



# Louisiana Board of Pharmacy

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April 10, 2019

Senator John A. Alario, Jr, President  
Louisiana Senate  
Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

**Electronic Mail – Delivery Receipt Requested**

Re: Report No. 1 of 3 for Regulatory Project 2019-1A ~ Marijuana Pharmacies

Dear Senator Alario:

The Board has initiated the rulemaking process to amend a portion of its rules for marijuana pharmacies. Some of the proposed amendments were requested by private citizens and some of the proposed amendments are intended to facilitate the communication of recommendations from physicians to the pharmacies. In connection with this regulatory project, the following documents are attached.

- Waiver from Occupational Licensing Review Commission Page 2
- Notice of Intent Page 4
- Proposed Rule Changes Page 5
- Family Impact Statement Page 8
- Poverty Impact Statement Page 9
- Provider Impact Statement Page 10
- Regulatory Flexibility Analysis Page 11
- Solicitation of Comments Page 12
- Fiscal & Economic Impact Statement Page 14
- Acts 496 and 708 of 2018 Regular Legislature Page 19

As indicated in the solicitation, we will convene a public hearing on May 29, 2019 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at [mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov) or 225.925.6481.

For the Board:

Malcolm J. Broussard  
Executive Director

- cc: Chair, Senate Health & Welfare Committee  
Via Email: [APA.S-H&W@legis.la.gov](mailto:APA.S-H&W@legis.la.gov)
- Speaker, House of Representatives  
Via Email: [APA.HouseSpeaker@legis.la.gov](mailto:APA.HouseSpeaker@legis.la.gov)
- Chair, House Health & Welfare Committee  
Via Email: [APA.H-HW@legis.la.gov](mailto:APA.H-HW@legis.la.gov)
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Via Email: [Pat.Witty@la.gov](mailto:Pat.Witty@la.gov)
- Editor, *Louisiana Register*  
Via Email: [Reg.Submission@la.gov](mailto:Reg.Submission@la.gov)
- Reference File

**From:** [Boards Commissions](#)  
**To:** [Malcolm J. Broussard](#); [Boards Commissions](#)  
**Cc:** [Zach Rau \(RauZ@legis.la.gov\)](#); [Rachel Feigley \(FeigleyR@legis.la.gov\)](#); [Catherine Brindley](#)  
**Subject:** RE: Pharmacy Board - Regulatory Project 2019-1 ~ Marijuana Pharmacies  
**Date:** Wednesday, March 20, 2019 10:25:47 AM  
**Attachments:** [image001.png](#)

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Good Morning,

The following proposed rules do not require approval by the Commission as they do not meet the definition of "occupational regulation" under La. R.S. 37:43(7): LAC 46:LIII.2441, 2443, and 2457.

LAC 46:LIII.2447 should be presented to the Commission. I will put it on the agenda for the next meeting. Please send a redline document and summary of just that rule proposal so that I can file it in the submissions folder.

Thanks,  
Ellen

## Ellen Palmintier

*Assistant Executive Counsel  
Director of Boards & Commissions*



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**From:** Malcolm J. Broussard [mailto:mbroussard@pharmacy.la.gov]  
**Sent:** Tuesday, March 19, 2019 5:06 PM  
**To:** Boards Commissions  
**Cc:** Zach Rau (RauZ@legis.la.gov); Rachel Feigley (FeigleyR@legis.la.gov); Catherine Brindley  
**Subject:** Pharmacy Board - Regulatory Project 2019-1 ~ Marijuana Pharmacies

Good afternoon,

The Board of Pharmacy has directed the initiation of the rulemaking process to amend portions of its rules relative to marijuana pharmacies. In connection with *Regulatory Project 2019-1 ~ Marijuana Pharmacies*, you should find the following documents attached to this message:

- Memorandum to Occupational Licensing Review Commission;
- Notice of Intent; and
- Fiscal & Economic Impact Statement.

It is our understanding this regulatory project does not require prior approval by the Commission. If so, we would appreciate a communication to that effect to share with the Office of the State Register. In the alternative, we would appreciate confirmation of the scheduling of this project on the agenda for the Commission's next meeting.

On the premise prior approval is not required, we have also copied the Legislative Fiscal Office on this message, for their review and approval of our draft fiscal note. We hope to publish the Notice of Intent in the April 20, 2019 edition of the state register.

Please let me know if you have any questions about these documents or need additional information.

Thanks,  
Malcolm

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy  
[mbroussard@pharmacy.la.gov](mailto:mbroussard@pharmacy.la.gov)

## **Notice of Intent**

### **Department of Health Board of Pharmacy**

Marijuana Pharmacies (LAC 46:LIII.2441, 2443, 2457)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend §2441, §2443, and §2457 of its rules for marijuana pharmacies. The proposed amendments for §2441 will amend the definition of advertising so as to permit the dissemination of educational information about marijuana products; it will also update the definition of marijuana to conform to the current statutory definition. The proposed amendments for §2443 will repeal the limits on the amount of tetrahydrocannabinol (THC) in the dosage form and the packaging for marijuana products, and will also require the inclusion of a product identification code on the label of a marijuana product. The proposed amendments for §2457 will remove the requirements for the physician recommendation to exist in written form and will add the requirement for the patient's debilitating medical condition to be recorded on the recommendation.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

Subchapter E. Marijuana Pharmacy

\* \* \*

§2441. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

\* \* \*

Advertisement – all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana, excluding information of an educational nature designed to inform citizens of the nature and form of the state’s therapeutic marijuana program and its legally permitted products.

