

Potpourri Notice

Department of Health Board of Pharmacy

Marijuana Pharmacy (LAC 46:LIII.Chapter 24)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy published a Notice of Intent in the January 20, 2017 edition of the *Louisiana Register* to add a new subchapter to *Chapter 24 ~ Limited Service Providers* of its rules – *Subchapter E. Marijuana Pharmacy*. The proposed rule was prepared in response to Act 261 of the 2015 Legislature and Act 96 of the 2016 Legislature; it establishes standards for the packaging and labeling of marijuana products as well as the dispensing of such products in pharmacies licensed by the board.

The board conducted a public hearing on March 2, 2017 to receive comments and testimony on the proposed rule. During their subsequent meeting on March 14, 2017, the board considered the comments and testimony and voted to recommend several revisions to the original proposed rule to address several comments. In particular, the board has proposed 16 sets of revisions: (1) Clarify the definition of approved safe by removing the introductory clause, which will require all approved safes to be equipped with an alarm system [§2441.A.3]; (2) An extensive revision of the laboratory testing standards to harmonize them with the standards being promulgated by the Dept. of Agriculture & Forestry [§2443.B]; (3) To change ‘edible dosage forms’ to ‘gelatin-based chewables, which will eliminate the opportunity for marijuana product dosage forms to include food or candy items infused with marijuana, items never contemplated in the enabling legislation [§2443.C.1.d]; (4) To harmonize the product design standards and the packaging standards to prohibit targeting of individuals less than 18 years of age [§2443.C.2.c.iv & 2443.D.1.e.i]; (5) To provide for the use of package inserts as supplementary labeling [§2443.D.2.d]; (6) To clarify that dispensing of marijuana shall be limited to those pharmacies holding a marijuana pharmacy permit [§2445.B]; (7) To remove the restriction on political campaign contributions for those firms seeking to apply for a marijuana pharmacy permit [§2447.A.4.a]; (8) To reduce the number of persons who would be disqualified from ownership of a marijuana pharmacy permit to members and their families serving on the board or as its staff [§2447.A.4.b]; (9) To reduce the amount of funds necessary to demonstrate financial capacity, from \$1 million to \$100,000 [§2447.A.10]; (10) To clarify an imprecise reference to the enabling legislation [§2447.A.15.f]; (11) To increase the amount of time available to the person awarded a pharmacy permit to initiate operations [§2447.A.20]; (12) To correct an oversight relative to the fees required for the renewal of a marijuana pharmacy permit [§2447.B.2]; (13) To reduce the restriction imposed on the type of packaging required of the pharmacist dispensing the marijuana product, and to add specific language authorizing the pharmacist to compound a marijuana product formulation [§2451.E]; (14) To amend the list of items which can be sold in a marijuana pharmacy to include ‘other retail products’ [§2451.N]; (15) To amend the standards of practice to allow a pharmacist to dispense an emergency supply of marijuana product pursuant to an emergency oral authorization [§2457.D.1.a]; and (16) To amend the standards of practice to replace ‘authorized prescriber’ with ‘recommending physician’ since marijuana cannot be prescribed, only recommended [§2457.D.1.c & 2457.D.2 & 2457.E.2.b.iii & 2457.E.2.b.ix].

The original proposal is resubmitted, as revised, for publication in the Potpourri section of the *Louisiana Register*. The Legislative Fiscal Office has evaluated the impact of the proposed revisions of the original proposed rule and has opined that while the proposed changes are substantive they do not impact the original fiscal statement approved by their office.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding these proposed revisions of the original proposed rule. A public hearing on these proposed revisions is scheduled for Monday, June 26, 2017 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

Subchapter E. Marijuana Pharmacy

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§2441. Definitions

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Approved safe means a safe which conforms to or exceeds all of the following standards:

- a. Shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
- b. If it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way it cannot be readily removed; and
- c. Is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

§2443. Marijuana products

A. – B.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 form of product 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. Residual solvents;
 - iv. Heavy metals; and
 - v. Mycotoxins.
 - b. Product shall not be released for delivery to a pharmacy for sale or consumption until it has passed all analysis limits for:
 - i. Microbiological contaminants;
 - ii. Active ingredient analysis for accuracy of potency; and
 - iii. Homogeneity.
 - c. 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. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for the analyses being conducted.

B.3. – B.3. ...

4. Testing Specifications

- a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the recommended microbial and fungal limits for cannabis products as follows:
 - i. Total yeast and mold: < 10,000 colony-forming units per gram (CFU/g); and
 - ii. E. coli (pathogenic strains) and Salmonella spp: < 1 CFU/g.

