TM and any conventional treatment. Physicians should caution against driving, operating machinery or any task that requires the patient to be alert and the need for secure storage to reduce the risk of exposure to children or diversion. Patients should be advised that TM is experimental, unconventional, and has not been approved by the USFDA for the treatment of the patient's DMC, 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 chart. If the patient is a minor a custodial parent or legal guardian should be fully informed of the risks and benefits and consent to such use (Rules, 7717A.5).
- *On-Going Use.* Once recommended, the patient should be monitored at appropriate intervals to assess benefits, assure TM remains indicated, and evaluate progress toward treatment objectives (Rules, 7717A.6).
- *Medical Records.* Accurate and complete records must be created and maintained. The chart should include the date, type, quantity, dosage, route, and frequency of all TM recommendations or copies of all such recommendations. (Rules, 7717A.7).
- *Termination.* TM should not be initiated or terminated if the physician determines the patient is not a qualifying candidate, has failed to demonstrate clinical benefit, engaged in diversion, excessive use, misuse, or abuse or has otherwise consumed or disposed of TM other than in compliance with directions (Rules, 7717B).
- *Non-delegation.* By law (La. R.S. 40:1046A(1)), only physicians can recommend TM. Also, a physician cannot delegate to any other healthcare professional the authority to diagnose the patient as having a DMC (Rules, 7707).
- *Location.* A physician may not examine patients at any location where TM is provided *e.g.*, dispensed (Rules, 7707).
- *Ownership/Investment Interest.* If registered to recommend TM, a physician (or immediate family) may not have an ownership or investment interest, or any contract or other arrangement to provide goods or services, in or with a licensed TM pharmacy or a producer licensed by the State to produce marijuana (Rules, 7707).
- *Board Action.* Violation of the law or the Board's Rules may lead to action against a physician's license or TM registration (Rules, 7723).
- *Out-of-State Patients are not Eligible for TM.* TM may only be recommended to a patient who is a resident of Louisiana (Rules, Def. of *patient*, 7705).
- *Forms of TM Dispensed.* TM may be dispensed by an authorized marijuana pharmacy in any form permitted by the Pharmacy Board *except* for inhalation, raw or crude marijuana (La. R.S. 40:1046A(1), Rules, Def. of *marijuana*, 7705)).
- *Form for Recommending TM.* The required contents and example of a form for recommendation TM is contained in the Board's Rules (7721, 7729).