\* \* \*

Marijuana – all parts of plants of the genus Cannabis, whether growing or not, the seeds thereof, the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin, but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination, or cannabidiol when contained in a drug product approved by the United States Food and Drug Administration.

\* \* \*

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended LR.

§2443. Marijuana Products

A. – C.3. ...

D. Packaging and Labeling Requirements.

1. Packaging.

a. ...

b. Any product containing pharmaceutical grade marijuana or its principal psychoactive constituent tetrahydrocannabinol (THC) shall be packaged so that one dose contains no more than 10 milligrams of THC.

c. If it is not intended for the entire product to be used at a single time, the packaging must be re-sealable in a manner that maintains its child-resistant property for multiple openings. Single doses may be placed in a package with other single doses; however, the total amount of active THC contained within the larger packaging shall not exceed 100 milligrams.

d. – e.v. ...

2. Labeling.

a. – a.vii. ...

viii. A product identification code registered with the board.

b. – E.4.f. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR.

\* \* \*

## §2457. Standards of Practice

A. – C.2.a. ...

### D. Recordkeeping Requirements

#### 1. Prescription/recommendation/order (hereinafter, “request”) for Marijuana

##### a. ~~Authorization for Emergency Dispensing.~~

~~An emergency situation exists when administration of the marijuana product is necessary for immediate treatment, an appropriate alternate treatment is not available, and the recommending physician cannot reasonably provide a written recommendation. In the case of an emergency situation, a pharmacist may dispense a marijuana product upon receiving oral authorization directly from a recommending physician, provided that:~~

- ~~i. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written recommendation signed by the recommending physician);~~
  - ~~ii. the oral authorization shall be immediately reduced to written form by the pharmacist and shall contain, at a minimum, the following information:
    - ~~(a) Full name and address of the patient;~~
    - ~~(b) Drug product name, strength, and dosage form;~~
    - ~~(c) Quantity of product recommended;~~
    - ~~(d) Directions for use;~~
    - ~~(e) Name, address, telephone number, and CDS license number of the recommending physician; and~~
    - ~~(f) Name of the pharmacist receiving the oral authorization.~~~~
  - ~~iii. if the recommending physician is not known to the pharmacist, he shall make a reasonable effort to determine that the oral authorization came from a physician authorized to recommend marijuana products in Louisiana, which may include a callback to the physician using his telephone number as listed in the telephone directory or other good faith efforts to insure his identity; and~~
  - ~~iv. within seven days after authorizing an emergency oral recommendation, the physician shall cause a written recommendation for the emergency quantity authorized to be delivered to the dispensing pharmacist. The recommendation shall have written on its face “Authorization for Emergency Dispensing,” and the date of the oral authorization. The written recommendation may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven day period. Upon receipt, the dispensing pharmacist shall attach this recommendation to the oral emergency authorization which had earlier been reduced to written form. The pharmacist shall notify the board if the recommending physician fails to deliver a written recommendation to him within the required time; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written recommendation from the recommending physician.~~
- ~~b. In the event the pharmacy receives a request in written form by facsimile, the pharmacy may begin the preparation of the product to be dispensed, but the pharmacist shall not dispense the product until the original form of the request is delivered to him in the pharmacy and he has compared it to the product prepared for dispensing.~~
- ~~c. The written request shall bear the manual signature of the recommending physician. No other form of signature shall be valid, including (but not limited to) stamps, computer generated signatures, or signatures of anyone other than the recommending physician.~~
- ~~d. ...~~
- ~~e. The request shall identify the physician issuing the request as well as the person and the person’s debilitating medical condition for which the marijuana product is intended.~~

2. – 6. ...

### E. Professional Practice Standards

1. ...

#### 2. Labeling of Marijuana Product Dispensed

a. – b.viii. ...

ix. Directions for use of the product as included in the recommending physician’s request;

b.x. – E.5.e.iv. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017),  
amended LR

FAMILY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

The proposed rule amendments will have no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

The proposed rule amendments will have no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

The proposed rule amendments will have no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

The proposed rule amendments will have no effect on family earnings or family budget.

V. The effect on the behavior and personal responsibility of children.

The proposed rule amendments will have no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

The proposed rule amendments will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.



POVERTY IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the rule proposed for adoption, repeal, or amendment.

I. The effect on household income, assets, and financial security.

The proposed rule amendments will have no effect on household income, assets, or financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

The proposed rule amendments will have no effect on early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

The proposed rule amendments will have no effect on employment or workforce development.

IV. The effect on taxes and tax credits.

The proposed rule amendments will have no effect on taxes or tax credits.

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

The proposed rule amendments will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

PROVIDER IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

I. The effect on the staffing level requirements or qualifications required to provide the same level of service.

The proposed rule amendments will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

II. The total direct and indirect effect on the cost to the provider to provide the same level of service.

The proposed rule amendments will have no effect on the cost to the provider to provide the same level of service.

