Louisiana Board of Pharmacy

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April 4, 2023

Senator P. Page Cortez
President, Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 1 of 3 for Regulatory Project 2023-07 ~ Marijuana Pharmacy

Dear Senator Cortez:

The Board seeks to amend Chapter 24, Subchapter E of its rules relative to marijuana pharmacies in response to Acts 444 and 491 of the 2022 regular session and an effort to reduce the number of regulations for marijuana pharmacies.

In connection with this regulatory project, the following items are appended:

As indicated in the solicitation, we will convene a public hearing at 9:00 a.m. on Friday, May 26, 2023 to receive public comments and testimony on these proposed rule changes. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information about this project, please contact me directly at jfontenot@pharmacy.la.gov or 225.925.6481.

For the Board:

M. Joseph Fontenot Jr.
Digitally signed by M. Joseph Fontenot Jr.
Date: 2023.04.04 12:13:26 -05'00'

M. Joseph Fontenot Jr.
Executive Director

cc: Chair, Senate Health & Welfare Committee
Via Email: APA.S-H&W@legis.la.gov
Speaker, House of Representatives
Via Email: APA.HouseSpeaker@legis.la.gov
Chair, House Health & Welfare Committee
Via Email: APA.H-HW@legis.la.gov
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Reference File

NOTICE OF INTENT

Department of Health

Board of Pharmacy

Marijuana Pharmacy (LAC 46:LIII.Chapter 24.Subchapter E)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Board of Pharmacy hereby gives notice of its intent to amend Chapter 24, Subchapter E of its rules relative to marijuana pharmacies in response to Acts 444 and 491 of the 2022 regular session and in an effort to reduce the number of regulations. The proposal repeals §§ 2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician. The proposed rule changes replace references to the Department of Agriculture and Forestry (LDAF) with Department of Health (LDH) and references to physicians with authorized clinicians. The proposed rule changes shift the responsibility of product requirements from the producers which supply the product to the pharmacies which receive and dispense the product.

The proposed rule changes remove requirements for producer testing, packaging, labeling, and distribution; duplication listing bulk raw product in allowed dosage form list; the restriction to ten active marijuana permits at a time, including the description of the 9 LDH regions; the requirement to include a blueprint of the proposed marijuana pharmacy and documentation of the applicant's financial capacity to operate a marijuana pharmacy with the initial application for a permit; the description of the manner in which the Board may verify information contained in each application; the issuance of duplicate permits; the requirement to develop a written alcohol-free, drug-free, and smoke-free workplace policy; the requirement for product to be immediately placed in a safe or vault upon delivery; the inclusion of "federal" in the list of officials that may enter any area of the marijuana pharmacy; the requirement to notify LBP of certain security related events; and the reference to security requirements identified elsewhere in the Subchapter.

The proposed rule changes add the definition of authorized clinician; a requirement for the pharmacy to have access to laboratory tests from the producer; a requirement for each marijuana pharmacy to offer home delivery to patients in each zip code within its region at least once per month; and an allowance for, and requirements related to dispensing marijuana products to visiting qualifying patients.

The proposed rule changes amend the reference to rules and statutes which authorize fees to be collected by the Board.

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. develop an annual, nontransferable specialty license for a pharmacy to dispense recommended marijuana for therapeutic use, to limit the number of such licenses to a maximum of 10, and to adopt rules regarding the geographical locations of dispensing pharmacies in the state; and~~

~~2. adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such rules to include, at a minimum, the following:~~

~~a. standards, procedures, and protocols for the effective use of recommended marijuana for therapeutic use as authorized by state law and related rules;~~

~~b. standards, procedures, and protocols for the dispensing and tracking of recommended therapeutic marijuana;~~

~~c. procedures and protocols to provide that no recommended therapeutic marijuana may be dispensed from, produced from, obtained from, sold to, or transferred to a location outside of this state;~~

~~d. standards, procedures, and protocols for determining the amount of usable recommended therapeutic marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amount for topical treatments;~~

~~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. standards and procedures for the revocation, suspension, and nonrenewal of licenses;~~

~~g. other licensing, renewal, and operational standards deemed necessary by the Board of Pharmacy;~~

~~h. standards and procedures for testing recommended therapeutic marijuana samples for levels of tetrahydrocannabinols (THC) or other testing parameters deemed appropriate by the Board of Pharmacy;~~

~~i. standards for the protection of health, safety, and security for dispensers of recommended therapeutic marijuana;~~

~~j. standards for the licensure of dispensers of recommended therapeutic marijuana; and~~

~~k. standards for financial capacity to operate a marijuana pharmacy.~~

~~l. limitations on dispensing of raw or crude marijuana.~~

~~B. Marijuana is classified as a schedule I controlled substance by the U.S. Department of Justice, Drug Enforcement Administration.~~

~~1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing, distribution, dispensing, or administering of any schedule I controlled substance, including marijuana, is a violation of federal law.~~

~~2. Neither Louisiana law nor this Part can preempt federal law. Therefore, the provisions of this Subchapter notwithstanding, persons engaged in the activities described herein remain subject to the full force of federal law enforcement, including arrest and prosecution of criminal charges, the assessment of civil fines and forfeitures, as well as administrative consequences such as forfeiture of federal controlled substance registrations and exclusion from Medicare and other federal payer programs.~~

~~C. For the foregoing reasons, pharmacists and other persons credentialed by the board may wish to consult with their own legal counsel as well as any health care facility, private or governmental payor with which they are affiliated, professional liability insurers, and financial institutions with which they maintain depository relationships before engaging in the activities described herein.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended LR 48:1902 (July 2022), repealed LR

§2441. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section:

