



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
Telephone 225.925.6496 ~ E-mail: [info@pharmacy.la.gov](mailto:info@pharmacy.la.gov)



July 28, 2023

Senator P. Page Cortez  
President, Louisiana Senate  
Via Email: [APA.SenatePresident@legis.la.gov](mailto:APA.SenatePresident@legis.la.gov)

## Electronic Mail – Delivery Receipt Requested

Re: **Report No. 2 of 3** for Regulatory Project 2023-07 (Summary Report) ~ Marijuana Pharmacy

Dear Senator Cortez:

As we indicated in our first report to your office on April 4, 2023, the Board seeks to amend Chapter 24, Subchapter E of its rules relative to marijuana pharmacies in response to Acts 444 and 491 of the 2022 regular session and an effort to reduce the number of regulations for marijuana pharmacies.

Subsequent to the publication of our Notice of Intent in the April 2023 edition of the *Louisiana Register*, we conducted a public hearing on May 26 to receive comments and testimony on the proposed rule. We received no comments or testimony. The Board subsequently determined no revisions were warranted. On June 7 we submitted the project to the Department of Justice's Occupational Licensing Review Program and are awaiting their approval. In connection with this regulatory project, you should find the following documents in this package:

- *Notice of Intent*, as published in the April 2023 edition of the *Louisiana Register*
- Record from the May 26, 2023 Public Hearing
- Full text of proposed rule, as intended for publication in the *Louisiana Register*

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rules without amendment as a Rule in the September 20, 2023 edition of the *Louisiana Register* with an immediate effective date. If you have any questions about the enclosed information or our procedures, please contact me directly at [jfontenot@pharmacy.la.gov](mailto:jfontenot@pharmacy.la.gov) or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr.  
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)  
Editor, *Louisiana Register* - Via Email: [Reg.Submission@la.gov](mailto:Reg.Submission@la.gov)  
Reference File

## **NOTICE OF INTENT**

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

#### **Marijuana Pharmacy (LAC 46:LIII.Chapter 24)**

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy hereby gives notice of its intent to amend Chapter 24, Subchapter E of its rules relative to marijuana pharmacies in response to Acts 444 and 491 of the 2022 regular session and in an effort to reduce the number of regulations. The proposal repeals §§2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician. The proposed Rule changes replace references to the Department of Agriculture and Forestry (LDAF) with the Department of Health (LDH) and references to physicians with authorized clinicians. The proposed Rule changes shift the responsibility of product requirements from the producers which supply the product to the pharmacies which receive and dispense the product.

The proposed Rule changes remove requirements for producer testing, packaging, labeling, and distribution; duplication listing bulk raw product in allowed dosage form list; the restriction to ten active marijuana permits at a time, including the description of the 9 LDH regions; the requirement to include a blueprint of the proposed marijuana pharmacy and documentation of the applicant's financial capacity to operate a marijuana pharmacy with the initial application for a permit; the description of the manner in which the board may verify information contained in each application; the issuance of duplicate permits; the requirement to develop a written alcohol-free, drug-free, and smoke-free workplace policy; the requirement for product to be immediately placed in a safe or vault upon delivery; the inclusion of "federal" in the list of officials that may enter any area of the marijuana pharmacy; the requirement to

notify LBP of certain security related events; and the reference to security requirements identified elsewhere in the Subchapter.

The proposed Rule changes add the definition of authorized clinician; a requirement for the pharmacy to have access to laboratory tests from the producer; a requirement for each marijuana pharmacy to offer home delivery to patients in each zip code within its region at least once per month; and an allowance for, and requirements related to dispensing marijuana products to visiting qualifying patients.

The proposed Rule changes amend the reference to rules and statutes which authorize fees to be collected by the board.

#### **Title 46**

### **PROFESSIONAL AND OCCUPATIONAL STANDARDS**

#### **Part LIII. Pharmacists**

#### **Chapter 24. Limited Service Providers**

##### **Subchapter E. Marijuana Pharmacy**

##### **§2440. Preamble; Warning; Consultation Suggested**

Repealed.

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 48:1902 (July 2022), repealed LR 49:

##### **§2441. Definitions**

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

\* \* \*

*Advertisement*—Repealed.

