

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

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January 13, 2016

Committee on Health and Welfare
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Committee on Health and Welfare
House of Representatives of the
State of Louisiana
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**Re: Report Relative to Act 261; La.Rev.Stat.§40:1046(2015)
Recommendations for Therapeutic Marijuana**

Dear Sirs:

Pursuant to Act 261; La.Rev.Stats§40:1046(2015), the Louisiana State Board of Medical Examiners is submitting the enclosed report relative to the findings and recommendations as to additional qualifying diseases or conditions for which a physician may issue a written request or recommendations for therapeutic marijuana.

Yours very truly,

**LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS**

By: _____

Cecilia Ann Mouton, M.D.
Executive Director

**REPORT — FINDINGS AND RECOMMENDATIONS
AS TO ADDITIONAL QUALIFYING DISEASES OR CONDITIONS
FOR WHICH A PHYSICIAN MAY ISSUE A WRITTEN REQUEST OR
RECOMMENDATION FOR THERAPEUTIC- MARIJUANA**

(Act 261; La. Rev. Stat. §40:1046 (2015))

By The

LOUISIANA STATE
BOARD OF MEDICAL EXAMINERS

Submitted To The

COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA SENATE,

And

COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA HOUSE OF REPRESENTATIVES,

January 11, 2016

Respectfully submitted,
Cecilia Mouton, M.D.
Executive Director
LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS
630 Camp Street
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I. BACKGROUND

During the 2015 Regular Session, the Louisiana Legislature adopted Act 261 (SB 143 Sen. Mills) dealing with the use of therapeutic marijuana for qualifying medical conditions. Act 261 (the “Act”) charged the Board with carrying out both near-term and continuing duties. *First*, the Act directed that it **promulgate rules** by January 1, 2016 authorizing physicians to prescribe marijuana for therapeutic use for patients diagnosed with a qualifying medical condition identified in La. Rev. Stat. §40:1046 (the “law”). *Second*, the Act tasked the Board with submitting to the Health & Welfare Committees of the Louisiana Senate and House “[O]n an annual basis not less than sixty days prior to the beginning of the regular session of the legislature a report as to any additional diseases or medical conditions that should be added to the list of eligible diseases and conditions for prescription.”¹ Currently, the law allows a physician to prescribe a yet undeveloped tetrahydrocannabinols or any chemical derivative of tetrahydrocannabinols for therapeutic use by patients suffering from any one of three (3) qualifying medical conditions *e.g.*, glaucoma, symptoms resulting from administration of chemotherapy cancer treatment, and spastic quadriplegia. La. Rev. Stat. §40:1046A.

The Board’s Response/Action

1. As to the rulemaking project—The Board considered the Act’s directives at its July 2015 meeting, approved draft rules at its August 2015 meeting, and by Notice of Intent published in the September 20, 2015, edition of the *Louisiana Register*, Vol. 41, No. 9, pp. 1818-1823, proposed to adopt rules governing physician written requests or recommendations for the therapeutic use of marijuana by patients suffering from a qualifying medical condition. The rules (LAC 46:XLV.7701-7729) were subsequently promulgated in the same form as previously noticed in the December 2015 edition of the *Louisiana Register*, Vol. 41, No. 12, pp. 2631-2635.

2. As to the annual report—Given that identifying medical conditions for which a controlled substance, or any particular drug, may be appropriate is not a task that the Board has traditionally performed, it enlisted the assistance of others familiar with the peer reviewed scientific literature and the results of any available medically acceptable clinical trials on the topic. In so doing, it convened a group of academic clinicians designated by the three medical centers/universities in this state: Louisiana State University Health Science Center, New Orleans;

¹ La. Rev. Stat. §40:1046A.

