

Louisiana Board of Pharmacy

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



July 6, 2022

Senator P. Page Cortez President, Louisiana Senate

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail - Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2022-3 ~ Marijuana Pharmacies

Dear Senator Cortez:

As we indicated in our first report to your office on April 8, the Board initiated this regulatory project to amend its rules for marijuana pharmacies to reduce some of the regulatory restrictions for licensed pharmacy personnel in those pharmacies as well as to require those pharmacies to make marijuana product testing results available whenever patients request that information.

Subsequent to the publication of our *Notice of Intent* in the April 2022 edition of the *Louisiana Register*, we conducted a public hearing on May 27 to receive comments and testimony on the proposed rule changes. We received no comments or testimony. The Board subsequently determined no revisions were warranted. During their June 29 meeting, the Occupational Licensing Review Commission authorized the Board to complete the promulgation process. In connection with this regulatory project, you should find the following documents in this package:

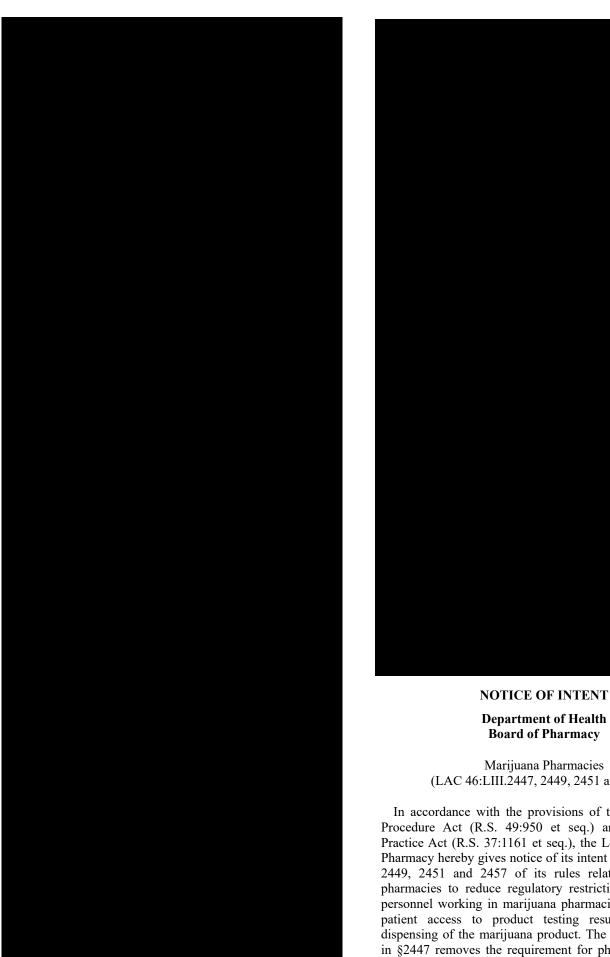
Notice of Intent, as published in the April 2022 <u>Louisiana Register</u>
 Record from the May 27, 2022 Public Hearing
 Full text of proposed rule, as intended for publication in the <u>Louisiana Register</u>
 Page 8

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rule changes without amendment as a *Rule* in the August 20, 2022 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 or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr. Executive Director

cc: Chair, Senate Health & Welfare Committee – <u>APA.S-H&W@legis.la.gov</u>
Speaker, House of Representatives – <u>APA.HouseSpeaker@legis.la.gov</u>
Chair, House Health & Welfare Committee – <u>APA.H-HW@legis.la.gov</u>
Editor, <u>Louisiana Register</u> – <u>Reg.Submission@la.gov</u>
Reference File



Department of Health

(LAC 46:LIII.2447, 2449, 2451 and 2457)

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 Louisiana Board of Pharmacy hereby gives notice of its intent to amend §§2447, 2449, 2451 and 2457 of its rules relative to marijuana pharmacies to reduce regulatory restrictions on pharmacy personnel working in marijuana pharmacies and to provide patient access to product testing results prior to the dispensing of the marijuana product. The proposed changes in §2447 removes the requirement for pharmacy personnel working in a marijuana pharmacy to obtain an additional credential issued by the board. The proposed changes in

§2449 eliminates the separate therapeutic marijuana designation credential currently issued by the board and repeals the associated credentialing procedures. The proposed changes in §2451 remove the restriction against pharmacy technician candidates working in a marijuana pharmacy and clarify the requirements for the dispensing process. The proposed changes in §2457 remove the restrictions on licensed pharmacy personnel working in a marijuana pharmacy, and further, require the pharmacist to comply with a patient request to review product testing results for the marijuana product prior to dispensing that product.