\* \* \*

*Approved Safe*—Repealed.

a. - c. Repealed.

*Approved Vault*—Repealed.

a. - b.vi.(d). Repealed.

*Authorized Clinician*—licensed health professionals authorized pursuant to R.S. 40:1046.

\* \* \*

*LDAF*—Repealed.

\* \* \*

*Pharmaceutical Grade Marijuana*—marijuana or marijuana products that are not adulterated and are:

a. - b. ...

c. where each step of the production, cultivating, trimming, curing, manufacturing, processing, and packaging method has been documented by using standard operation procedures verified by the Louisiana Department of Health.

\* \* \*

*Physician*—Repealed.

\* \* \*

*Producer*—a person licensed by the Louisiana Department of Health to cultivate marijuana for therapeutic use.

\* \* \*

*Production Facility*—a secure facility where the production of marijuana occurs and that is operated by a person to whom the Louisiana Department of Health has issued a producer license.

\* \* \*

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 45:1473 (October 2019), LR 46:1227 (September 2020), amended LR 49:

##### **§2443. Marijuana Products**

###### **A. Exclusive Source**

1. The exclusive source of marijuana products shall be the producers licensed for that activity by LDH.

2. Repealed.

3. Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be received by any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed by any marijuana pharmacy.

###### **B. Laboratory Testing**

1. - 7. Repealed.

8. The marijuana pharmacy shall have access to the laboratory test results from the producer for each final product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and authorized clinicians who recommended such marijuana products dispensed to their patients.

###### **C. Product Dosage Forms**

1. The marijuana pharmacy shall limit their dispensing of pharmaceutical grade marijuana products to the following dosage forms:

a. - h. ...

i. Repealed.

2. The marijuana pharmacy may dispense other products from raw or crude marijuana, including dried flower, buds, and other plant material, intended for the following methods of administration:

a. - b. ...

3. No marijuana product shall:

a. - b.iv. ...

c. have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved for use by LDH.

4. ...

###### **D. - E.4.f. Repealed.**

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 45:1473 (October 2019), amended LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:1902 (July 2022), amended LR 49:

##### **§2445. Marijuana Pharmacy Permit**

###### **A. - D. ...**

E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or more without obtaining a new marijuana pharmacy permit shall be subject to disciplinary review by the board.

###### **F. ...**

G. - H. Repealed.

I. - L. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1543 (August 2017), amended LR 49:

#### **§2447. Licensing Procedures**

A. - A.6.d. ...

e. - e.xi. Repealed.

A.6.f. - A.9. ...

10. - 10.c. Repealed.

11. ...

12. - 12.e. Repealed.

13. The application shall be accompanied by payment of the permit fees and administrative hearing fee authorized by LAC 46:LIII.115 and R.S. 40:1013.

14. - 20. ...

B. - B.1. ...

2. The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall complete, sign and date a permit renewal application form supplied by the board, and further, shall include all information requested on the form and attach the pharmacy permit renewal fee and state controlled dangerous substance license renewal fee authorized in LAC 46:LIII.115 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.

3. - 4. ...

5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the board office no later than 30 days after the expiration date of the permit may be processed by the board staff, provided the appropriate delinquent fee authorized in LAC 46:LIII.115 is included with the application.

6. - 7. ...

C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits

1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee, the delinquent fee, the administrative hearing fee, and the reinstatement fees authorized in LAC 46:LIII.115 and the program fee authorized in R.S. 40:1013.

2. ...

D. - D.1. ...

2. Repealed.

3. - 4. ...

5. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit an application form for that purpose supplied by the board and pay the appropriate fee authorized in LAC 46:LIII.115. The board may require an inspection of the new location prior to the issuance of the permit for the new location. No marijuana pharmacy shall commence operation in a new location until approved by the board.

6. - 8. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1544 (August 2017), amended LR 46:577 (April 2020), LR 48:2102 (August 2022), amended LR 49:

#### **§2449. Marijuana Pharmacy Personnel**

Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1546 (August 2017), amended LR 48:2103 (August 2022), repealed LR 49:

#### **§2451. Operation of Marijuana Pharmacy**

A. - K.5. ...

L. Repealed.

M. The receipt of all deliveries from producers shall be carried out under the direct supervision of a pharmacist who shall be present to accept the delivery.

