

Louisiana Board of Pharmacy

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



June 7, 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 2022-1 ~ Raw Marijuana Products

Dear Senator Cortez:

As we indicated in our first report to your office on February 8, the Board initiated this regulatory project to implement the provisions of Act 424 of the 2021 Legislature authorizing the use of raw or crude marijuana for therapeutic purposes and to remove an unnecessary restriction on the storage of marijuana products in marijuana pharmacies. The proposed rule changes add raw products to the list of allowable dosage forms, establish testing standards for raw products, and specifies the dispensing limitations for raw products identified in the legislation. Further, the proposed rule changes allow marijuana pharmacies to temporarily store marijuana products outside safes and vaults but still within the prescription department during their operating hours to facilitate efficient dispensing procedures.

Subsequent to the publication of our *Notice of Intent* in the February 2022 edition of the *Louisiana Register*, we conducted a public hearing on March 25 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 May 13 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 February 2022 <u>Louisiana Register</u>
 Record from the March 25, 2022 Public Hearing
 Full text of proposed rule, as intended for publication in the *Louisiana Register* 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 July 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 mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

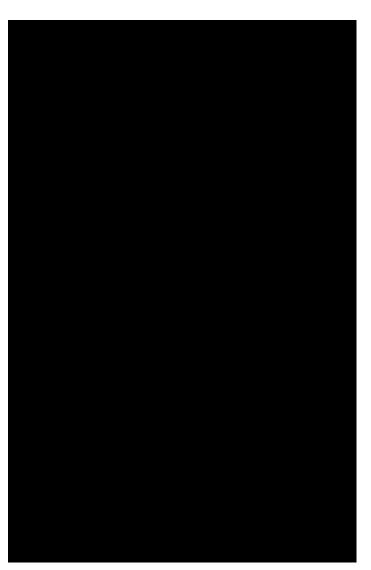
Malcolm J. Broussard Executive Director

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, Louisiana Register - Reg.Submission@la.gov

Reference File





NOTICE OF INTENT

Department of Health Board of Pharmacy

Raw Marijuana Products (LAC 46:LIII.2440, 2443, 2453, 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 §§2440, 2443, 2453, and 2457 of its rules relative to marijuana pharmacies to implement the provisions of Act 424 of the 2021 Legislature. The proposed changes in §2440 make a technical change in the reference to the initial enabling legislation for the medical marijuana program and identifies the mandates within 2021 legislation. The proposed changes in §2443 add raw marijuana products to those items which producers are authorized to distribute to marijuana pharmacies, identify laboratory testing standards for such raw products, add additional dosage forms including pectin-based chewables as well as combustible and edible dosage

forms and removes the prohibition on inclusion of marijuana in beverages. The proposed changes in §2453 authorize marijuana pharmacies to temporarily maintain a supply of marijuana products outside safes and vaults during their hours of operation. The proposed changes in §2457 remove the reference to referral as a description of a recommendation form, adds a requirement for recommendations for raw products when intended for persons under the age of 21 years, and identifies the dispensing limitations of raw marijuana products included in the 2021 legislation.

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 24. Limited Service Providers Subchapter E. Marijuana Pharmacy §2440. Preamble; Warning; Consultation Suggested

- A. Pursuant to Act 261 of the Regular Session of the 2015 Legislature as well as subsequent amendments, the Board of Pharmacy was directed to:
 - 1. ...
- 2. Adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such rules to include, at a minimum, the following:
 - a. d. ...
- e. Standards, procedures, and protocols to ensure all recommended therapeutic marijuana dispensed, with the exception of raw or crude marijuana product, is consistently pharmaceutical grade.

f. - k. ...

l. limitations on dispensing of raw or crude marijuana.

B. - C. ...

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:

§2443. Marijuana Products

- A. Exclusive Source
- 1. The exclusive source of marijuana products shall be the producers licensed for that activity by the Department of Agriculture and Forestry (LDAF).
- 2. Licensed producers shall prepare pharmaceutical grade marijuana products as well as raw marijuana products for distribution to marijuana pharmacies licensed by the board.