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 24. Limited Service Providers Subchapter E. Marijuana Pharmacy §2447. Licensing Procedures

A. - C.2. ...

D. Maintenance of Marijuana Pharmacy Permit

1. - 2. ...

- 3. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the permit shall notify the board and request approval of the contemplated name or trade name. The board shall reasonably accommodate such requests, unless there is cause not to do so (e.g., duplicative or misleading names). The marijuana pharmacy shall not change its name or trade name until approved by the board.
- 4. Prior to any modification, remodeling, expansion, reduction, or other physical, non-cosmetic alteration of the marijuana pharmacy, the owner of the permit shall notify the board and request approval of the contemplated change(s). The board shall reasonably accommodate such request, unless there is cause not to do so (e.g., inconsistent with operating requirements). The marijuana pharmacy shall not make such changes until approved by the board.
- 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 R.S. 37:1184. 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. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the pharmacist-in-charge for the marijuana pharmacy permit.
- 7. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the owner's managing officer for the marijuana pharmacy permit.
- 8. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall notify the board in accordance with the rules governing the permanent closure of a pharmacy as described in Chapter 11 of this Part.

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:

§2449. Marijuana Pharmacy Personnel

A. ..

- B.1. The PIC shall insure and document the initial and continuing competency of the entire professional staff to provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the PIC shall provide access to education and training in the following domains:
- a. policies and procedures of the pharmacy, especially those relating to the tasks and functions that employee is expected to perform;
- b. professional conduct, ethics, and patient confidentiality; and
- c. developments in the therapeutic use of marijuana. Further, the PIC shall document such education and training, provide such records to the board when requested, and retain such records for at least two years after the employee disassociates with the pharmacy.
- 2. Further, the PIC shall document such education and training, provide such records to the board when requested, and retain such records for at least two years after the employee disassociates with the pharmacy.
- C. The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy interns) and Chapter 9 (pharmacy technicians) of this Part.
- D. In addition to the scope of practice limitations found in Chapter 9 of this Part, pharmacy technicians practicing in a marijuana pharmacy shall not:
- 1. consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient medication record;
- 2. consult with the physician who issued the recommendation/prescription/order for marijuana to the patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;
- 3. interpret the patient's clinical data or provide medical advice;
- 4. perform professional consultations with physicians, nurses, or other health care professionals or their authorized agents; or
- 5. determine whether a different brand or formulation of marijuana should be dispensed for the marijuana product or formulation recommended/prescribed/ordered by the physician or requested by the patient or his caregiver.

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 LP 48:

§2451. Operation of Marijuana Pharmacy

A. - E. ...

F. Only a pharmacist may dispense marijuana, however, other licensed pharmacy personnel may assist the pharmacist in the dispensing process. The sale of dispensed marijuana products may be accomplished by any pharmacy employee.

G. - 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), LR 47:590 (May 2021), LR 48:

§2457. Standards of Practice

A. - A.6. ...

- B. Minimum Staffing Requirements
- 1. There shall be at least one pharmacist on duty at all times the pharmacy is open for business.
- 2. Every pharmacist practicing in the pharmacy shall possess a Louisiana pharmacist license in active status as well as access privileges to the state prescription monitoring program.
- 3. A pharmacy intern, pharmacy technician or pharmacy technician candidate may assist the pharmacist in the prescription department, but only when in possession of valid credentials issued by the board. The supervising pharmacist may establish a delegate credential in the state prescription monitoring program for any licensed pharmacy personnel affiliated with that pharmacy.
- 4. Additional clerical personnel may also be present at the pharmacy.