N. - O. ...

P. No person associated with a marijuana pharmacy shall enter into any agreement with an authorized clinician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase marijuana.

Q. Delivery of Dispensed Marijuana Products

1. A marijuana pharmacy shall dispense a marijuana product to a patient or his caregiver in the marijuana pharmacy. At the patient's request, the caregiver may deliver a dispensed marijuana product to the patient's location.

2. Each marijuana pharmacy shall offer home delivery to patients in each zip code within its region at least once per month.

3. At the patient or caregiver's request, the marijuana pharmacy may deliver or facilitate the delivery of a dispensed marijuana product to the patient's location.

4. The delivery of a dispensed marijuana product is subject to the following requirements:

a. The marijuana pharmacy shall not deliver or facilitate the delivery of a marijuana product to a location outside the state.

b. The marijuana pharmacy shall ensure the physical integrity and security of the marijuana product while in transit.

c. In the event the delivery of the marijuana product is not completed, the marijuana product shall be returned to the marijuana pharmacy from which it was dispensed.

d. In the event the pharmacist-in-charge of the marijuana pharmacy cannot assure the integrity and security of a returned marijuana product, the pharmacy shall dispose of the marijuana product.

R. ...

S. Board representatives, local law enforcement or other state or local government officials may enter any area of a marijuana pharmacy if necessary to perform their governmental duties.

T. - U. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1547 (August 2017), amended

LR 46:1227 (September 2020), amended LR 47:590 (May 2021), LR 48:2103 (August 2022), amended LR 49:

#### **§2453. Security Requirements for Marijuana Pharmacies**

Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 48:1903 (July 2022), repealed LR 49:

#### **§2455. Reportable Security Events**

A. - B. ...

C. - D. Repealed.

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 49:

#### **§2457. Standards of Practice**

A. Environmental Standards

1. The prescription department shall be of sufficient size commensurate with the nature and scope of practice. The space occupied by the prescription department shall be restricted to authorized personnel only, as determined by the pharmacist-in-charge, and shall not be accessible to the general public. A marijuana pharmacy shall not permit any person less than eighteen years of age to enter the prescription department, with the exception of patients being counseled by the pharmacist.

2. - 4. ...

5. The prescription department shall be secured by one or more physical barriers with suitable locks and a monitored alarm system capable of detecting unauthorized entry.

A.6. - B.4. ...

5. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.

C. - C.2.a. ...

D. Recordkeeping Requirements

1. When the pharmacy receives a request for marijuana from a recommending authorized clinician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with §1123 of this Part.

2. - 5. ...

E. Professional Practice Standards

1. Recommendation / opinion (hereinafter, "request") for Therapeutic Marijuana

a. The pharmacist may accept any request for a marijuana product which has been:

i. issued by an authorized clinician in possession of a current and unrestricted license to practice in this state as well as a current and unrestricted state controlled substance license with therapeutic marijuana privileges from the board; and

ii. received directly from the authorized clinician and not from the patient or any third party other than the entity transmitting the request, either by electronic means conforming with the provisions of 21 CFR 1311 or its successor, or in the alternative, by facsimile bearing a handwritten or digital signature of the authorized clinician.

b. The request shall disclose the following information at a minimum:

i. name, address, telephone number, and national provider identifier (NPI) number of the authorized clinician issuing the request;

ii. - v. ...

vi. self-certification the authorized clinician holds a current and unrestricted license to practice in this state; and

vii. signature of the authorized clinician issuing the recommendation, excluding any proxy or agent.

c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of time is indicated by the authorized clinician. A pharmacist shall not dispense marijuana product pursuant to an expired request.

d. - e. ...

2. ...