3.

B. Laboratory Testing

1. ...

- 2. A producer shall make available each such batch at the production facility for testing by a laboratory approved by LDAF. The laboratory employee shall select a random sample from each such batch.
- a. Medical marijuana concentrate shall not be used to produce any final product until it has passed all analysis limits for:

i. - v. ...

b. Product shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has passed all concentrate analysis limits for:

- . iii. ...
- c. Final products not produced from concentrate, e.g., dried and cured flower, shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has passed all analysis limits for:
- i. active ingredient analysis for characterization of potency;
- ii. pesticide active ingredients, including but not limited to the most recent list of targeted pesticides published by LDAF;
 - iii. heavy metals;
 - iv. mycotoxins;
 - v. microbiological contaminants; and
 - vi. homogeneity.
- d. LDAF personnel may select a random sample at any point in the process for the purpose of analysis for anything the LDAF deems necessary.
- e. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for the analyses being conducted.

3. ...

4. Testing Specifications

a. - c.iv. ...

d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it does not contain any residues appearing on LDAF's approved list and any approved residues present are less than the limits allowed by LDAF.

e. ...

- f. With respect to the test for homogeneity, a marijuana sample shall be deemed passed if each aliquot tested is within plus or minus 15 percent of the total aliquots average finding for potency for each labeled active ingredient. Any solid product will be considered not homogenous if 10 percent of the product contains more than 20 percent of the total active ingredient.
- g. Every sample shall undergo an active ingredient analysis or potency analysis.

i. - i.(d). ...

ii. For product samples, the potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing. The maximum variance permitted is 15 percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC. For final products containing THCA, the total THC determined shall also be within the variance allowed for the THC as labeled.

5. - 8. ...

C. Product Dosage Forms

1. The producer shall limit their production of pharmaceutical grade products to the following dosage forms:

a. - c.

d. gelatin-based or pectin-based chewables;

e. - h. .

- i. bulk raw product.
- 2. The producer may produce other products from raw or crude marijuana, including dried flower, buds, and other plant material, intended for the following methods of administration:

- a. combustible forms for inhalation, including but not limited to pre-rolls; and
 - b. edible forms for ingestion.
 - 3. No marijuana product shall:
- a. include alcoholic liquor, dietary supplements, or any drug, except for marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than 0.5 percent of alcohol by volume, or ethanol-based tinctures.
- b. be manufactured or sold in a form or with a design that:

i. - iv. ...

- c. have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved by the commissioner of LDAF.
- 4. Any marijuana product not in compliance with the provisions of this Section shall be deemed adulterated.

D. - E.4.f. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR 45:1473 (October 2019), LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:

§2453. Security Requirements for Marijuana Pharmacies

A. A marijuana pharmacy shall:

1. - 3. ..

4. keep all approved safes and vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana, provided that during hours of operation the pharmacist-in-charge may authorize the placement of a limited quantity of dispensing stock outside such safes or vaults but within the secure prescription department.

A.5. - H. ...

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:

§2457. Standards of Practice

A. - D.5. ...

- E. Professional Practice Standards
- 1. Recommendation / opinion (hereinafter, "request") for Therapeutic Marijuana

a. - a.ii. ...

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

i. - iii. ...

iv. type of marijuana product requested;

v. - vii.

- c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of time is indicated by the physician. A pharmacist shall not dispense marijuana product pursuant to an expired request.
- d. Requests for raw or crude marijuana products intended for persons under 21 years of age shall specifically indicate a recommendation for raw or crude forms of marijuana for such persons.

- e. A marijuana pharmacy shall transfer an unexpired request for marijuana product to another marijuana pharmacy when requested by the patient or his caregiver.
 - 2. 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.

E.3. - E.6.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:

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 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 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 or 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 authorize the use of raw or crude marijuana for therapeutic purposes, which could provide more appropriate dosage forms for children, which could affect healthcare of children or other dependents.