C. - D. ...

- E. Professional Practice Standards
 - 1. 1.d....
- 2. Upon request by the patient or caregiver and prior to dispensing any marijuana product to a patient, the pharmacist shall provide product testing results available to the pharmacist for the product contemplated for dispensing.
 - 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 physician.
 - b. Dispensing Limitations
- i. A pharmacist shall not dispense more than two and one-half ounces, or 71 grams, of raw or crude marijuana every 14 days to any person.
- 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 physician 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
 - 4. Labeling of Marijuana Product Dispensed
- a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by the LDAF, 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. name and address of the pharmacy dispensing the product;
- ii. telephone number or other contact information of the pharmacy dispensing the product;
 - iii. name of the recommending physician;
 - iv. name of the patient;
 - v. date the product was dispensed;
- vi. prescription number, which shall be a unique identifier for that specific transaction:

- vii. name of the marijuana product, including any concentration, strength, or other identifiers of the marijuana product;
 - viii. quantity of marijuana dispensed;
 - ix. directions for use of the product;
- x. expiration date of the product, which shall not exceed the expiration date determined by the producer of the product; and
- xi. other information selected by the dispensing pharmacist to inform the patient as to the best use of the product for the intended purpose.
- 5. The pharmacy shall comply with the rules on drug utilization review and patient counseling in Chapter 5 of this Part.
- 6. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with the reporting requirements as found in Chapter 29 of this Part.
 - 7. Disposal of Marijuana Product
- a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is determined to be misbranded, adulterated, expired, deteriorated, undesired, excess, unauthorized, or unfit for dispensing.
- b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the product shall be removed from active dispensing stock and quarantined in the pharmacy pending its disposal
- c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the waste with other ground materials so the resulting mixture is at least 50% non-marijuana waste by volume. Material used to grind with the waste may include:
 - i. yard waste;
 - ii. paper waste;
 - iii. cardboard waste;
 - iv. plastic waste; or
 - v. soil or sand.
- d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable shall be disposed of by delivery to an approved solid waste facility for final disposition.
- i. Examples of acceptable permitted solid waste facilities include:
 - (a). compost; anaerobic digester;
 - (b). landfill, incinerator; or
 - (c). waste-to-energy facility.
- e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain, at a minimum, the following information:
- i. brand name and other specific identifiers of the marijuana product disposed;
 - ii. quantity of product disposed;
 - iii. manner of disposal; and
- iv. signatures of the pharmacist-in-charge disposing the product plus at least one witness who is either a credentialed staff member of that pharmacy or an agent of the board.

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:

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 remove restrictions on pharmacy technician candidates on working in marijuana pharmacies, which could improve employment opportunities with a potentially beneficial effect on family earnings or 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 changes.

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 remove hiring restrictions, which could improve employment opportunities with a potentially beneficial 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 may improve employment opportunities in marijuana pharmacist..
- 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 businesses.
- 3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on compliance or reporting requirements for small businesses.
- 4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule changes do not include design or operational standards.
- 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:

- 1. 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 the qualifications for that staff 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, Executive Director-Designate, 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 amendment.

Public Hearing

A public hearing to solicit comments and testimony on the proposed rule changes is scheduled for 9:00 a.m. on Friday, May 27, 2022 at the Board office. During the hearing, all interested persons will be afforded an opportunity to submit comments or testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. noon that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

Malcolm J. Broussard Executive Director

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

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 \$750 in FY 2022 and \$750 in FY 2023. By repealing the necessity of a separate credential, the Board will no longer incur the \$500 annual maintenance fee for that credential in its licensure information system. There will be no additional expenditures or cost savings to LBP or other state or local governmental units.

The proposed rule changes reduce regulatory barriers for licensed pharmacy personnel working in marijuana pharmacies and enhances the information provided to patients about medical cannabis products dispensed to them.

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

The proposed rule changes will not affect revenue collections of state or local governmental units. The credential this rule would repeal is issued virtually at no charge.