- b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it meets the following standards:
 - i. Aflatoxin B1 < 20 parts per billion (ppb);
 - ii. Aflatoxin B2 < 20 ppb;
 - iii. Aflatoxin G1 < 20 ppb;
 - iv. Aflatoxin G2 < 20 ppb; and
 - v. Ochratoxin < 20 ppb.
 - c. With respect to the heavy metals test, a marijuana sample shall be deemed to have passed if it meets the following standards:
 - i. Arsenic < 10 parts per million (ppm);
 - ii. Cadmium < 4.1 ppm;
 - iii. Lead < 10 ppm; and
 - iv. Mercury < 2 ppm.
 - 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 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.
 - e. With respect to the residual solvent test, a marijuana sample shall be deemed to have passed if the following solvents are below the listed limits:
 - i. Butanes < 800 ppm;
 - ii. Heptanes < 500 ppm;
 - iii. Benzene < 1 ppm;
 - iv. Toluene < 1 ppm;
 - v. Hexanes < 10 ppm;
 - vi. Total Xylenes < 1 ppm; and
 - vii. Ethanol < 5,000 ppm.
 - f. With respect to the test for homogeneity, a marijuana sample shall be deemed to have failed if ten percent of the sample contains more than twenty percent of the total active ingredient.
 - g. Every sample shall undergo an active ingredient analysis or potency analysis.
 - i. For medical marijuana concentrate samples, the potency test is to establish the presence of active ingredients and their concentrations for accurate calculations of amounts needed for the production of products. The analysis must identify the following substances:
 - (a) THC (tetrahydrocannabinol);
 - (b) THCA (tetrahydrocannabinolic acid);
 - (c) CBD (cannabidiol); and
 - (d) CBDA (cannabidiolic acid).
 - 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 fifteen 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.
5. Procedures for Sample Failures
- a. In the event a medical marijuana concentrate sample fails testing for pesticides, heavy metals or mycotoxin, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.
 - b. In the event a medical marijuana concentrate sample fails residual solvent testing, then, with prior approval of LDAF, the product may be subjected to an appropriate remedy, e.g., vacuum drying, reformulated and tested again. The reformulation must pass all required tests for a medical marijuana concentrate in duplicate before it can be released for use in products. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF. A batch of medical marijuana concentrate can only reformulated once and only to remedy excessive residual solvents.
 - c. In the event a product fails the microbiological testing, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.
 - d. In the event a product fails the potency or homogeneity testing, then, with prior approval of LDAF, the product can be re-sized and tested again. The reformulated product shall be tested again in duplicate and pass all required tests before it can be released for sale or consumption.

If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF.

6. In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such test result at the same time it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results including all relevant chromatograms and quality control documentation for at least five years and make them available to LDAF at its request.
 7. The laboratory shall dispose of any remaining medical marijuana concentrate or product samples no sooner than 60 days following the completion of any testing, in compliance with the disposal rules promulgated by LDAF.
 8. A producer shall provide the laboratory test results to the marijuana pharmacy for each batch of marijuana used in a product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and physicians who recommended such marijuana products dispensed to their patients.
- C. – C.1.c. ...
- d. Gelatin-based chewables;
- C.1.e – C.2.c.iii.
- iv. Is customarily associated with persons under the age of eighteen years; or
- C.2.d – D.1.d. ...
- e. Packaging selected by the producer shall be subject to the following restrictions:
 - i. Shall not specifically target individuals under the age of 18 years;
- D.1.e.ii – D.2.c. ...
- d. The producer may utilize a package insert which is enclosed or attached to the product container to provide the information required in this Section. If the producer elects to use such supplementary labeling, the label affixed to the outer surface of the product container shall contain the following information, at a minimum
 - i. the batch or lot number referenced at Subsection D.2.a.i;
 - ii. the potency of the THC and CBD referenced at Subsection D.2.a.iv;
 - iii. the net weight referenced at Subsection D.2.a.v;
 - iv. the expiration date referenced at Subsection D.2.a.vi; and
 - v. the caution statement referenced at Subsection D.2.b.i.
- E. – 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

§2445. Marijuana pharmacy permit

- A. – A. ...
- B. The dispensing of marijuana for therapeutic purposes shall be limited to those pharmacies holding a marijuana pharmacy permit issued by the board, and only when that permit is in active or restricted status.
- C. – L. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

§2447. Licensing procedures

- A. – A.3. ...
4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
 - a. Within the two year period preceding the date of the application, the person or any member of the person's immediate family served as a member of the board or its staff.
- A.5 – A.9. ...
10. The applicant shall supplement the application form with sufficient documentation of the applicant's financial capacity to properly operate a marijuana pharmacy, including but not limited to, evidence of his escrow account, letter of credit, or surety bond of at least one hundred thousand dollars in a financial institution headquartered in Louisiana.
 - a. The pharmacy's one hundred thousand dollar escrow account, letter of credit, or surety bond shall be payable to the board in the event the board determines after a due process

hearing that the pharmacy has failed to timely and successfully complete the construction of the pharmacy or to operate such pharmacy in compliance with the provisions of this Subchapter.