Tulane University School of Medicine, New Orleans; Louisiana State University Health Science Center, Shreveport; and an affiliate of the Louisiana State University, the Pennington Biometrical Research Center, Baton Rouge, Louisiana² to conduct a review of the medical literature and assist the Board prepare its first annual report. The group met in October 2015 at the Board's request and selected a chair, Dr. John England, LSUHSC-NO, who subsequently presented the group's findings and recommendations to the Board during its December 2015 meeting.

II. FINDINGS AND RECOMMENDATIONS

Based on the medical literature and scientific information currently available, and with due consideration of the findings, suggestions and recommendations of the academic clinicians on which the Board relied heavily in this matter, this report is submitted pursuant to and as prescribed by La. Rev. Stat. §40:1046 and includes a summary of the scientific findings and the Board's recommendations respecting additional conditions which the legislature may wish to consider adding (or deleting) from the current qualifying medical conditions for which a written request or order for therapeutic marijuana may lawfully be recommended by a physician.

Findings

1. There is strong scientific evidence to support the use of marijuana for indications of *spasticity*. Such evidence suggests that limiting the treatment of spasticity to quadriplegia, may be an overly restrictive.
2. There is modest scientific data to support the effectiveness of marijuana for the indications currently approved by the United States Food and Drug Administration (the "FDA") *e.g.*, chemotherapy-induced nausea and vomiting and weight gain in HIV/AIDS wasting syndrome.
3. Additional studies are needed to test the efficacy of medicinal marijuana for improving outcomes in cases of chronic pain, epilepsy and HIV/AIDS progression.
4. There is insufficient scientific data to support the use of marijuana for depression, anxiety or sleep disorders, psychoses, post-traumatic stress disorder (PTSD) and Tourette's Syndrome.

² The Board would like to acknowledge and thank the designating institutions and their physician representatives for their efforts and assistance in compiling the information that is contained in this Report.

5. There is insufficient scientific data to support the use of marijuana for the treatment of glaucoma. Moreover, neither the FDA nor the American Glaucoma Society recommend marijuana for the treatment of glaucoma for various reasons *e.g.*, its adverse effects, short duration of action and lack of other evidence supporting its capacity to alter the course of the disease.

Recommendations

In consideration of the above findings, the Board offers the following recommendations for legislative consideration:

1. Amending and expanding the language of the current qualifying medical condition contained in La. Rev. Stat. §40:1046A from *spastic quadriplegia* to simply *spasticity* and deleting the word *quadriplegia*.
2. Amending and expanding the language of the current qualifying medical contained in La. Rev. Stat. §40:1046A relating to *symptoms and resulting from the administration of chemotherapy cancer treatment* to include the other FDA approved indication for the use of marijuana; namely; *“to promote weight gain in HIV/AIDS wasting syndromes.”*
3. Amending and removing *glaucoma* from the current list of qualifying medical conditions contained in La. Rev. Stat. §40:1046A.
4. Finally, in order to insure the public health, safety and welfare the Board suggests that therapeutic marijuana, which may be made available to Louisiana patients upon the written request or order of a treating physician, should be subject to the same evidence-based review and regulatory oversight as other medications prescribed by physicians. Indeed, only in this manner will the legislature, the Board, physicians and the public be in a position to evaluate the efficacy of its use in connection with a given disease or condition. To accomplish this task, it is necessary that the potentially therapeutic chemicals in marijuana must be purified and tested in randomized, double-blind, placebo-controlled clinical trials.

For this reason, the Board suggests that the legislature consider pursuing available avenues that would promote and facilitate the ability of qualified scientific researchers within this state (*e.g.*, the state’s medical universities and their affiliates), to conduct research

concerning marijuana's potential therapeutic chemicals for treatment of the aforementioned and other diseases and conditions. Among others, these avenues may include: (1) the pursuit of mechanisms that would allow physicians and researchers in Louisiana the ability to obtain existing formulations of cannabis to begin conducting clinical trials; and (2) requesting that the federal government change the United States Drug Enforcement Administration's scheduling of marijuana from a controlled dangerous substance ("CDS") Schedule I to a CDS Schedule II in order to facilitate such research.

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