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

The proposed rule changes will reduce regulatory barriers for licensed pharmacy personnel working in marijuana pharmacies by repealing the necessity for a separate credential to work in such pharmacies, and by repealing the restriction which prohibits pharmacy technician candidates from working in marijuana pharmacies. In addition, the proposed rule changes will require cannabis product testing results to be made available to patients when requested prior to the dispensing of those products. While some pharmacies may choose to keep printed copies of product testing results for patients, these test results will also be available through QR codes by marijuana pharmacy suppliers at no cost to pharmacies.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The repeal of regulatory barriers for licensed pharmacy personnel working or seeking to work in marijuana pharmacies will improve employment opportunities for those personnel. The proposed rule changes will not affect competition at marijuana pharmacies.

Joe Fontenot Executive Director-Designate 2204#048 Evan Brasseaux Interim Deputy Fiscal Officer Legislative Fiscal Office



Louisiana Board of Pharmacy

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Baton Rouge, Louisiana 70809-1700
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Summary of Testimony & Public Comments re Regulatory Project 2022-3 ~ Marijuana Pharmacies at May 27, 2022 Public Hearing

No comments or testimony received.

RULE

Department of Health Board of Pharmacy

Marijuana Pharmacies (LAC 46:LIII.2447, 2449, 2451 and 2457)

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 Louisiana Board of Pharmacy has amended §§2447, 2449, 2451 and 2457 of its rules relative to marijuana pharmacies to reduce regulatory restrictions on pharmacy personnel working in marijuana pharmacies and to provide patient access to product testing results prior to the dispensing of the marijuana product. The changes in §2447 remove the requirement for pharmacy personnel working in a marijuana pharmacy to obtain an additional credential issued by the board. The changes in §2449 eliminate the separate therapeutic marijuana designation credential currently issued by the board and repeal the associated credentialing procedures. The changes in §2451 remove the restriction against pharmacy technician candidates working in a marijuana pharmacy and clarify the requirements for the dispensing process. The changes in §2457 remove the restrictions on licensed pharmacy personnel working in a marijuana pharmacy, and further, require the pharmacist to comply with a patient request to review product testing results for the marijuana product prior to dispensing that product. 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

A. – C.2. ...

D. Maintenance of Marijuana Pharmacy Permit

1.-2. ...

§2447. Licensing Procedures

- 3. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the permit shall notify the board and request approval of the contemplated name or trade name. The board shall reasonably accommodate such requests, unless there is cause not to do so (e.g., duplicative or misleading names). The marijuana pharmacy shall not change its name or trade name until approved by the board.
- 4. Prior to any modification, remodeling, expansion, reduction, or other physical, non-cosmetic alteration of the marijuana pharmacy, the owner of the permit shall notify the board and request approval of the contemplated change(s). The board shall reasonably accommodate such request, unless there is cause not to do so (e.g., inconsistent with operating requirements). The marijuana pharmacy shall not make such changes until approved by the board.
- 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 R.S. 37:1184. 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. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the pharmacist-incharge for the marijuana pharmacy permit.
- 7. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the owner's managing officer for the marijuana pharmacy permit.

8. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall notify the board in accordance with the rules governing the permanent closure of a pharmacy as described in Chapter 11 of this Part.

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:

§2449. Marijuana Pharmacy Personnel

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- B. 1. The PIC shall insure and document the initial and continuing competency of the entire professional staff to provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the PIC shall provide access to education and training in the following domains:
- a. policies and procedures of the pharmacy, especially those relating to the tasks and functions that employee is expected to perform.
 - b. professional conduct, ethics, and patient confidentiality; and
 - c. developments in the therapeutic use of marijuana.
- 2. Further, the PIC shall document such education and training, provide such records to the board when requested, and retain such records for at least two years after the employee disassociates with the pharmacy.
- C. The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy interns) and Chapter 9 (pharmacy technicians) of this Part.
- D. In addition to the scope of practice limitations found in Chapter 9 of this Part, pharmacy technicians practicing in a marijuana pharmacy shall not:
- 1. consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient's medication record;
- 2. consult with the physician who issued the recommendation/prescription/order for marijuana to the patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;
 - 3. interpret the patient's clinical data or provide medical advice;
 - 4. perform professional consultations with physicians, nurses, or other health care professionals or their authorized agents;
- 5. determine whether a different brand or formulation of marijuana should be dispensed for the marijuana product or formulation recommended/prescribed/ordered by the physician or requested by the patient or his caregiver.

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:

§2451. Operation of Marijuana Pharmacy

A. E. ...

or

F. Only a pharmacist may dispense marijuana, however, other licensed pharmacy personnel may assist the pharmacist in the dispensing process. The sale of dispensed marijuana products may be accomplished by any pharmacy employee.

 $G.-U.\ \dots$

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), LR 47:590 (May 2021), LR 48:

§2457. Standards of Practice

A. – A.6. ...

- B. Minimum Staffing Requirements
 - 1. There shall be at least one pharmacist on duty at all times the pharmacy is open for business.
- 2. Every pharmacist practicing in the pharmacy shall possess a Louisiana pharmacist license in active status as well as access privileges to the state prescription monitoring program.
- 3. A pharmacy intern, pharmacy technician or pharmacy technician candidate may assist the pharmacist in the prescription department, but only when in possession of valid credentials issued by the board. The supervising pharmacist may establish a delegate credential in the state prescription monitoring program for any licensed pharmacy personnel affiliated with that pharmacy.
 - 4. Additional clerical personnel may also be present at the pharmacy.

C. - D. ...

E. Professional Practice Standards

1. − 1.d. ...

- 2. Upon request by the patient or caregiver and prior to dispensing any marijuana product to a patient, the pharmacist shall provide product testing results available to the pharmacist for the product contemplated for dispensing.
 - 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 physician.
 - b. Dispensing Limitations
- i. A pharmacist shall not dispense more than two and one-half ounces, or 71 grams, of raw or crude marijuana every 14 days to any person.
- 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 physician 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.
 - 4. Labeling of Marijuana Product Dispensed
- a. The pharmacist shall not dispense any marijuana product that does not bear the product label required by the LDAF; 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:
 - name and address of the pharmacy dispensing the product;
 - ii. telephone number or other contact information of the pharmacy dispensing the product;
 - iii. name of the recommending physician;
 - iv. name of the patient;
 - v. date the product was dispensed;
 - vi. prescription number, which shall be a unique identifier for that specific transaction;
- vii. name of the marijuana product, including any concentration, strength, or other identifiers of the marijuana product;
 - viii. quantity of marijuana dispensed;
 - ix. directions for use of the product;
- x. expiration date of the product, which shall not exceed the expiration date determined by the producer of the product; and

- xi. other information selected by the dispensing pharmacist to inform the patient as to the best use of the product for the intended purpose.
 - 5. The pharmacy shall comply with the rules on drug utilization review and patient counseling in Chapter 5 of this Part.
- 6. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with the reporting requirements as found in Chapter 29 of this Part.
 - 7. Disposal of Marijuana Product
- a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is determined to be misbranded, adulterated, expired, deteriorated, undesired, excess, unauthorized, or unfit for dispensing.
- b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the product shall be removed from active dispensing stock and quarantined in the pharmacy pending its disposal.
- c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the waste with other ground materials so the resulting mixture is at least 50% non-marijuana waste by volume. Material used to grind with the waste may include:
 - i. yard waste;
 - ii. paper waste;
 - iii. cardboard waste;
 - iv. plastic waste; or
 - v. soil or sand.
- d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable shall be disposed of by delivery to an approved solid waste facility for final disposition.
 - i. Examples of acceptable permitted solid waste facilities include:
 - (a) compost; anaerobic digester;
 - (b) landfill, incinerator; or
 - (c) waste-to-energy facility.
- e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain, at a minimum, the following information:
 - i. brand name and other specific identifiers of the marijuana product disposed;
 - ii. quantity of product disposed;
 - iii. manner of disposal; and
- iv. signatures of the pharmacist-in-charge disposing the product plus at least one witness who is either a credentialed staff member of that pharmacy or an agent of the board.

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:

M. Joseph Fontenot, Jr.

Executive Director