3. Dispensing Marijuana Products

a. Prior to dispensing any marijuana product to a patient, the pharmacist shall review the patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending authorized clinician.

b. - b.i. ...

ii. Subject to the above limitation on dispensing raw or crude marijuana products, a pharmacist may dispense marijuana products on multiple occasions as indicated by the authorized clinician and needed by the patient until the request expires; however, the pharmacist shall not dispense more than a 90-day supply of marijuana product at one time nor more than a one-year supply pursuant to a single request.

c. Dispensing Marijuana Products to Visiting Qualifying Patients.

i. A visiting qualifying patient may obtain medical marijuana from a marijuana pharmacy, subject to the dispensing limitations of Subparagraph 3.b of this Subsection, upon producing evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.

ii. A pharmacist may dispense medical marijuana to a visiting qualifying patient, subject to the dispensing limitations of Subparagraph 3.b of this Subsection, upon obtaining evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.

4. Labeling of Marijuana Product Dispensed

a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by LDH, and further, the pharmacy dispensing label shall not overlay or obscure the producer label in any way.

b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:

i. - ii. ...

iii. name of the recommending authorized clinician;

4.iv. - 7.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 45:1473 (October 2019), LR 47:246 (February 2021), LR 47:1111 (August 2021), LR 48:1903 (July 2022), LR 48:2103 (August 2022), amended LR 49:

## **§2459. Advertising**

Repealed.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1552 (August 2017), repealed LR 49:

### **Family Impact Statement**

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.

1. The Effect on the Stability of the Family. The proposed rule changes will have no effect on the stability of the family.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed rule changes will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The Effect on the Functioning of the Family. The proposed rule changes will have no effect on the functioning of the family.

4. The Effect on Family Earnings and Family Budget. The proposed rule changes will have no effect on family earnings and family budget.

5. The Effect on the Behavior and Personal Responsibility of Children. The proposed rule changes will have no effect on the behavior and personal responsibility of children.

6. The Ability of the Family or a Local Government to Perform the Function as Contained in the Proposed Rule. The proposed rule changes 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**

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.

1. The Effect on Household Income, Assets, and Financial Security. The proposed rule changes will have no effect on household income, assets, or financial security.

2. The Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed rule changes will have no effect on early childhood development or preschool through postsecondary education development.

3. The Effect on Employment and Workforce Development. The proposed rule changes will have no effect on employment and workforce development.

4. The Effect on Taxes and Tax Credits. The proposed rule changes will have no effect on taxes or tax credits.

5. The Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation, and Utilities Assistance. The proposed rule changes will have no effect on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

### **Small Business Analysis**

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:

1. The Establishment of Less Stringent Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on compliance or reporting requirements for small businesses.

2. The Establishment of Less Stringent Schedules or Deadlines for Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on schedules or deadlines for compliance or reporting requirements for small business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule changes will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

5. 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 in the proposed rule changes.

### **Provider Impact Statement**

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:

The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed rule changes will have no effect on the staffing level requirements or qualifications required to provide the same level of service.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed rule changes will have no effect on the cost to the provider to provide the same level of service.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of service. The proposed rule changes will have no effect on the ability of the provider to provide the same level of service.

### **Public Comments**

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding the proposed Rule amendments. The deadline for the receipt of all written comments is 12 p.m. on Friday, May 26, 2023.

## Public Hearing

A public hearing to solicit comments and testimony on the proposed Rule changes is scheduled for 9 a.m. on Friday, May 26, 2023 at the Board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot Jr.  
Executive Director

## FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Marijuana Pharmacy

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

The proposed rule changes will require the Louisiana Board of Pharmacy (LBP) to publish the proposed and final rules in the state register, resulting in printing expenses of \$2,000 in FY 2023 and \$2,000 in FY 2024.

There may be additional costs associated with inspections of additional pharmacies due to the elimination of the ten permit limit. The maximum number of marijuana pharmacies including satellite locations authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. Compliance inspections cost approximately \$300 and are conducted approximately every 18 months. The annual cost of inspections will depend upon the number of marijuana pharmacies in operation and is indeterminable. These costs will be funded through self-generated revenues from application fees.

The proposed rule changes in Chapter 24, Subchapter E are in response to Acts 444 and 491 of the 2022 regular session and an effort by LBP to reduce the number of regulations on marijuana pharmacies. The proposal repeals §§ 2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician.

The proposed rule changes replace references to the Department of Agriculture and Forestry (LDAF) with Department of Health (LDH) and references to physicians with authorized clinicians licensed to practice in this state. The proposed rule changes shift the responsibility of product requirements from the producers which supply the product to the pharmacies which receive and dispense the product.

The proposed rule changes remove requirements for producer testing, packaging, labeling, and distribution; duplication listing bulk raw product in allowed dosage form list; the restriction to ten active marijuana pharmacy permits at a time, including the description of the 9 LDH regions; the requirement to include a blueprint of the proposed marijuana pharmacy and documentation of the applicant's financial capacity to operate a marijuana pharmacy with the initial application for a permit; the description of the manner in which the Board may verify information contained in each application; the issuance of duplicate permits; the requirement to develop a written alcohol-free, drug-free, and smoke-free workplace policy; the requirement for product to be immediately placed in a safe or vault upon delivery; the inclusion of "federal" in the list of officials that may enter any area of the marijuana pharmacy; the requirement to notify LBP of certain security related events; and the reference to security requirements identified elsewhere in the Subchapter.

The proposed rule changes add the definition of authorized clinician; a requirement for the pharmacy to have access to laboratory tests from the producer; a requirement for each marijuana pharmacy to offer home delivery to patients in each zip code within its region at least once per month; and an allowance for, and requirements related to dispensing marijuana products to visiting qualifying patients.

The proposed rule changes amend the reference to rules and statutes which authorize fees to be collected by LBP.

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

LBP may realize additional revenues through pharmacy permit application fees associated with the elimination of the ten permit limit. The maximum number of marijuana pharmacies authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. The application fees total \$550 (\$500 for the application plus the annual \$25 Controlled Dangerous Substance license fee and the annual \$25 Prescription Monitoring Program fee), and annual fees total \$250. The annual revenues realized will depend upon the number of marijuana pharmacies in operation and is indeterminable.

### III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule change in Section 2451, which was a result of Act 491 (2022RS), will benefit consumers by requiring home delivery to patients in each zip code at least once per month, resulting in increased access to care. There will be a cost to marijuana pharmacies to provide delivery services, the amount of which is indeterminable.

The proposed rule changes benefit marijuana pharmacies by reducing the number of regulations to align with ordinary community pharmacy permit requirements more closely. The reduction in regulations, specifically security requirements, should provide an economic benefit for marijuana pharmacies, particularly for new permits.

The proposed rule changes also address recent legislative changes, including changing the licensing of contractors who cultivate, extract, process, produce, and transport therapeutic marijuana to LDH.

### IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed changes eliminate the rule which limits the number of marijuana pharmacy permits to ten. Under current law, the maximum number of allowed marijuana pharmacies in the state is thirty. The opening of additional marijuana pharmacies will increase employment and competition.

M. Joseph Fontenot Jr.  
Executive Director  
2304#022

Evan Brasseaux  
Interim Deputy Fiscal Officer  
Legislative Fiscal Office



# Louisiana Board of Pharmacy

3388 Brentwood Drive  
Baton Rouge, Louisiana 70809-1700  
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**NOTICE IS HEREBY GIVEN** that a Public Hearing has been ordered and called for 9:00 a.m. on Friday, May 26, 2023 at the Board office, for the purpose to wit:

## **A G E N D A**

**Revised 04-19-2023**

1. Call to Order **9:00 A.M.**
2. Appearances
3. Solicitation of Comments & Testimony on Proposed Rule Changes
  - A. Regulatory Project 2023-05 ~ Pharmacy Change of Ownership
  - B. Regulatory Project 2023-06 ~ Staffing Ratios
  - C. Regulatory Project 2023-07 ~ Marijuana Pharmacy
  - D. Regulatory Project 2023-08 ~ DATA-Waiver Registration Elimination
4. Opportunity for Public Comment
5. Adjourn **12:01 P.M.**

### **Public Comments**

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative by personal delivery to M. Joseph Fontenot Jr., Executive Director, at the Board office. He is responsible for responding to inquiries regarding the proposed Rule amendments. The deadline for the receipt of all written comments is 12 p.m. on Friday, May 26, 2023.

### **Public Hearing**

During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.



# Louisiana Board of Pharmacy

Public Hearing Attendance Record ~ May 26, 2023

*Regulatory Project 2023-05 ~ Pharmacy Change of Ownership*

*Regulatory Project 2023-06 ~ Staffing Ratios*

*Regulatory Project 2023-07 ~ Marijuana Pharmacy*

*Regulatory Project 2023-08 ~ DATA-Waiver Registration Elimination*

	Name	Address	E-mail	Group or Agency Represented
1.				
2.				
3.			N/A	
4.				
5.				



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3388 Brentwood Drive  
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## **Summary of Testimony & Public Comments**

**Regulatory Project 2023-07 ~ Marijuana Pharmacy  
at  
May 26, 2023 Public Hearing**

**No comments or testimony received.**

## RULE

### Department of Health Board of Pharmacy

#### Marijuana Pharmacy (LAC 46:LIII.Chapter 24.Subchapter E)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy amended Chapter 24, Subchapter E of its rules relative to marijuana pharmacies in response to Acts 444 and 491 of the 2022 regular session and in an effort to reduce the number of regulations. The changes repeals §§ 2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician. The rule changes replace references to the Department of Agriculture and Forestry (LDAF) with Department of Health (LDH) and references to physicians with authorized clinicians. The rule changes shift the responsibility of product requirements from the producers which supply the product to the pharmacies which receive and dispense the product.

The rule changes remove requirements for producer testing, packaging, labeling, and distribution; duplication listing bulk raw product in allowed dosage form list; the restriction to ten active marijuana permits at a time, including the description of the 9 LDH regions; the requirement to include a blueprint of the proposed marijuana pharmacy and documentation of the applicant's financial capacity to operate a marijuana pharmacy with the initial application for a permit; the description of the manner in which the Board may verify information contained in each application; the issuance of duplicate permits; the requirement to develop a written alcohol-free, drug-free, and smoke-free workplace policy; the requirement for product to be immediately placed in a safe or vault upon delivery; the inclusion of "federal" in the list of officials that may enter any area of the marijuana pharmacy; the requirement to notify LBP of certain security related events; and the reference to security requirements identified elsewhere in the Subchapter.

The rule changes add the definition of authorized clinician; a requirement for the pharmacy to have access to laboratory tests from the producer; a requirement for each marijuana pharmacy to offer home delivery to patients in each zip code within its region at least once per month; and an allowance for, and requirements related to dispensing marijuana products to visiting qualifying patients.

The rule changes amend the reference to rules and statutes which authorize fees to be collected by the Board. This Rule is hereby adopted on the day of promulgation.

## Title 46

### PROFESSIONAL AND OCCUPATIONAL STANDARDS

#### Part LIII: Pharmacists

#### Chapter 24. Limited Service Providers

##### Subchapter E. Marijuana Pharmacy

#### §2440. Preamble; Warning; Consultation Suggested – Repealed.

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 48:1902 (July 2022), repealed LR

#### §2441. Definitions

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

\* \* \*

*Advertisement*—Repealed.

\* \* \*

*Approved Safe*—Repealed.

*Approved Vault*—Repealed.

*Authorized Clinician* – licensed health professionals authorized pursuant to R.S. 40:1046.

\* \* \*

*LDAF*—Repealed.

\* \* \*

*Pharmaceutical Grade Marijuana*—marijuana or marijuana products that are not adulterated and are:

- a. – b. ...
- c. where each step of the production, cultivating, trimming, curing, manufacturing, processing, and packaging method has been documented by using standard operation procedures verified by the Louisiana Department of Health.

\* \* \*

*Physician*—Repealed.

\* \* \*

*Producer*—a person licensed by the Louisiana Department of Health to cultivate marijuana for therapeutic use.

\* \* \*

*Production Facility*—a secure facility where the production of marijuana occurs and that is operated by a person to whom the Louisiana Department of Health has issued a producer license.

\* \* \*

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 45:1473 (October 2019), LR 46:1227 (September 2020), amended LR

### **§2443. Marijuana Products**

#### **A. Exclusive Source**

- 1. The exclusive source of marijuana products shall be the producers licensed for that activity by LDH.
- 2. Repealed.
- 3. Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be received by any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed by any marijuana pharmacy.

#### **B. Laboratory Testing**

- 1. – 7. Repealed.
- 8. The marijuana pharmacy shall have access to the laboratory test results from the producer for each final product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and authorized clinicians who recommended such marijuana products dispensed to their patients.

#### **C. Product Dosage Forms**

- 1. The marijuana pharmacy shall limit their dispensing of pharmaceutical grade marijuana products to the following dosage forms:
  - a. – h. ...
  - i. Repealed.
- 2. The marijuana pharmacy may dispense other products from raw or crude marijuana, including dried flower, buds, and other plant material, intended for the following methods of administration:
  - a. – b. ...
- 3. No marijuana product shall:
  - a. – b.iv. ...
  - c. have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved for use by LDH.
- 4. ...

D. – E.4.f. Repealed.

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 45:1473 (October 2019), amended LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:1902 (July 2022), amended LR

#### **§2445. Marijuana Pharmacy Permit**

A. – D. ...

E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or more without obtaining a new marijuana pharmacy permit shall be subject to disciplinary review by the board.

F. ...

G. Repealed.

H. Repealed.

I. – L. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1543 (August 2017), amended LR

#### **§2447. Licensing Procedures**

A. – A.6.d. ...

e. Repealed.

A.6.f. – A.9. ...

10. Repealed.

11. ...

12. Repealed.

13. The application shall be accompanied by payment of the permit fees and administrative hearing fee authorized by LAC 46:LIII.115 and R.S. 40:1013.

14. – 20. ...

B. – B.1. ...

2. The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall complete, sign and date a permit renewal application form supplied by the board, and further, shall include all information requested on the form and attach the pharmacy permit renewal fee and state controlled dangerous substance license renewal fee authorized in LAC 46:LIII.115 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.

B.3. – B.4. ...

5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the board office no later than 30 days after the expiration date of the permit may be processed by the board staff, provided the appropriate delinquent fee authorized in LAC 46:LIII.115 is included with the application.

B.6. – B.7. ...

C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits

1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee, the delinquent fee, the administrative hearing fee, and the reinstatement fees authorized in LAC 46:LIII.115 and the program fee authorized in R.S. 40:1013.

2. ...

D. – D.1. ...

2. Repealed.

D.3. – D.4. ...

5. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit an application form for that purpose supplied by the board and pay the appropriate fee authorized in LAC 46:LIII.115. The board may require an inspection of the new location prior to the issuance of the permit for the new location. No marijuana pharmacy shall commence operation in a new location until approved by the board.

D.6. – D.8. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1544 (August 2017), amended LR 46:577 (April 2020), LR 48:2102 (August 2022), amended LR

**§2449. Marijuana Pharmacy Personnel— Repealed.**

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1546 (August 2017), amended LR 48:2103 (August 2022), repealed LR

**§2451. Operation of Marijuana Pharmacy**

A. – K.5. ...

L. Repealed.

M. The receipt of all deliveries from producers shall be carried out under the direct supervision of a pharmacist who shall be present to accept the delivery.

N. – O. ...

P. No person associated with a marijuana pharmacy shall enter into any agreement with an authorized clinician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase marijuana.

Q. Delivery of Dispensed Marijuana Products.

1. A marijuana pharmacy shall dispense a marijuana product to a patient or his caregiver in the marijuana pharmacy. At the patient's request, the caregiver may deliver a dispensed marijuana product to the patient's location.

2. Each marijuana pharmacy shall offer home delivery to patients in each zip code within its region at least once per month.

3. At the patient or caregiver's request, the marijuana pharmacy may deliver or facilitate the delivery of a dispensed marijuana product to the patient's location.

4. The delivery of a dispensed marijuana product is subject to the following requirements:

a. The marijuana pharmacy shall not deliver or facilitate the delivery of a marijuana product to a location outside the state.

b. The marijuana pharmacy shall ensure the physical integrity and security of the marijuana product while in transit.

c. In the event the delivery of the marijuana product is not completed, the marijuana product shall be returned to the marijuana pharmacy from which it was dispensed.

d. In the event the pharmacist-in-charge of the marijuana pharmacy cannot assure the integrity and security of a returned marijuana product, the pharmacy shall dispose of the marijuana product.

R. ...

S. Board representatives, local law enforcement or other state or local government officials may enter any area of a marijuana pharmacy if necessary to perform their governmental duties.

T. – U. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1547 (August 2017), amended LR 46:1227 (September 2020), amended LR 47:590 (May 2021), LR 48:2103 (August 2022), amended LR

### **§2453. Security Requirements for Marijuana Pharmacies – Repealed.**

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 48:1903 (July 2022), repealed LR

### **§2455. Reportable Security Events**

A. – B. ...

C. – D. Repealed.

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

### **§2457. Standards of Practice**

#### **A. Environmental Standards**

1. The prescription department shall be of sufficient size commensurate with the nature and scope of practice. The space occupied by the prescription department shall be restricted to authorized personnel only, as determined by the pharmacist-in-charge, and shall not be accessible to the general public. A marijuana pharmacy shall not permit any person less than eighteen years of age to enter the prescription department, with the exception of patients being counseled by the pharmacist.

A.2. – A.4. ...

5. The prescription department shall be secured by one or more physical barriers with suitable locks and a monitored alarm system capable of detecting unauthorized entry.

6. ...

B. – B.4. ...

5. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.

C. – C.2.a. ...

#### **D. Recordkeeping Requirements**

1. When the pharmacy receives a request for marijuana from a recommending authorized clinician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with Section 1123 of this Part.

2. – 5. ...

#### **E. Professional Practice Standards**

##### **1. Recommendation / opinion (hereinafter, “request”) for Therapeutic Marijuana**

a. The pharmacist may accept any request for a marijuana product which has been:

i. issued by an authorized clinician in possession of a current and unrestricted license to practice in this state as well as a current and unrestricted state controlled substance license with therapeutic marijuana privileges from the board; and

ii. received directly from the authorized clinician and not from the patient or any third party other than the entity transmitting the request, either by electronic means conforming with the provisions of 21 CFR 1311 or its successor, or in the alternative, by facsimile bearing a handwritten or digital signature of the authorized clinician.

b. The request shall disclose the following information at a minimum:

i. name, address, telephone number, and national provider identifier (NPI) number of the authorized clinician issuing the request;

ii. – v. ...

vi. self-certification the authorized clinician holds a current and unrestricted license to practice in this state; and

vii. signature of the authorized clinician issuing the recommendation, excluding any proxy or agent.

c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of time is indicated by the authorized clinician. A pharmacist shall not dispense marijuana product pursuant to an expired request.

d. – e. ...

2. ...

### 3. Dispensing Marijuana Products

a. Prior to dispensing any marijuana product to a patient, the pharmacist shall review the patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending authorized clinician.

b. – b.i ...

ii. Subject to the above limitation on dispensing raw or crude marijuana products, a pharmacist may dispense marijuana products on multiple occasions as indicated by the authorized clinician and needed by the patient until the request expires; however, the pharmacist shall not dispense more than a 90-day supply of marijuana product at one time nor more than a one-year supply pursuant to a single request.

#### c. Dispensing Marijuana Products to Visiting Qualifying Patients.

i. A visiting qualifying patient may obtain medical marijuana from a marijuana pharmacy, subject to the dispensing limitations of Paragraph (3)(b) of this Subsection, upon producing evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.

ii. A pharmacist may dispense medical marijuana to a visiting qualifying patient, subject to the dispensing limitations of Paragraph (3)(b) of this Subsection, upon obtaining evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.

### 4. Labeling of Marijuana Product Dispensed

a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by LDH, and further, the pharmacy dispensing label shall not overlay or obscure the producer label in any way.

b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:

i. – ii. ...

iii. name of the recommending authorized clinician;

iv. – xi. ...

5. – 7.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 45:1473 (October 2019), LR 47:246 (February 2021), LR 47:1111 (August 2021), LR 48:1903 (July 2022), LR 48:2103 (August 2022), amended LR

### **§2459. Advertising – Repealed**

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1552 (August 2017), repealed LR

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