- b. The board shall permit the pharmacy's escrow account, letter of credit, or surety bond to be reduced by twenty five thousand dollars upon the successful achievement of each of the following milestones:
 - i. A determination by the board that the pharmacy is fully operational and able to commence and has begun dispensing of marijuana as provided in this Subchapter;
 - ii. A determination by the board that the pharmacy remained operational and without substantial interruption and without any violation of law or regulation for a one year period; and
 - iii. A determination by the board that the pharmacy remained operational and without substantial interruption and without any violation of law or regulation for a second one year period.
 - iv. The pharmacy shall maintain the escrow account, letter of credit, or surety bond for a minimum of twenty five thousand dollars for the remainder of its operation.

A.10.c. – A.15.e. ...

- f. Any other reason provided by any federal law or rule or state law or rule that is not inconsistent with La. R.S. 40:1046 or 40:1047 or this Subchapter.

A.16. – A.19. ...

- 20. If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such pharmacy within 310 days of being notified of the marijuana pharmacy permit award, the board may, in the board's discretion, rescind such marijuana pharmacy permit, unless such delay was caused by force majeure. A marijuana pharmacy shall be deemed to have commenced operation if the pharmacy is capable of operating in accordance with the applicant's approved application. In the event a marijuana pharmacy permit is rescinded pursuant to this subsection, the board shall award a marijuana pharmacy permit by selecting among the qualified applicants who applied for the marijuana pharmacy permit that was rescinded. If no other qualified applicant applied for such marijuana pharmacy permit or satisfied the criteria for awarding a permit, the board shall publish, in accordance with this section, a notice of open applications for marijuana pharmacy permits.

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 R.S. 37:1184 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.

B.3. – D.9. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

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§2451. Operation of marijuana pharmacy

A. – D. ...

- E. A marijuana pharmacy shall sell marijuana products only in a secure and light-resistant container. Nothing herein shall preclude a pharmacist from compounding a marijuana product appropriate for his patient.

F. – M. ...

- N. No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may elect to sell over-the-counter (OTC) medications, durable medical equipment (DME), and other retail products from the same premises but outside the prescription department.

O. – U. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

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§2457. Standards of practice

A. – C.2.a. ...

D. Recordkeeping Requirements

1. Prescription/recommendation/order (hereinafter, “request”) for marijuana

a. Authorization for Emergency Dispensing.

An emergency situation exists when administration of the marijuana product is necessary for immediate treatment, an appropriate alternate treatment is not available, and the recommending physician cannot reasonably provide a written recommendation. In the case of an emergency situation, a pharmacist may dispense a marijuana product upon receiving oral authorization directly from a recommending physician, provided that:

- i. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written recommendation signed by the recommending physician);
- ii. the oral authorization shall be immediately reduced to written form by the pharmacist and shall contain, at a minimum, the following information:
 - (a) Full name and address of the patient;
 - (b) Drug product name, strength, and dosage form;
 - (c) Quantity of product recommended;
 - (d) Directions for use;
 - (e) Name, address, telephone number, and CDS license number of the recommending physician; and
 - (f) Name of the pharmacist receiving the oral authorization.
- iii. if the recommending physician is not known to the pharmacist, he shall make a reasonable effort to determine that the oral authorization came from a physician authorized to recommend marijuana products in Louisiana, which may include a callback to the physician using his telephone number as listed in the telephone directory or other good faith efforts to insure his identity; and
- iv. within seven days after authorizing an emergency oral recommendation, the physician shall cause a written recommendation for the emergency quantity authorized to be delivered to the dispensing pharmacist. The recommendation shall have written on its face “Authorization for Emergency Dispensing,” and the date of the oral authorization. The written recommendation may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven day period. Upon receipt, the dispensing pharmacist shall attach this recommendation to the oral emergency authorization which had earlier been reduced to written form. The pharmacist shall notify the board if the recommending physician fails to deliver a written recommendation to him within the required time; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written recommendation from the recommending physician.

D.1.b. – D.1.b. ...

- c. The written request shall bear the manual signature of the recommending physician. No other form of signature shall be valid, including (but not limited to) stamps, computer generated signatures, or signatures of anyone other than the recommending physician.

D.1.d. – D.1.d. ...

2. When the pharmacy receives a request for marijuana from a recommending physician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with §1123 of the board’s rules.

D.3. – E.2.b.ii. ...

- iii. Name of the recommending physician;

E.2.b.iv. – E.2.b.viii. ...

- ix. Directions for use of the product as included in the recommending physician’s request;

E.2.b.x. – E.5.e.iv. ...

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

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