III. The overall effect on the ability of the provider to provide the same level of service.

The proposed rule amendments will have no effect on the ability of the provider to provide the same level of service.

REGULATORY FLEXIBILITY ANALYSIS  
FOR ADMINISTRATIVE RULES

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

There are no compliance or reporting requirements in the proposed rule amendments.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no specific schedules for deadlines in the proposed rule amendments.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

There are no compliance or reporting requirements in the proposed rule amendments.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

One of the proposed rule amendments will require the inclusion of an additional data element on the label for a marijuana product, for a product identification code. The producer is free to determine how to incorporate that data element on the label. One of the proposed rule amendments will require the physician to include the patient's debilitating medical condition in the recommendation. This requirement mirrors the same requirement in the rules from the state medical board, and establishes the eligibility for the patient to receive the marijuana product.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions for small businesses.

## SOLICITATION OF COMMENTS

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to Malcolm J Broussard, Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding these proposed rule amendments. A public hearing on these proposed rule amendments is scheduled for 9:00 a.m. on Wednesday, May 29, 2019 at the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard  
Executive Director  
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment:

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

The proposed rule changes will result in an initial expenditure increase of \$20,000 in FY 20 and \$18,000 annually beginning in FY 21 and in subsequent fiscal years for the LA Board of Pharmacy (LBP). The proposed rule changes will require vendors of medical marijuana to register product identification codes with the LBP, which necessitates the Board acquiring an additional software module for the state's marijuana tracking system to track product identification codes for marijuana products at a cost of \$18,000 per year. The proposed rule changes will also require a one-time expenditure of \$2,000 in FY 20 for the Board to publish the proposed and final rule amendments.

The proposed rule changes amend the definition of "advertisements" regarding medical marijuana; amend the definition of "marijuana"; delete limitations on the amount of tetrahydrocannabinol (THC) that can be included in a marijuana product; add the aforementioned addition of product identification codes for marijuana products; delete provisions associated with emergency dispensing of medical marijuana; revise record-keeping requirements for pharmacists regarding recommendations of medical marijuana; and revise labeling requirements describing the directions for use of a dispensed marijuana product.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

The proposed rule changes will not affect revenue collections for state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes affect marijuana product producers, as they will no longer be limited in the amount of tetrahydrocannabinol (THC) per dose or per package; they will be able to produce marijuana products appropriate for the qualifying medical conditions in Louisiana. Additionally, the proposed rule changes modify advertising restrictions on marijuana pharmacies, allowing them to disseminate educational information regarding marijuana products. Furthermore, the proposed rule changes require marijuana product producers to register product identification codes with the LBP. Lastly, the proposed rule changes revise labeling requirements describing the directions for use of a dispensed marijuana product, removing the requirement that they be limited to the information in a physician's recommendation.

The proposed rule changes affect physicians who recommend medical marijuana and their patients, as well as dispensers of medical marijuana, by deleting provisions associated with emergency dispensing of medical marijuana. Furthermore, the proposed rule changes amend recordkeeping requirements for pharmacists associated with recommendations of medical marijuana, requiring they bear the recommending physician's name, the patient's name, and the authorized condition for which medical marijuana is recommended.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

Person Preparing Statement:	Malcolm J. Broussard Executive Director	Dept.:	Health
Phone:	(225) 925-6481	Office:	Board of Pharmacy
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809	Title:	Marijuana Pharmacies
		Effective Date of Rule:	Upon promulgation Sept. 1, 2019 (est.)

SUMMARY  
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

The proposed rule changes will result in an initial expenditure increase of \$20,000 in FY 20 and \$18,000 annually beginning in FY 21 and in subsequent fiscal years for the LA Board of Pharmacy (LBP). The proposed rule changes will require vendors of medical marijuana to register product identification codes with the LBP, which necessitates the Board acquiring an additional software module for the state's marijuana tracking system to track product identification codes for marijuana products at a cost of \$18,000 per year. The proposed rule changes will also require a one-time expenditure of \$2,000 in FY 20 for the Board to publish the proposed and final rule amendments.

The proposed rule changes amend the definition of "advertisements" regarding medical marijuana; amend the definition of "marijuana"; delete limitations on the amount of tetrahydrocannabinol (THC) that can be included in a marijuana product; add the aforementioned addition of product identification codes for marijuana products; delete provisions associated with emergency dispensing of medical marijuana; revise record-keeping requirements for pharmacists regarding recommendations of medical marijuana; and revise labeling requirements describing the directions for use of a dispensed marijuana product.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS  
(Summary)

The proposed rule changes will not affect revenue collections for state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule changes affect marijuana product producers, as they will no longer be limited in the amount of tetrahydrocannabinol (THC) per dose or per package; they will be able to produce marijuana products appropriate for the qualifying medical conditions in Louisiana. Additionally, the proposed rule changes modify advertising restrictions on marijuana pharmacies, allowing them to disseminate educational information regarding marijuana products. Furthermore, the proposed rule changes require marijuana product producers to register product identification codes with the LBP. Lastly, the proposed rule changes revise labeling requirements describing the directions for use of a dispensed marijuana product, removing the requirement that they be limited to the information in a physician's recommendation.