* * *

~~*Advertisement* - all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana, excluding information of an educational nature designed to inform citizens of the nature and form of the state's therapeutic marijuana program and its legally permitted products.~~

* * *

~~*Approved Safe* - a safe which conforms to or exceeds all of the following standards:~~

~~a. shall have the following specifications or the equivalent:~~

~~i. 30 man-minutes against surreptitious entry;~~

~~ii. 10 man-minutes against forced entry;~~

~~iii. 20 man-hours against lock manipulation; and~~

~~iv. 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.~~

~~*Approved Vault*~~

~~a. a vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or~~

~~b. a vault constructed after September 1, 1971:~~

~~i. the walls, floors, and ceilings of which are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;~~

~~ii. the door and frame unit of which vault shall conform to the following specifications or the equivalent:~~

~~(a). thirty man-minutes against surreptitious entry;~~

~~(b). ten man-minutes against forced entry;~~

~~(c). twenty man-hours against lock manipulation; and~~

~~(d). twenty man-hours against radiological techniques;~~

~~iii. which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking or the equivalent, for use during the hours of operation in which the vault door is open;~~

~~iv. the walls or perimeter of which are equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve, and if necessary, alarm buttons at strategic points of entry to the perimeter area of the vault;~~

~~v. the door of which shall be equipped with one or more contact switches; and~~

~~vi. which vault has one of the following:~~

~~(a). complete electrical lacing of the walls, floor and ceiling;~~

~~(b). sensitive ultrasonic equipment within the vault;~~

~~(c). sensitive sound accumulator system; or~~

~~(d). such other device designed to detect illegal entry as may be approved by the board.~~

Authorized Clinician – licensed health professionals authorized pursuant to R.S. 40:1046.

* * *

~~*LDAF* – the Louisiana Department of Agriculture and Forestry~~.

* * *

Pharmaceutical Grade Marijuana—marijuana or marijuana products that are not adulterated and are:

a. – b. …

c. where each step of the production, cultivating, trimming, curing, manufacturing, processing, and packaging method has been documented by using standard operation procedures ~~approved by the commissioner of the Department of Agriculture and Forestry~~ verified by the Louisiana Department of Health.

* * *

~~*Physician* – an individual currently licensed by the state Board of Medical Examiners to engage in the practice of medicine.~~

* * *

Producer—a person licensed by the Louisiana Department of ~~Agriculture and Forestry~~ Health to cultivate marijuana for therapeutic use.

* * *

Production Facility—a secure facility where the production of marijuana occurs and that is operated by a person to whom the Louisiana Department of ~~Agriculture and Forestry~~ Health has issued a producer license.

* * *

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended LR 45:1473 (October 2019), LR 46:1227 (September 2020), amended LR

§2443. Marijuana Products

A. Exclusive Source

1. The exclusive source of marijuana products shall be the producers licensed for that activity by LDH ~~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.~~ Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be ~~distributed to~~ received by any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed by any marijuana pharmacy.

B. Laboratory Testing

~~1. Prior to manufacturing any marijuana product, the producer shall segregate all harvested marijuana into homogenized batches.~~

~~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. 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 marijuana pharmacy for sale or consumption until it has passed all concentrate analysis limits for:~~

~~i. microbiological contaminants;~~

~~ii. active ingredient analysis for accuracy of potency; and~~

~~iii. homogeneity.~~

~~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. From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a pharmacy until the laboratory provides the results from its tests and analyses, the producer shall segregate and withhold from use the entire batch with the exception of the samples removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a pharmacy prior to the time the laboratory has completed its testing and analysis and provided those results, in written or electronic form, to the producer or the producer's designated employee.

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 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. 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 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. 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 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. 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 be 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.~~ 1. ~~A producer shall provide the laboratory test results to the~~ The marijuana pharmacy shall have access to the laboratory test results from the producer for each ~~batch of marijuana used in a~~ final product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and ~~physicians~~ authorized clinicians who recommended such marijuana products dispensed to their patients.

C. Product Dosage Forms

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

a. – h. …

~~i. bulk raw product~~.

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

a. – b. …

3. No marijuana product shall:

a. – b.iv. …

c. have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved for use by ~~the commissioner of LDAF~~ LDH.

4. ...

~~D. Packaging and Labeling Requirements~~

~~1. Packaging~~

~~a. The producer shall ensure every product intended for dispensing to a patient is placed within a child resistant, light-resistant, tamper-evident container prior to sale or transport to the pharmacy.~~

~~i. A package shall be deemed child-resistant if it satisfies the standard for 'special packaging' as set forth in the United States Consumer Product Safety Commission's "poison prevention packaging" as found in 16 CFR 1700.1(b)(4) or its successor.~~

~~ii. A package shall be deemed light-resistant if it satisfies the standard set forth in chapter 671, "containers: performance testing," of the *United States Pharmacopeia* (*USP*).~~

~~iii. A package shall be deemed tamper-evident if it clearly indicates prior access to the container.~~

~~b. Packaging selected by the producer shall be subject to the following restrictions:~~

~~i. shall not specifically target individuals under the age of 18 years;~~

~~ii. shall not bear any resemblance to a trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;~~

~~iii. shall not use the words "candy" or "candies";~~

~~iv. shall not use a cartoon, color scheme, image, graphic or feature that might make the package attractive to children; and~~

~~v. shall not use a seal, flag, crest, coat of arms or other insignia that could reasonably lead any person to believe the product has been endorsed, manufactured by, or used by any state, parish, municipality, or any agent thereof.~~

~~2. Labeling~~

~~a. Each product shall be labeled by the producer prior to its sale to the marijuana pharmacy.~~

~~b. Each label shall be securely affixed to the package and shall comply with labeling standards for marijuana products promulgated by LDAF.~~

~~c. The label for each product shall bear a product identification code registered with the board.~~

