

RULE

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 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 The changes repealed §§2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician.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 the 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 49:1719 (October 2023).

§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 49:1719 (October 2023).

§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 49:1719 (October 2023).

§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 49:1720 (October 2023).

§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 49:1720 (October 2023).

§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 49:1720 (October 2023).

§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 49:1720 (October 2023).

§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 49:1721 (October 2023).

§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 49:1721 (October 2023).

§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 49:1721 (October 2023).

§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 49:1722 (October 2023).

M. Joseph Fontenot Jr.
Executive Director

2310#017