The proposed rule changes affect physicians who recommend medical marijuana and their patients, as well as dispensers of medical marijuana, by deleting provisions associated with emergency dispensing of medical marijuana. Furthermore, the proposed rule changes amend recordkeeping requirements for pharmacists associated with recommendations of medical marijuana, requiring they bear the recommending physician's name, the patient's name, and the authorized condition for which medical marijuana is recommended.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

Malcolm J. Broussard  
Signature of Agency Head or Designee

Evan Braasch, Staff Director  
Legislative Fiscal Officer or Designee

Malcolm J Broussard, Executive Director  
Typed Name and Title of Agency Head or Designee

4/9/19  
Date of Signature

March 20, 2019  
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT  
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

- A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed amendments for §2441 will amend the definition of advertising so as to permit the dissemination of educational information about marijuana products; it will also update the definition of marijuana to conform to the current statutory definition. The proposed amendments for §2443 will repeal the limits on the amount of tetrahydrocannabinol (THC) in the dosage form and the packaging for marijuana products, and will also require the inclusion of a product identification code on the label of a marijuana product. The proposed amendment for §2447 will make a technical change in the licensing procedure to provide the permit for a marijuana pharmacy will be issued following an inspection of the facility which has been awarded the permit. The proposed amendments for §2457 will remove the requirements for the physician recommendation to exist in written form and will add the requirement for the patient's debilitating medical condition to be recorded on the recommendation.

- B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

Acts 496 and 708 of the 2018 Legislature expanded the original list of qualifying medical conditions eligible for treatment with medical cannabis products. The Board's original rule contains limits on the amount of tetrahydrocannabinol (THC) in medical cannabis products, which were based on the original set of qualifying medical conditions. The new qualifying medical conditions require larger doses of THC; therefore, the Board proposes to repeal the original THC limits. The Board is also responding to stakeholder comments requesting permission to disseminate educational information about medical cannabis products; the proposed amendments modify the definition of advertising to exclude such educational information. Finally, in order to facilitate the reporting of medical cannabis dispensing transactions to the state prescription monitoring program, the Board proposes to require the development of product identification codes and the inclusion of such codes on the label of medical cannabis products.

- C. Compliance with Act 11 of the 1986 First Extraordinary Session:  
(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

The Board will acquire software to track the medical cannabis product identification codes with the state medical marijuana tracking system; the price quoted is \$18,000 per year. In addition, the Board has allocated \$1,000 each for printing the Notice of Intent and the Final Rule. The Board operates on self-generated funds.

- (2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?  
(a) \_\_\_ Yes. If yes, attach documentation.  
(b) X No. If no, provide justification as to why this rule change should be published at this time.

The new qualifying medical conditions require larger doses of THC. The medical cannabis product producers need flexibility to manufacture products appropriate for the Louisiana population. The proposed amendments will repeal the existing THC limits and enable the production of medical cannabis products appropriate for the state's population. The proposed amendment will also enable the dispensing transactions to be reported to the state prescription monitoring program, as required by the enabling legislation.

D. Compliance with Act 820 of the 2008 Regular Session

- (1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of "small businesses", the Board is unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. To the extent any pharmacy licensed by the Board would qualify as a small business, there are nine marijuana pharmacies. Further, there are two marijuana product producers.

- (2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

There are no reporting requirements in the proposed rule amendments.

- (3) A statement of the probable effect on impacted small businesses.

The Board does not anticipate the proposed rule amendments will have any impact on small businesses.

- (4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

There are no alternative methods for achieving the purpose of the proposed rule amendments.

FISCAL AND ECONOMIC IMPACT STATEMENT  
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

- 1. What is the anticipated increase (decrease) in costs to implement the proposed action?

<u>COSTS</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
PERSONAL SERVICES	\$ 0	\$ 0	\$ 0
OPERATING EXPENSES	\$ 2,000	\$ 0	\$ 0
PROFESSIONAL SERVICES	\$ 18,000	\$ 18,000	\$ 18,000
OTHER CHARGES	\$ 0	\$ 0	\$ 0
EQUIPMENT	\$ 0	\$ 0	\$ 0
MAJOR REPAIR & CONSTR.	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 20,000</b>	<b>\$ 18,000</b>	<b>\$ 18,000</b>
POSITIONS (#)	0	0	0

- 2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The proposed rule changes will result in an initial expenditure increase of \$20,000 in FY 20 and \$18,000 annually beginning in FY 21 and in subsequent fiscal years for the LA Board of Pharmacy (LBP). The proposed rule changes require vendors of medical marijuana to register product identification codes with the LBP, which necessitates the Board acquiring an additional software module for the state's marijuana tracking system to track product identification codes for marijuana products at a cost of \$18,000 per year. The proposed rule changes will also require a one-time expenditure of \$2,000 in FY 20 for the Board to publish the proposed and final rule amendments.

The proposed rule changes amend the definition of "advertisements" regarding medical marijuana; amend the definition of "marijuana"; delete limitations on the amount of tetrahydrocannabinol (THC) that can be included in a marijuana product; add the aforementioned addition of product identification codes for marijuana products; delete provisions associated with emergency dispensing of medical marijuana; revises recordkeeping requirements for recommendations of medical marijuana; and revise labeling requirements describing the directions for use of a dispensed marijuana product.



3. Sources of funding for implementing the proposed rule or rule change.

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 20,000	\$ 18,000	\$ 18,000
DEDICATED	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
OTHER (Specify)	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 20,000</b>	<b>\$ 18,000</b>	<b>\$ 18,000</b>

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board has sufficient funds available to implement the proposed rule amendments.

B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.
2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

The proposed rule amendments will have no effect on local governmental units.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

- A. What increase (decrease) in revenues can be anticipated from the proposed action?

<u>SOURCE</u>	<u>FY 19-20</u>	<u>FY 20-21</u>	<u>FY 21-22</u>
STATE GENERAL FUND	\$ 0	\$ 0	\$ 0
AGENCY SELF-GENERATED	\$ 0	\$ 0	\$ 0
DEDICATED FUNDS	\$ 0	\$ 0	\$ 0
FEDERAL FUNDS	\$ 0	\$ 0	\$ 0
LOCAL FUNDS	\$ 0	\$ 0	\$ 0
<b>TOTAL</b>	<b>\$ 0</b>	<b>\$ 0</b>	<b>\$ 0</b>

- B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

The proposed rule changes will not affect revenue collections for state or local governmental units.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

- A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule changes affect marijuana product producers, as they will no longer be limited in the amount of tetrahydrocannabinol (THC) per dose or per package; they will be able to produce marijuana products appropriate for the qualifying medical conditions in Louisiana. Additionally, the proposed rule changes modify advertising restrictions on marijuana pharmacies, allowing them to disseminate educational information regarding marijuana products. Furthermore, the proposed rule changes require marijuana product producers to register product identification codes with the LBP. Lastly, the proposed rule changes revise labeling requirements describing the directions for use of a dispensed marijuana product, removing the requirement that they be limited to the information in a physician's recommendation.

The proposed rule changes affect physicians who recommend medical marijuana and their patients, as well as dispensers of medical marijuana by deleting provisions associated with emergency dispensing of medical marijuana. Furthermore, the proposed rule changes amend recordkeeping requirements associated with recommendations of medical marijuana, requiring they bear the recommending physician's name, the patient's name, and the authorized condition for which medical marijuana is recommended.


Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

The proposed rule amendments will have no effect on receipts or revenue.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule changes will not affect competition or employment.

  
\_\_\_\_\_  
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director  
Typed Name and Title of Agency Head or Designee

March 20, 2019  
Date of Signature

# ACT No. 496

HOUSE BILL NO. 627

BY REPRESENTATIVES LYONS, ARMES, BAGNERIS, BILLIOT, BOUIE, BRASS, CHAD BROWN, CARPENTER, GARY CARTER, COX, FALCONER, GAINES, GLOVER, HALL, JIMMY HARRIS, HUNTER, JACKSON, JAMES, JEFFERSON, JENKINS, JORDAN, TERRY LANDRY, LEGER, MARINO, NORTON, PIERRE, AND SMITH

1 AN ACT

2 To amend and reenact R.S. 40:1046(A)(2) and (H)(2)(c) and to enact R.S. 40:1046(H)(2)(c)  
3 as amended and reenacted by Section 2 of Act No. 96 of the 2016 Regular Session  
4 of the Legislature of Louisiana, relative to health conditions for which a  
5 recommendation or prescription of medical marijuana is authorized; to authorize the  
6 recommendation of or prescription for medical marijuana in treating certain  
7 conditions associated with autism spectrum disorder; to provide for enactment of  
8 certain provisions upon reclassification of marijuana by the United States Drug  
9 Enforcement Administration; to provide for effectiveness; and to provide for related  
10 matters.

11 Be it enacted by the Legislature of Louisiana:

12 Section 1. R.S. 40:1046(A)(2) and (H)(2)(c) are hereby amended and reenacted to  
13 read as follows:

14 §1046. Recommendation of marijuana for therapeutic use; rules and regulations;  
15 Louisiana Board of Pharmacy and the adoption of rules and regulations  
16 relating to the dispensing of recommended marijuana for therapeutic use; the  
17 Department of Agriculture and Forestry and the licensure of a production  
18 facility

19 A.

20 \* \* \*

21 (2)(a) For purposes of this Subsection, "debilitating medical condition"  
22 means ~~cancer, positive status for human immunodeficiency virus, acquired immune~~

1           ~~deficiency syndrome, cachexia or wasting syndrome, seizure disorders, epilepsy,~~  
 2           ~~spasticity, Crohn's disease, muscular dystrophy, or multiple sclerosis.~~ any of the  
 3           following:

- 4                     (i) Cancer.
- 5                     (ii) Positive status for human immunodeficiency virus.
- 6                     (iii) Acquired immune deficiency syndrome.
- 7                     (iv) Cachexia or wasting syndrome.
- 8                     (v) Seizure disorders.
- 9                     (vi) Epilepsy.
- 10                    (vii) Spasticity.
- 11                    (viii) Crohn's disease.
- 12                    (ix) Muscular dystrophy.
- 13                    (x) Multiple sclerosis.
- 14                    (xi) Any of the following conditions associated with autism spectrum

15           disorder:

16                    (aa) Repetitive or self-stimulatory behavior of such severity that the physical  
 17                    health of the person with autism is jeopardized.

18                    (bb) Avoidance of others or inability to communicate of such severity that  
 19                    the physical health of the person with autism is jeopardized.

20                    (cc) Self-injuring behavior.

21                    (dd) Physically aggressive or destructive behavior.

22                    (b) No physician shall recommend medical marijuana for treatment of any  
 23                    condition associated with autism spectrum disorder for a patient who is under the age  
 24                    of eighteen unless the physician complies with the provisions of this Section and  
 25                    consults with a pediatric subspecialist.

26                    (c) If the United States Food and Drug Administration approves the use of  
 27                    medical marijuana in the same form provided for in this Part for any debilitating  
 28                    medical condition specifically identified in this Paragraph, that medical condition  
 29                    shall no longer be covered by the provisions of this Part.

1           ~~(c)~~(d) If the United States Food and Drug Administration approves the use  
2           of medical marijuana in a form or derivative different than provided for in this Part  
3           for any debilitating medical condition specifically identified in this Paragraph, the  
4           disease state shall remain covered by the provisions of this Part. The patient shall  
5           first be treated by the approved form or derivative of medical marijuana through  
6           utilization of step therapy or fail first protocols. If, after use of the United States  
7           Food and Drug Administration approved form or derivative of medical marijuana,  
8           the physician determines that the preferred treatment required under step therapy or  
9           fail first protocol has been ineffective in the treatment of the patient's debilitating  
10          medical condition, he may recommend the form of medical marijuana provided for  
11          in this Part for use by the patient as medically necessary.

\* \* \*

H.

\* \* \*

(2)

\* \* \*

17           (c) The Louisiana State University Agricultural Center or the Southern  
18          University Agricultural Center may conduct research on marijuana for therapeutic  
19          use if the center is licensed as a production facility pursuant to this Section. Effective  
20          January 1, 2020, and annually thereafter, the Louisiana State University Agricultural  
21          Center and the Southern University Agricultural Center shall submit a report to the  
22          Senate and House committees on health and welfare, to include data and outcomes  
23          of the research conducted pursuant to this Paragraph.

\* \* \*

25          Section 2. R.S. 40:1046(A)(2) as amended and reenacted by Section 2 of Act No.  
26          96 of the 2016 Regular Session of the Legislature of Louisiana is hereby amended and  
27          reenacted and R.S. 40:1046(H)(2)(c) is hereby enacted to read as follows:

1           §1046. Prescription of marijuana for therapeutic use; rules and regulations;  
2           Louisiana Board of Pharmacy and the adoption of rules and regulations  
3           relating to the dispensing of prescribed marijuana for therapeutic use; the  
4           Department of Agriculture and Forestry and the licensure of a production  
5           facility

6           A.

7   \*       \*       \*

8           (2)(a) For purposes of this Subsection, "debilitating medical condition"  
9           means any of the following:

10           (i) ~~cancer~~; Cancer.

11           (ii) ~~positive status for human immunodeficiency virus~~; Positive status for  
12           human immunodeficiency virus.

13           (iii) ~~acquired immune deficiency syndrome~~; Acquired immune deficiency  
14           syndrome.

15           (iv) ~~cachexia or wasting syndrome~~; Cachexia or wasting syndrome.

16           (v) ~~seizure disorders~~; Seizure disorders.

17           (vi) ~~epilepsy~~; Epilepsy.

18           (vii) ~~spasticity~~; Spasticity.

19           (viii) ~~Crohn's disease~~; Crohn's disease.

20           (ix) ~~muscular dystrophy~~, or Muscular dystrophy.

21           (x) ~~multiple sclerosis~~; Multiple sclerosis.

22           (xi) Any of the following conditions associated with autism spectrum  
23           disorder:

24           (aa) Repetitive or self-stimulatory behavior of such severity that the physical  
25           health of the person with autism is jeopardized.

26           (bb) Avoidance of others or inability to communicate of such severity that  
27           the physical health of the person with autism is jeopardized.

28           (cc) Self-injuring behavior.

29           (dd) Physically aggressive or destructive behavior.

CODING: Words in ~~struck through~~ type are deletions from existing law; words underscored are additions.

1                    (b) No physician shall prescribe medical marijuana for treatment of any  
 2                    condition associated with autism spectrum disorder for a patient who is under the age  
 3                    of eighteen unless the physician complies with the provisions of this Section and  
 4                    consults with a pediatric subspecialist.

5                    ~~(b)~~(c) If the United States Food and Drug Administration approves the use  
 6                    of medical marijuana in the same form provided for in this Part for any debilitating  
 7                    medical condition specifically identified in this Paragraph, that medical condition  
 8                    shall no longer be covered by the provisions of this Part.

9                    ~~(c)~~(d) If the United States Food and Drug Administration approves the use  
 10                    of medical marijuana in a form or derivative different than provided for in this Part  
 11                    for any debilitating medical condition specifically identified in this Paragraph, the  
 12                    disease state shall remain covered by the provisions of this Part. The patient shall  
 13                    first be treated by the approved form or derivative of medical marijuana through  
 14                    utilization of step therapy or fail first protocols. If, after use of the United States  
 15                    Food and Drug Administration approved form or derivative of medical marijuana,  
 16                    the physician determines that the preferred treatment required under step therapy or  
 17                    fail first protocol has been ineffective in the treatment of the patient's debilitating  
 18                    medical condition, he may prescribe the form of medical marijuana provided for in  
 19                    this Part for use by the patient as medically necessary.

20                    \*           \*           \*

21                    H.

22                    \*           \*           \*

23                    (2)

24                    \*           \*           \*

25                    (c) The Louisiana State University Agricultural Center or the Southern  
 26                    University Agricultural Center may conduct research on marijuana for therapeutic  
 27                    use if the center is licensed as a production facility pursuant to this Section. Effective  
 28                    January 1, 2020, and annually thereafter, the Louisiana State University Agricultural  
 29                    Center and the Southern University Agricultural Center shall submit a report to the

1 Senate and House committees on health and welfare, to include data and outcomes  
2 of the research conducted pursuant to this Paragraph.

3 \* \* \*

4 Section 3. This Section and Section 1 of this Act shall become effective upon  
5 signature by the governor or, if not signed by the governor, upon expiration of the time for  
6 bills to become law without signature by the governor, as provided by Article III, Section  
7 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved  
8 by the legislature, this Section and Section 1 of this Act shall become effective on the day  
9 following such approval.

10 Section 4. This Section and Section 2 of this Act shall become effective and  
11 operative if and upon the date when the United States Drug Enforcement Administration  
12 reclassifies marijuana from a Schedule I drug to a Schedule II drug under the authority of  
13 the Controlled Substances Act, 21 U.S.C. 801 et seq.

\_\_\_\_\_  
SPEAKER OF THE HOUSE OF REPRESENTATIVES

\_\_\_\_\_  
PRESIDENT OF THE SENATE

\_\_\_\_\_  
GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_



# ACT No. 708

2018 Regular Session

HOUSE BILL NO. 579

BY REPRESENTATIVES JAMES AND COX

1 AN ACT

2 To amend and reenact R.S. 40:1046(A)(1) and (2) and (J), and R.S. 40:1046(A)(1) and (2)  
3 and (J) as amended and reenacted by Section 2 of Act No. 96 of the 2016 Regular  
4 Session of the Legislature of Louisiana and to enact R.S. 40:1046(K) and R.S.  
5 40:1046(K) of Section 2 of Act No. 96 of the 2016 Regular Session of the  
6 Legislature of Louisiana, relative to the authorization of marijuana for therapeutic  
7 use; to provide for debilitating medical conditions; to provide for definitions; and to  
8 provide for related matters.

9 Be it enacted by the Legislature of Louisiana:

10 Section 1. R.S. 40:1046(A)(1) and (2) and (J) are hereby amended and and reenacted  
11 and R.S. 40:1046(K) is hereby enacted to read as follows:

12 §1046. Recommendation of marijuana for therapeutic use; rules and regulations;  
13 Louisiana Board of Pharmacy and the adoption of rules and regulations  
14 relating to the dispensing of recommended marijuana for therapeutic use; the  
15 Department of Agriculture and Forestry and the licensure of a production  
16 facility

17 A.(1) Notwithstanding any other provision of this Part, a physician licensed  
18 by and in good standing with the Louisiana State Board of Medical Examiners to  
19 practice medicine in this state and who is domiciled in this state may recommend,  
20 in any form as permitted by the rules and regulations of the Louisiana Board of  
21 Pharmacy except for inhalation, and raw or crude marijuana, tetrahydrocannabinols,

1 or a chemical derivative of tetrahydrocannabinols for therapeutic use by patients  
2 clinically diagnosed as suffering from a debilitating medical condition.

3 (2)(a) For purposes of this Subsection, "debilitating medical condition"  
4 means cancer, glaucoma, Parkinson's disease, positive status for human  
5 immunodeficiency virus, acquired immune deficiency syndrome, cachexia or  
6 wasting syndrome, seizure disorders, epilepsy, spasticity, severe muscle spasms,  
7 intractable pain, Crohn's disease, muscular dystrophy, ~~or~~ multiple sclerosis, or post-  
8 traumatic stress disorder.

9 (b) Intractable pain means a pain state in which the cause of the pain cannot  
10 be removed or otherwise treated with the consent of the patient and which, in the  
11 generally accepted course of medical practice, no relief or cure of the cause of the  
12 pain is possible, or none has been found after reasonable efforts. It is pain so chronic  
13 and severe as to otherwise warrant an opiate prescription.

14 (c) If the United States Food and Drug Administration approves the use of  
15 medical marijuana in the same form provided for in this Part for any debilitating  
16 medical condition specifically identified in this Paragraph, that medical condition  
17 shall no longer be covered by the provisions of this Part.

18 ~~(c)~~(d) If the United States Food and Drug Administration approves the use  
19 of medical marijuana in a form or derivative different than provided for in this Part  
20 for any debilitating medical condition specifically identified in this Paragraph, the  
21 disease state shall remain covered by the provisions of this Part. The patient shall  
22 first be treated by the approved form or derivative of medical marijuana through  
23 utilization of step therapy or fail first protocols. If, after use of the United States  
24 Food and Drug Administration approved form or derivative of medical marijuana,  
25 the physician determines that the preferred treatment required under step therapy or  
26 fail first protocol has been ineffective in the treatment of the patient's debilitating  
27 medical condition, he may recommend the form of medical marijuana provided for  
28 in this Part for use by the patient as medically necessary.

29 \* \* \*

1                   J. Notwithstanding any other provision of law to the contrary, employers and  
 2                   their worker's compensation insurers shall not be obliged or ordered to pay for  
 3                   medical marijuana in claims arising under Title 23 of the Louisiana Revised Statutes  
 4                   of 1950, the Louisiana Workers' Compensation Law.

5                   K. The provisions of this Section shall terminate on January 1, 2020.

6                   Section 2. R.S. 40:1046(A)(1) and (2) and (J) as amended and reenacted by Section  
 7                   2 of Act No. 96 of the 2016 Regular Session of the Legislature of Louisiana are hereby  
 8                   amended and reenacted and R.S. 40:1046(K) is hereby enacted to read as follows:

9                   Section 2. R.S. 40:1046 is hereby amended and reenacted to read as follows:

10                   §1046. Prescription of marijuana for therapeutic use; rules and regulations;  
 11                   Louisiana Board of Pharmacy and the adoption of rules and  
 12                   regulations relating to the dispensing of prescribed marijuana for  
 13                   therapeutic use; the Department of Agriculture and Forestry and the  
 14                   licensure of a production facility

15                   A.(1) Notwithstanding any other provision of this Part, a physician  
 16                   licensed by and in good standing with the Louisiana State Board of Medical  
 17                   Examiners to practice medicine in this state and who is domiciled in this state  
 18                   may prescribe, in any form as permitted by the rules and regulations of the  
 19                   Louisiana Board of Pharmacy except for inhalation, and raw or crude  
 20                   marijuana, tetrahydrocannabinols, or a chemical derivative of  
 21                   tetrahydrocannabinols for therapeutic use by patients clinically diagnosed as  
 22                   suffering from a debilitating medical condition ~~glaucoma, symptoms~~  
 23                   ~~resulting from the administration of chemotherapy cancer treatment, and~~  
 24                   ~~spastic quadriplegia in accordance with rules and regulations promulgated by~~  
 25                   ~~the Louisiana State Board of Medical Examiners. The Louisiana State Board~~  
 26                   ~~of Medical Examiners shall submit to the Senate and House committees on~~  
 27                   ~~health and welfare on an annual basis not less than sixty days prior to the~~  
 28                   ~~beginning of the regular session of the legislature a report as to any~~  
 29                   ~~additional diseases or medical conditions that should be added to the list of~~  
 30                   ~~eligible diseases and conditions for prescription.~~

1                    (2)(a) For purposes of this Subsection, "debilitating medical  
 2                    condition" means cancer, glaucoma, positive status for human  
 3                    immunodeficiency virus, acquired immune deficiency syndrome, cachexia  
 4                    or wasting syndrome, seizure disorders, epilepsy, spasticity, severe muscle  
 5                    spasms, intractable pain, Crohn's disease, muscular dystrophy, or multiple  
 6                    sclerosis, or post-traumatic stress disorder.

7                    (b) Intractable pain means a pain state in which the cause of the pain  
 8                    cannot be removed or otherwise treated with the consent of the patient and  
 9                    which, in the generally accepted course of medical practice, no relief or cure  
 10                   of the cause of the pain is possible, or none has been found after reasonable  
 11                   efforts. It is pain so chronic and severe as to otherwise warrant an opiate  
 12                   prescription.

13                   ~~(b)~~(c) If the United States Food and Drug Administration approves  
 14                   the use of medical marijuana in the same form provided for in this Part for  
 15                   any debilitating medical condition specifically identified in this Paragraph,  
 16                   that medical condition shall no longer be covered by the provisions of this  
 17                   Part.

18                   ~~(c)~~(d) If the United States Food and Drug Administration approves  
 19                   the use of medical marijuana in a form or derivative different than provided  
 20                   for in this Part for any debilitating medical condition specifically identified  
 21                   in this Paragraph, the disease state shall remain covered by the provisions of  
 22                   this Part. The patient shall first be treated by the approved form or derivative  
 23                   of medical marijuana through utilization of step therapy or fail first  
 24                   protocols. If, after use of the United States Food and Drug Administration  
 25                   approved form or derivative of medical marijuana, the physician determines  
 26                   that the preferred treatment required under step therapy or fail first protocol  
 27                   has been ineffective in the treatment of the patient's debilitating medical  
 28                   condition, he may prescribe the form of medical marijuana provided for in  
 29                   this Part for use by the patient as medically necessary.

\* \* \*

1                   J. Notwithstanding any other provision of law to the contrary, employers and  
 2                   their worker's compensation insurers shall not be obliged or ordered to pay for  
 3                   medical marijuana in claims arising under Title 23 of the Louisiana Revised Statutes  
 4                   of 1950, the Louisiana Workers' Compensation Law.

5                   K. The provisions of this Section shall terminate on January 1, 2020.

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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PRESIDENT OF THE SENATE

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_