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 standards but do include a provision for temporary relaxation of security standards for marijuana products to facilitate efficient dispensing operations in marijuana pharmacies.
- 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 Malcolm J Broussard, 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 amendment.

Public Hearing

A public hearing to solicit comments and testimony on the proposed rule changes is scheduled for 9:00 am on Friday, March 25, 2022 at the board office which is located at 3388 Brentwood Drive, Baton Rouge, Louisiana 70809. 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: Raw Marijuana Products

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 \$1,000 in FY 22. There will be no additional expenditures or cost savings for LBP or other state or local governmental units.

The proposed rule changes authorize the use of raw marijuana products, establish laboratory and testing standards and permissible dosage forms for such products, as well as dispensing limitations for such products at marijuana pharmacies. Other proposed rule changes include an allowance for the temporary placement of marijuana products outside safes and vaults but within the prescription department to facilitate efficient dispensing operations in marijuana pharmacies.

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

The proposed rule change will not affect revenue collections of state or local governmental units.

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

The proposed rule changes will authorize producers of marijuana products to include raw marijuana products among

the items they may distribute to marijuana pharmacies. The marijuana pharmacies may sell raw marijuana products pursuant to recommendations, subject to certain dispensing limitations. The addition of new products and dosage forms may increase sales transactions in pharmacies , however, additional product selection may lead to substitutional rather than additive sales. This rule does not directly influence existing recommendation volume by prescribers.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

To the extent the addition of new products and dosage forms increases the number of sales transactions in marijuana pharmacies, it is possible the pharmacies may need to hire more employees, which would improve employment opportunities in those geographical areas. The proposed rule changes may also stimulate price competition among the marijuana pharmacies.

Malcolm J. Broussard Executive Director 2202#020 Alan M. Boxberger Interim Fiscal Officer Legislative Fiscal Office





Louisiana Board of Pharmacy

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Summary of Testimony & Public Comments
re
Regulatory Project 2022-1 ~ Raw Marijuana Products
at
March 25, 2022 Public Hearing

No comments or testimony received.

RULE

Department of Health

Board of Pharmacy

Raw Marijuana Products (LAC 46:LIII.2440, 2443, 2453, 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 §§2440, 2443, 2453, and 2457 of its rules relative to marijuana pharmacies to implement the provisions of Act 424 of the 2021 Legislature. The changes in §2440 make a technical change in the reference to the initial enabling legislation for the medical marijuana program and identifies the mandates within the 2021 legislation. The changes in §2443 add raw marijuana products to those items which producers are authorized to distribute to marijuana pharmacies, identify laboratory testing standards for such raw products, add additional dosage forms including pectin-based chewables as well as combustible and edible dosage forms and removes the prohibition on inclusion of marijuana in beverages. The changes in §2453 authorize marijuana pharmacies to temporarily maintain a supply of marijuana products outside safes and vaults during their hours of operation. The changes in §2457 remove the reference to referral as a description of a recommendation form, adds a requirement for recommendations for raw products when intended for persons under the age of 21 years, and identifies the dispensing limitations of raw marijuana products included in the 2021 legislation. 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

- A. Pursuant to Act 261 of the Regular Session of the 2015 Legislature as well as subsequent amendments, the Board of Pharmacy was directed to:
 - 1. ...
- 2. Adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such rules to include, at a minimum, the following:
 - $a.-d.\,\dots$
- e. Standards, procedures, and protocols to ensure all recommended therapeutic marijuana dispensed, with the exception of raw or crude marijuana product, is consistently pharmaceutical grade.

f.-k. ...

- 1. limitations on dispensing of raw or crude marijuana.
- B. C. ...

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:

§2443. Marijuana Products

A. Exclusive Source

- 1. The exclusive source of marijuana products shall be the producers licensed for that activity by the Department of Agriculture and Forestry (LDAF).
- 2. Licensed producers shall prepare pharmaceutical grade marijuana products as well as raw marijuana products for distribution to marijuana pharmacies licensed by the board.

- 3. ...
- B. Laboratory Testing
 - 1. ...
- 2. A producer shall make available each such batch at the production facility for testing by a laboratory approved by LDAF. The laboratory employee shall select a random sample from each such batch.
- a. Medical marijuana concentrate shall not be used to produce any final product until it has passed all analysis limits for:

i. – v. ...

b. Product shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has passed all concentrate analysis limits for:

i. – iii. ..

- c. Final products not produced from concentrate, e.g., dried and cured flower, shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has passed all analysis limits for:
 - i. active ingredient analysis for characterization of potency;
- ii. pesticide active ingredients, including but not limited to the most recent list of targeted pesticides published by LDAF;
 - iii. heavy metals;
 - iv. mycotoxins;
 - v. microbiological contaminants; and
 - vi. homogeneity.
- d. LDAF personnel may select a random sample at any point in the process for the purpose of analysis for anything the LDAF deems necessary.
- e. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for the analyses being conducted.
 - 3. ..
 - 4. Testing Specifications
 - a.-c.iv. ...
- d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it does not contain any residues appearing on LDAF's approved list and any approved residues present are less than the limits allowed by LDAF.
 - e. ..
- f. With respect to the test for homogeneity, a marijuana sample shall be deemed passed if each aliquot tested is within plus or minus 15 percent of the total aliquots average finding for potency for each labeled active ingredient. Any solid product will be considered not homogeneous if 10 percent of the product contains more than 20 percent of the total active ingredient.
 - g. Every sample shall undergo an active ingredient analysis or potency analysis.

i. - i.(d) ...

ii. For product samples, the potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing. The maximum variance permitted is 15 percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC. For final products containing THCA, the total THC determined shall also be within the variance allowed for the THC as labeled.

- C. Product Dosage Forms
 - 1. The producer shall limit their production of pharmaceutical grade products to the following dosage forms:
 - a. c. ...
 - d. Gelatin-based or pectin-based chewables;
 - e. h. ...
 - i. Bulk raw product.
 - 2. The producer may produce other products from raw or crude marijuana, including dried flower, buds, and other plant material, intended for the following methods of administration:
 - a. Combustible forms for inhalation, including but not limited to pre-rolls; and
 - b. Edible forms for ingestion.
 - 3. No marijuana product shall:
- a. include alcoholic liquor, dietary supplements, or any drug, except for marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than 0.5 percent of alcohol by volume, or ethanol-based tinctures.
 - b. be manufactured or sold in a form or with a design that:
 - $i. iv. \dots$
- c. have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved by the commissioner of LDAF.
 - 4. Any marijuana product not in compliance with the provisions of this Section shall be deemed adulterated.
 - D. E.4.f. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR 45:1473 (October 2019), LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:

§2453. Security Requirements for Marijuana Pharmacies

- A. A marijuana pharmacy shall:
 - $1. 3. \dots$
- 4. keep all approved safes and vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana, provided that during hours of operation the pharmacist-in-charge may authorize the placement of a limited quantity of dispensing stock outside such safes or vaults but within the secure prescription department.
 - A.5. H. ...

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:

§2457. Standards of Practice

A. – D.5. ...

- E. Professional Practice Standards
 - 1. Recommendation / opinion (hereinafter, "request") for Therapeutic Marijuana
 - a. a.ii. ...
 - b. The request shall disclose the following information at a minimum:

 - iv. type of marijuana product requested;
 - v. vii. ...
- c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of time is indicated by the physician. A pharmacist shall not dispense marijuana product pursuant to an expired request.

- d. Requests for raw or crude marijuana products intended for persons under 21 years of age shall specifically indicate a recommendation for raw or crude forms of marijuana for such persons.
- e. A marijuana pharmacy shall transfer an unexpired request for marijuana product to another marijuana pharmacy when requested by the patient or his caregiver.

2. 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.

3.-6.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:

M. Joseph Fontenot, Jr.

Executive Director