~~d. The producer may utilize a two-dimensional quick response (QR) code or 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;~~

~~ii. the potency of any THC or CBD contained therein;~~

~~iii. the net weight;~~

~~iv. the expiration date; and~~

~~v. any caution statements.~~

~~E. Distribution of Marijuana Products to Marijuana Pharmacies~~

~~1. The producer shall maintain complete inventory records in the Louisiana medical marijuana tracking system (LMMTS), as required and delineated in rules promulgated by LDAF.~~

~~2. The producer shall maintain comprehensive records in LMMTS of all marijuana products distributed to the marijuana pharmacies, whether by transport and delivery to the pharmacy or by transfer to the agent of the pharmacy at the production facility.~~

~~3. In the event the producer delivers the products to the pharmacy, such activities must be in compliance with the rules for that activity promulgated by LDAF.~~

~~4. In the event the pharmacy elects to send an agent to the production facility to retrieve products ordered by the pharmacy, the personnel at the production facility shall verify the identity and credentials of the pharmacy's agent before releasing the products to the agent.~~

~~a. The producer shall provide a copy of the transport manifest generated by LMMTS, which shall contain the following information:~~

~~i. the name and address of the producer selling the product;~~

~~ii. the name and address of the pharmacy purchasing the product;~~

~~iii. the name and quantity (by weight or unit) of marijuana products included in the delivery;~~

~~iv. the date of transport and time of departure from the production facility;~~

~~v. the make, model, and license plate number of the delivery vehicle;~~

~~vi. the date and time of arrival at the pharmacy; and~~

~~vii. the name and signature of the pharmacy's agent.~~

~~b. The pharmacy's agent shall compare the transport manifest to the products transferred to his possession, and when correct, shall return a signed copy of the manifest to the producer before departing from the production facility.~~

~~c. The pharmacy's agent shall place the products in a locked, safe, and secure storage compartment that is part of the motor vehicle, or in the alternative, in a locked storage container that has a separate key or combination pad, and further, the product shall not visible or recognizable from outside the vehicle, and further, the vehicle shall not bear the name of the pharmacy or any markings to indicate the vehicle contains marijuana.~~

~~d. The pharmacy's agent shall maintain physical control of the vehicle at all times during the transport, and shall not leave the vehicle unattended at any time.~~

~~e. The pharmacy's agent shall have access to a secure form of communication with the pharmacy as well as the ability to contact law enforcement through the 911 emergency system.~~

~~f. Upon arrival at the pharmacy, the pharmacy's agent shall deliver the product to a pharmacist for verification of receipt; the pharmacist shall time, date, and sign the delivery manifest.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR 45:1473 (October 2019), amended LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:1902 (July 2022), amended LR

§2445. Marijuana Pharmacy Permit

A. – D. …

E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or more without obtaining a new marijuana pharmacy permit shall be ~~deemed~~ subject to disciplinary review by the board ~~guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221~~.

F. …

G. ~~The board shall not have more than 10 active marijuana pharmacy permits at any given time. To facilitate compliance with that legislative restriction, the board recognizes the nine regions previously declared by the Department of Health, to wit:~~

~~1. metropolitan, composed of the parishes of Jefferson, Orleans, Plaquemines, and St. Bernard;~~

~~2. capitol, composed of the parishes of Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton Rouge, and West Feliciana;~~

~~3. Teche, composed of the parishes of Assumption, Lafourche, St. Charles, St. James, St. John, St. Mary, and Terrebonne;~~

~~4. Acadian, composed of the parishes of Acadia, Evangeline, Iberia, Lafayette, St. Landry, St. Martin, and Vermilion;~~

~~5. southwest, composed of the parishes of Allen, Beauregard, Calcasieu, Cameron, and Jefferson Davis;~~

~~6. central, composed of the parishes of Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon, and Winn;~~

~~7. northwest, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster;~~

~~8. northeast, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, and West Carroll; and~~

~~9. southeast, composed of the parishes of Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington.~~

~~H. To achieve an equitable distribution of the marijuana pharmacy permits across the state, the board shall reserve one marijuana pharmacy permit for each of the nine regions identified above. In the event the board is convinced of the need for a second permit in one region, it may issue that permit following the procedures identified in this Subchapter. Further expansion will require a legislative amendment of the original restriction.~~

~~I.~~ When the board is prepared to receive and process applications for and issue marijuana pharmacy permits, it shall publish on its internet web site, and in such other places as the board deems appropriate, a notice to that effect. Such notice shall include, but not be limited to:

1. the maximum number of permits to be awarded;
2. information on how to obtain an application;
3. the deadline for receipt of applications;
4. acceptable methods for submitting an application;
5. the preferred locations, if any, for the marijuana pharmacy permits; and
6. the criteria that shall be considered in awarding the marijuana pharmacy permits.

~~J.~~H. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and award marijuana pharmacy permits on a competitive basis based on the criteria set out in the notice for applications. In the event the board determines there are an insufficient number of qualified applicants to award all of the marijuana pharmacy permits the board has determined are desirable, the board may republish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.

~~K.~~I. The board shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

~~L.~~J. The board shall have the right to cancel a notice of open applications prior to the award of a marijuana pharmacy permit.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1543 (August 2017), amended LR

§2447. Licensing Procedures

A. – A.6.d. …

e. ~~a blueprint of the proposed marijuana pharmacy which shall, at a minimum, show and identify:~~

~~i. the square footage of the area which will constitute the prescription department;~~

~~ii. the square footage of the overall marijuana pharmacy;~~

~~iii. the square footage and location of areas used as storerooms or stockrooms;~~

~~iv. the size of the counter that will be used for the dispensing and sale of marijuana;~~

~~v. the location of the marijuana pharmacy sink and refrigerator, if any;~~

~~vi. the location of all approved safes and vaults that will be used to store marijuana;~~

~~vii. the location of the toilet facilities;~~

~~viii. the location of the break room and location of lockers for personal belongings;~~

~~ix. the location and size of the patient counseling area(s);~~

~~x. the location(s) where any other products or services will be offered; and~~

~~xi. the location of all areas that may contain marijuana showing the location of walls, partitions, counters, and all areas of ingress and egress;~~

~~f.~~ such other documents and information reasonably required by the board to determine the applicant's suitability for permitting or to protect the public's health and safety.

7. – 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 $100,000 in a financial institution headquartered in Louisiana.~~

~~a. The pharmacy's $100,000 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 $25,000 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 $25,000 for the remainder of its operation.~~

~~c. In the event a pharmacy voluntarily chooses not to renew the pharmacy permit and follows proper closure procedures, the board shall extinguish the obligations under the escrow account, letter of credit, or surety bond at the end of the permit's term.~~

~~11.~~10. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the application processing or permit selection process.

~~12. The board may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a marijuana pharmacy. The board may verify the information and assess the applicant's character and fitness by, among other actions:~~

~~a. contacting the applicant by telephone, electronic mail, mail, or such other means as is reasonable under the circumstances;~~

~~b. conducting one or more on-site visits of the location for the proposed marijuana pharmacy, or other pharmacies associated with the applicant or any of the applicant's owners;~~

~~c. conducting background checks or contacting references of the applicant, its managing officer, any of the corporate officers, or any shareholder, as well as the pharmacist-in-charge;~~

~~d. contacting state regulators in any other states where the applicant, the applicant's owners or corporate officers, or its pharmacist-in-charge are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; or~~

~~e. requiring a personal meeting with the owner's managing officer and the pharmacist-in-charge and the submission of additional information or documents.~~

~~13.~~11. The application shall be accompanied by payment of the permit fees and administrative hearing fee authorized by ~~R.S. 37:1184~~ LAC 46:LIII.115 and R.S. 40:1013.

~~14.~~12. When the staff has determined an entity's application package is complete, the application shall be referred to the board's application review committee, and further, the applicant shall be properly notified at least 30 days prior to the committee's hearing during which their application will be considered.

~~15.~~13. During the hearing held by the board's application review committee, the members shall consider, but are not limited to, the following criteria when evaluating an application for a marijuana pharmacy permit:

a. the character and fitness of the owner's managing officer, the pharmacist-in-charge, any of the owners and any other person who may have control or influence over the operation of the proposed marijuana pharmacy;

b. the location for the proposed marijuana pharmacy including, but not limited to:

i. its proximity to previously approved marijuana pharmacies or locations of proposed marijuana pharmacies with pending applications;

ii. whether the patient population in the area proposed by the marijuana pharmacy permit applicant justifies the need for a marijuana pharmacy, or an additional marijuana pharmacy, in that area;

iii. whether the proximity of the proposed marijuana pharmacy will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment; or

iv. whether the number of marijuana pharmacies in the locality is such that the granting of a permit is detrimental to the public interest. In reaching a conclusion in this respect, the board may consider the population of, the number of like permits and number of all permits existent in, the particular municipality and the immediate neighborhood concerned, the effect that a new permit may have on such town or neighborhood or on like permits existent in such municipality or neighborhood;

c. the applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana;

d. the applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and

e. the extent to which the applicant or any of the applicant's owners have a financial interest in any other permittee, licensee, registrant, or other applicant currently or previously credentialed by the board; and

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

~~16.~~14. Following their evaluation of the applications for a marijuana pharmacy permit, the committee shall develop a recommendation for presentation to the board at the board's next meeting. The board may accept the committee's recommendation, select an alternative applicant, reject all of the applicants, or return all the applicants to the committee for their reconsideration.

~~17.~~15. The board may disqualify any applicant who:

a. submits an incomplete, false, inaccurate, or misleading application;

b. fails to submit an application by the published deadline; or

c. fails to pay all applicable fees.

~~18.~~16. The decision of the board to award or not to award a marijuana pharmacy permit to an applicant shall be final.

~~19.~~17. Upon the approval of an application, the board shall award the marijuana pharmacy permit and state controlled dangerous substance license to the applicant. Upon completion of a satisfactory inspection of the pharmacy premises, the board shall issue the marijuana pharmacy permit and state controlled dangerous substance license to the applicant awarded the permit.

~~20.~~18. 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. Application for Renewal of Permit

1. All marijuana pharmacy permits expire at midnight on December 31 of every year, regardless of the date of its initial issuance.

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~~ LAC 46:LIII.115 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.

3. – 4. …

5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the board office no later than 30 days after the expiration date of the permit may be processed by the board staff, provided the appropriate delinquent fee authorized in ~~R.S. 37:1184~~ LAC 46:LIII.115 is included with the application.

6. – 7. …

C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits

1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee, the delinquent fee, the administrative hearing fee, and the reinstatement fees authorized in ~~R.S. 37:1184~~ LAC 46:LIII.115 and the program fee authorized in R.S. 40:1013.

2. …

D. – D.1. …

2. ~~A duplicate or replacement permit shall be issued upon the written request of the licensee and payment of the fee authorized in R.S. 37:1184. A duplicate or replacement license shall not serve or be used as an additional or second license.~~

~~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.~~3. 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.~~4. 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~~ LAC 46:LIII.115. The board may require an inspection of the new location prior to the issuance of the permit for the new location. No marijuana pharmacy shall commence operation in a new location until approved by the board.

~~6.~~5. 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.~~6. 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.~~7. 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 48:2102 (August 2022), amended LR

~~§2449. Marijuana Pharmacy Personnel~~

~~A. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.~~

~~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 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.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1546 (August 2017), amended LR 48:2103 (August 2022), repealed LR

§2451. Operation of Marijuana Pharmacy

A. – K.5. …

L. ~~The marijuana pharmacy shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the board upon request.~~

~~M.~~ The receipt of all deliveries from producers shall be carried out under the direct supervision of a pharmacist who shall be present to accept the delivery. ~~Upon delivery, the marijuana shall immediately be placed in an approved safe or approved vault within the pharmacy where marijuana is stored.~~

~~N.~~M. No marijuana pharmacy shall acquire, possess or dispense any controlled substance other than medical marijuana products authorized by R.S. 40:1046.

~~O.~~N. No marijuana shall be administered on the premises of a marijuana pharmacy, except during patient counseling, education or training.

~~P.~~O. No person associated with a marijuana pharmacy shall enter into any agreement with ~~a physician~~ an authorized clinician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase marijuana.

~~Q.~~P. Delivery of Dispensed Marijuana Products.

1. A marijuana pharmacy shall dispense a marijuana product to a patient or his caregiver in the marijuana pharmacy. At the patient's request, the caregiver may deliver a dispensed marijuana product to the patient's location.

2. Each marijuana pharmacy shall offer home delivery to patients in each zip code within its region at least once per month.

3. At the patient or caregiver's request, the marijuana pharmacy may deliver or facilitate the delivery of a dispensed marijuana product to the patient's location.

4. The delivery of a dispensed marijuana product is subject to the following requirements:

~~1.~~a. The marijuana pharmacy shall not deliver or facilitate the delivery of a marijuana product to a location outside the state.

~~2.~~b. The marijuana pharmacy shall ensure the physical integrity and security of the marijuana product while in transit.

~~3.~~c. In the event the delivery of the marijuana product is not completed, the marijuana product shall be returned to the marijuana pharmacy from which it was dispensed.

~~4.~~d. In the event the pharmacist-in-charge of the marijuana pharmacy cannot assure the integrity and security of a returned marijuana product, the pharmacy shall dispose of the marijuana product.

~~R.~~Q. No marijuana shall be sold when the marijuana pharmacy is closed and not open for business.

~~S.~~R. Board representatives, local law enforcement or other ~~federal,~~ state or local government officials may enter any area of a marijuana pharmacy if necessary to perform their governmental duties.

~~T.~~S. Right of Inspection. The board, or its agent, representative, or designee, is authorized:

1. to enter a marijuana pharmacy at any time during its hours of operation, or any other place, including a vehicle, wherein marijuana is held, dispensed, sold, or otherwise disposed of;

2. to inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein, including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities; and

3. to inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished material.

~~U.~~T. Inspection of Records. Every person required to prepare, obtain or keep records, logs, reports or other documents, and every person in charge, or having custody, of such documents shall maintain such documents in an auditable format for no less than two years. Upon request, such person shall make such documents immediately available for inspection and copying by the board or its authorized representative. In complying with this Section, no person shall use a foreign language or codes or symbols to designate marijuana types or persons in the keeping of any required document.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1547 (August 2017), amended LR 46:1227 (September 2020), amended LR 47:590 (May 2021), LR 48:2103 (August 2022), amended LR

~~§2453. Security Requirements for Marijuana Pharmacies~~

~~A. A marijuana pharmacy shall:~~

~~1. store all marijuana in an approved safe or vault, as defined in this Subchapter, and in such a manner as to prevent diversion, theft, or loss;~~

~~2. maintain all marijuana in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;~~

~~3. not permit any person less than eighteen years of age to enter the prescription department, with the exception of patients being counseled by the pharmacist;~~

~~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.~~

~~5. keep all locks and security equipment in good working order;~~

~~6. not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;~~

7. not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees;

8. keep the pharmacy securely locked and protected from entry by unauthorized employees;

9. keep the outside perimeter of the pharmacy premises well-lit; and

10. post a sign at all entry ways into any area of the pharmacy containing marijuana, including a room with an approved safe or vault, which sign shall be a minimum of 12 inches in height and 12 inches in width which shall state: "Do Not Enter – Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than 1/2 inch in height.

B. All pharmacies shall have an adequate security system to prevent and detect diversion, theft or loss of marijuana utilizing commercial grade equipment, which shall include at a minimum:

1. a perimeter alarm;

2. motion detector;

3. video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The pharmacy shall direct cameras at all approved safes and vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being stored or handled. At entry and exit points, the pharmacy shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the pharmacy;

4. 24 hour recordings from all video cameras, which the pharmacy shall make available for immediate viewing by the board or its authorized representative upon request and shall retain for at least 30 days. If a pharmacy is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the pharmacy shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmacy that it is not necessary to retain the recording:

a. all video recordings shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmacy shall erase all recordings prior to disposal or sale of the pharmacy;

5. *duress alarm*, which for purposes of this Subsection means a silent security alarm system signal generated by the entry of a designated code in into an arming station in order to signal that the alarm user is being forced to turn off the system;

6. *panic alarm*, which for purposes of this Subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring a law enforcement response;

7. *holdup alarm*, which for purposes of this Subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;

8. *automatic voice dialer*, which for purposes of this Subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;

9. a failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the pharmacy within five minutes of the failure, either by telephone, email, or text message;

10. the ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

11. a date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

12. the ability to remain operational during a power outage.

~~C. A pharmacy shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.~~

~~1. A pharmacy shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.~~

~~2. A pharmacy shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, and the board's authorized representative.~~

~~3. A pharmacy shall make available to the board upon request a current list of authorized employees and service employees that have access to the surveillance room.~~

~~D. A pharmacy shall keep all security equipment in good working order and shall test such equipment no less than two times per year.~~

~~E. When a pharmacy presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to, or actual, diversion, theft or loss, the board may require additional safeguards, including but not limited to, a supervised watchman service.~~

~~F. Any marijuana not stored in compliance with this Section, or stored at a location other than that for which the pharmacy permit was issued, shall be subject to embargo or seizure by the board.~~

~~G. In the event any marijuana pharmacy permit is revoked, suspended, or not renewed, the pharmacy shall dispose of its entire stock of marijuana in accordance with the disposal provisions in this Subchapter.~~

~~H. If a pharmacy has provided other safeguards which can be regarded in total as an adequate substitute for some element of protection required of the pharmacy, such added protection may be taken into account by the board in evaluating overall required security measures.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 48:1903 (July 2022), repealed LR

§2455. Reportable Security Events

A. – B. …

~~C. A pharmacy shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:~~

~~1. an alarm activation or other event that requires response by public safety personnel;~~

~~2. a breach of security;~~

~~3. the failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and~~

~~4. corrective measures taken, if any.~~

~~D. A pharmacy shall maintain and shall make available all documentation related to an occurrence that is reportable.~~

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

§2457. Standards of Practice

A. Environmental Standards

1. The prescription department shall be of sufficient size commensurate with the nature and scope of practice. The space occupied by the prescription department shall be restricted to authorized personnel only, as determined by the pharmacist-in-charge, and shall not be accessible to the general public. A marijuana pharmacy shall not permit any person less than eighteen years of age to enter the prescription department, with the exception of patients being counseled by the pharmacist.

2. – 4. …

5. The prescription department shall be secured by one or more physical barriers with suitable locks and a monitored alarm system capable of detecting unauthorized entry. ~~,and further, complies with security requirements identified elsewhere in this Subchapter.~~

6. …

B. – B.4. …

5. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.

C. – C.2.a. …

D. Recordkeeping Requirements

1. When the pharmacy receives a request for marijuana from a recommending ~~physician~~ authorized clinician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with Section 1123 of this Part.

2. – 5. …

E. Professional Practice Standards

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

a. The pharmacist may accept any request for a marijuana product which has been:

i. issued by ~~a physician~~ an authorized clinician in possession of a current and unrestricted license to practice in this state ~~medicine from the Louisiana State Board of Medical Examiners~~ as well as a current and unrestricted state controlled substance license with therapeutic marijuana privileges from the board; and

ii. received directly from the ~~physician~~ authorized clinician and not from the patient or any third party other than the entity transmitting the request, either by electronic means conforming with the provisions of 21 CFR 1311 or its successor, or in the alternative, by facsimile bearing a handwritten or digital signature of the ~~physician~~ authorized clinician.

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

i. name, address, telephone number, and national provider identifier (NPI) number of the ~~physician~~ authorized clincian issuing the request;

ii. name, address, and date of birth (or age) of the patient for whom the request was issued;

iii. identification of the debilitating medical condition for which the treatment has been requested;

iv. type of marijuana product requested;

v. date request was issued;

vi. self-certification the ~~physician~~ authorized clinician holds a current and unrestricted license to practice in this state ~~medicine issued by the Louisiana State Board of Medical Examiners~~; and

vii. signature of the ~~physician~~ authorized clinician issuing the recommendation, excluding any proxy or agent.

c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of time is indicated by the ~~physician~~ authorized clinician. A pharmacist shall not dispense marijuana product pursuant to an expired request.

d. – e. …

2. …

3. Dispensing Marijuana Products

a. Prior to dispensing any marijuana product to a patient, the pharmacist shall review the patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending ~~physician~~ authorized clinician.

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~~ authorized clinician and needed by the patient until the request expires; however, the pharmacist shall not dispense more than a 90-day supply of marijuana product at one time nor more than a one-year supply pursuant to a single request.

c. Dispensing Marijuana Products to Visiting Qualifying Patients

i. A visiting qualifying patient may obtain medical marijuana from a marijuana pharmacy, subject to the dispensing limitations of Paragraph (3)(b) of this Subsection, upon producing evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.

ii. A pharmacist may dispense medical marijuana to a visiting qualifying patient, subject to the dispensing limitations of Paragraph (3)(b) of this Subsection, upon obtaining evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.

4. Labeling of Marijuana Product Dispensed

a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by ~~the LDAF~~ LDH, and further, the pharmacy dispensing label shall not overlay or obscure the producer label in any way.

b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:

i. – ii. …

iii. name of the recommending ~~physician~~ authorized clinician;

iv. – xi. …

5. – 7.e.iv. …

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017), amended LR 45:1473 (October 2019), LR 47:246 (February 2021), LR 47:1111 (August 2021), LR 48:1903 (July 2022), LR 48:2103 (August 2022), amended LR

~~§2459. Advertising~~

~~A. The marijuana pharmacy shall not advertise through any public medium, including but not limited to newspapers, billboards, television, radio, internet, social media, or any other means designed to market its products to the general public.~~

~~B. The marijuana pharmacy may market its products through direct mail, brochures, or other means to Louisiana licensed physicians, but only when such advertising is directed solely to the practitioner and is not available to the general public.~~

~~C. Any advertisement permitted in Subsection B of this Section shall not:~~

~~1. make any deceptive, false, or misleading assertions or statements regarding any product; or~~

~~2. assert that its products are safe because they are regulated by LDAF or the board. The pharmacy may advertise that its products have been tested by an approved laboratory, but shall not assert that its products are safe because they are tested by an approved laboratory.~~

~~D. The marijuana pharmacy may attach a maximum of two separate signs to the exterior of the building which identify the business by its business or trade name, provided that neither sign exceeds the size limit of 1,600 square inches.~~

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1552 (August 2017), repealed LR

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 and 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.

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 and 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 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 business.

3. The Consolidation or Simplification of Compliance or Reporting Requirements for Small Businesses. The proposed rule changes will have no effect on consolidation or simplification of compliance or reporting requirements for small business.

4. The Establishment of Performance Standards for Small Businesses to Replace Design or Operational Standards Required in the Proposed Rule. The proposed rule changes will have no effect on establishment of performance standards for small businesses to replace design or operational standards for small business.

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 qualifications required 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 Jr., 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 amendments. The deadline for the receipt of all written comments is 12 p.m. on Friday, May 26, 2023.

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 26, 2023 at the Board office. During the hearing, all interested persons will be afforded an opportunity to submit comments and testimony, either verbally or in writing. The deadline for the receipt of all comments and testimony is 12 p.m. that same day. To request reasonable accommodations for persons with disabilities, please call the board office at 225.925.6496.

M. Joseph Fontenot Jr.

Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Marijuana Pharmacy

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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 $2,000 in FY 2023 and $2,000 in FY 2024.

There may be additional costs associated with inspections of additional pharmacies due to the elimination of the ten permit limit. The maximum number of marijuana pharmacies including satellite locations authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. Compliance inspections cost approximately $300 and are conducted approximately every 18 months. The annual cost of inspections will depend upon the number of marijuana pharmacies in operation and is indeterminable. These costs will be funded through self-generated revenues from application fees.

The proposed rule changes in Chapter 24, Subchapter E are in response to Acts 444 and 491 of the 2022 regular session and an effort by LBP to reduce the number of regulations on marijuana pharmacies. The proposal repeals §§ 2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician.

The proposed rule changes replace references to the Department of Agriculture and Forestry (LDAF) with Department of Health (LDH) and references to physicians with authorized clinicians licensed to practice in this state. The proposed rule changes shift the responsibility of product requirements from the producers which supply the product to the pharmacies which receive and dispense the product.

The proposed rule changes remove requirements for producer testing, packaging, labeling, and distribution; duplication listing bulk raw product in allowed dosage form list; the restriction to ten active marijuana pharmacy permits at a time, including the description of the 9 LDH regions; the requirement to include a blueprint of the proposed marijuana pharmacy and documentation of the applicant's financial capacity to operate a marijuana pharmacy with the initial application for a permit; the description of the manner in which the Board may verify information contained in each application; the issuance of duplicate permits; the requirement to develop a written alcohol-free, drug-free, and smoke-free workplace policy; the requirement for product to be immediately placed in a safe or vault upon delivery; the inclusion of "federal" in the list of officials that

may enter any area of the marijuana pharmacy; the requirement to notify LBP of certain security related events; and the reference to security requirements identified elsewhere in the Subchapter.

The proposed rule changes add the definition of authorized clinician; a requirement for the pharmacy to have access to laboratory tests from the producer; a requirement for each marijuana pharmacy to offer home delivery to patients in each zip code within its region at least once per month; and an allowance for, and requirements related to dispensing marijuana products to visiting qualifying patients.

The proposed rule changes amend the reference to rules and statutes which authorize fees to be collected by LBP.

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

LBP may realize additional revenues through pharmacy permit application fees associated with the elimination of the ten permit limit. The maximum number of marijuana pharmacies authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. The application fees total $550 ($500 for the application plus the annual $25 Controlled Dangerous Substance license fee and the annual $25 Prescription Monitoring Program fee), and annual fees total $250. The annual revenues realized will depend upon the number of marijuana pharmacies in operation and is indeterminable.

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

The proposed rule change in Section 2451, which was a result of Act 491 (2022RS), will benefit consumers by requiring home delivery to patients in each zip code at least once per month, resulting in increased access to care. There will be a cost to marijuana pharmacies to provide delivery services, the amount of which is indeterminable.

The proposed rule changes benefit marijuana pharmacies by reducing the number of regulations to align with ordinary community pharmacy permit requirements more closely. The reduction in regulations, specifically security requirements, should provide an economic benefit for marijuana pharmacies, particularly for new permits.

The proposed rule changes also address recent legislative changes, including changing the licensing of contractors who cultivate, extract, process, produce, and transport therapeutic marijuana to LDH.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed changes eliminate the rule which limits the number of marijuana pharmacy permits to ten. Under current law, the maximum number of allowed marijuana pharmacies in the state is thirty. The opening of additional marijuana pharmacies will increase employment and competition.

FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

Person Preparing Statement: M. Joseph Fontenot Jr.
Executive Director

Telephone: 225.925.6481

Return Address: 3388 Brentwood Drive
Baton Rouge, LA 70809

Dept.: Dept. of Health

Office: Board of Pharmacy

Title: Marijuana Pharmacy

Effective Date of Rule: Upon promulgation
November 20, 2023 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL 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 $2,000 in FY 2023 and $2,000 in FY 2024.

There may be additional costs associated with inspections of additional pharmacies due to the elimination of the ten permit limit. The maximum number of marijuana pharmacies including satellite locations authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. Compliance inspections cost approximately $300 and are conducted approximately every 18 months. The annual cost of inspections will depend upon the number of marijuana pharmacies in operation and is indeterminable. These costs will be funded through self-generated revenues from application fees.

The proposed rule changes in Chapter 24, Subchapter E are in response to Acts 444 and 491 of the 2022 regular session and an effort by LBP to reduce the number of regulations on marijuana pharmacies. The proposal repeals §§ 2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician.

The proposed rule changes replace references to the Department of Agriculture and Forestry (LDAF) with Department of Health (LDH) and references to physicians with authorized clinicians licensed to practice in this state. The proposed rule changes shift the responsibility of product requirements from the producers which supply the product to the pharmacies which receive and dispense the product.

The proposed rule changes remove requirements for producer testing, packaging, labeling, and distribution; duplication listing bulk raw product in allowed dosage form list; the restriction to ten active marijuana pharmacy permits at a time, including the description of the 9 LDH regions; the requirement to include a blueprint of the proposed marijuana pharmacy and documentation of the applicant's financial capacity to operate a marijuana pharmacy with the initial application for a permit; the description of the manner in which the Board may verify information contained in each application; the issuance of duplicate permits; the requirement to develop a written alcohol-free, drug-free, and smoke-free workplace policy; the requirement for product to be immediately placed in a safe or vault upon delivery; the inclusion of "federal" in the list of officials that may enter any area of the marijuana pharmacy; the requirement to notify LBP of certain security related events; and the reference to security requirements identified elsewhere in the Subchapter.

The proposed rule changes add the definition of authorized clinician; a requirement for the pharmacy to have access to laboratory tests from the producer; a requirement for each marijuana pharmacy to offer home delivery to patients in each zip code within its region at least once per month; and an allowance for, and requirements related to dispensing marijuana products to visiting qualifying patients.

The proposed rule changes amend the reference to rules and statutes which authorize fees to be collected by LBP.

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

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

LBP may realize additional revenues through pharmacy permit application fees associated with the elimination of the ten permit limit. The maximum number of marijuana pharmacies authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. The application fees total $550 ($500 for the application plus the annual $25 Controlled Dangerous Substance license fee and the annual $25 Prescription Monitoring Program fee), and annual fees total $250. The annual revenues realized will depend upon the number of marijuana pharmacies in operation and is indeterminable.

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

The proposed rule change in Section 2451, which was a result of Act 491 (2022RS), will benefit consumers by requiring home delivery to patients in each zip code at least once per month, resulting in increased access to care. There will be a cost to marijuana pharmacies to provide delivery services, the amount of which is indeterminable.

The proposed rule changes benefit marijuana pharmacies by reducing the number of regulations to align with ordinary community pharmacy permit requirements more closely. The reduction in regulations, specifically security requirements, should provide an economic benefit for marijuana pharmacies, particularly for new permits.

The proposed rule changes also address recent legislative changes, including changing the licensing of contractors who cultivate, extract, process, produce, and transport therapeutic marijuana to LDH.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed changes eliminate the rule which limits the number of marijuana pharmacy permits to ten. Under current law, the maximum number of allowed marijuana pharmacies in the state is thirty. The opening of additional marijuana pharmacies will increase employment and competition.

Joe Fontenot
Signature of Agency Head or Designee

M. Joseph Fontenot Jr. Executive Director
Typed Name and Title of Agency Head

April 03, 2023
Date of Signature

Evan Brasseaux, Interim Deputy Fiscal Officer
Legislative Fiscal Officer or Designee

4/3/23
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The proposed rule changes in Chapter 24, Subchapter E are in response to Acts 444 and 491 of the 2022 regular session and an effort by LBP to reduce the number of regulations. The proposal repeals §§ 2440, 2449, 2453, 2459 as well as the definitions of advertisement, approved safe, approved vault, LDAF, and physician. The proposed rule changes replace references to the Department of Agriculture and Forestry (LDAF) with Department of Health (LDH) and references to physicians with authorized clinicians licensed to practice in this state. The proposed rule changes shift the responsibility of product requirements from the producers which supply the product to the pharmacies which receive and dispense the product.

The proposed rule changes remove requirements for producer testing, packaging, labeling, and distribution; duplication listing bulk raw product in allowed dosage form list; the restriction to ten active marijuana permits at a time, including the description of the 9 LDH regions; the requirement to include a blueprint of the proposed marijuana pharmacy and documentation of the applicant's financial capacity to operate a marijuana pharmacy with the initial application for a permit; the description of the manner in which the Board may verify information contained in each application; the issuance of duplicate permits; the requirement to develop a written alcohol-free, drug-free, and smoke-free workplace policy; the requirement for product to be immediately placed in a safe or vault upon delivery; the inclusion of "federal" in the list of officials that may enter any area of the marijuana pharmacy; the requirement to notify LBP of certain security related events; and the reference to security requirements identified elsewhere in the Subchapter.

The proposed rule changes add the definition of authorized clinician; a requirement for the pharmacy to have access to laboratory tests from the producer; a requirement for each marijuana pharmacy to offer home delivery to patients in each zip code within its region at least once per month; and an allowance for, and requirements related to dispensing marijuana products to visiting qualifying patients.

The proposed rule changes amend the reference to fees to be collected by the Board. A copy of the notice of intent is appended.

B. Summarize the circumstances which require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

The proposed rule changes are in response to Acts 444 and 491 of the 2022 regular session, requests received by LBP for modification to the storage and security requirements for marijuana pharmacies, and an effort by LBP to reduce the number of regulations. The Board of Pharmacy determined it appropriate to amend Chapter 24, Subchapter E of its rules relative to marijuana pharmacies.

C. Compliance with Act 11 of the 1986 First Extraordinary Session

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

LBP has allocated $4,000 for printing the Notice of Intent and the Rule and may experience and indeterminable increase in inspection costs. LBP operates on self-generated funds.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ Yes. If yes, attach documentation.

(b) No NO. If no, provide justification as to why this rule change should be published at this time

LBP operates on self-generated funds, and they have determined the proposed rule changes are in the public's best interest.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 23	FY 24	FY 25
Personal Services Operating Expenses Professional Services Other Charges Equipment Major Repairs & Constr.	$2000	INCREASE	SEE BELOW
TOTAL	$2000	INCREASE	SEE BELOW
POSITIONS (#)	None	None	None

2. