Louisiana Administrative Code

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 Louisiana Legislature as well as ~~the~~ subsequent amendments ~~found in Act 96 of the Regular Session of the 2016 Louisiana Legislature~~, 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

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§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. ~~That~~ Licensed producers shall prepare pharmaceutical grade marijuana products as well as raw marijuana products for distribution to the 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 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.

~~c~~ 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.

~~d~~ 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 ~~satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the United States Environmental Protection Agency's "Tolerances and Exemptions for Pesticide Chemical Residues in Food" as found in 40 CFR 180 or its successor~~ does not contain any residues not 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 ~~to have failed~~ if 10 percent of the ~~sample~~ 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.

B.5. – B.8. …

C. Product Dosage Forms.

1. The producer shall limit their production of pharmaceutical grade marijuana 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.

~~2~~ 3. No marijuana product shall:

a. include alcoholic liquor, dietary supplements, or any drug, except for ~~pharmaceutical grade~~ 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 as a beverage~~.

~~c~~ b. be manufactured or sold in a form or with a design that:

i. – iv. …

~~d~~ 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.

~~3~~ 4. Any marijuana product not in compliance with the provisions of this ~~Paragraph~~ 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), amended LR 46:1227 (September 2020), LR 47:590 (May 2021), LR

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§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

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§2457. Standards of Practice

A. – D.5. …

E. Professional Practice Standards

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

1.a. – 1.b.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 may dispense marijuana product on multiple occasions as indicated by the physician and as 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 of marijuana product pursuant to a single request~~. 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.

~~d~~ 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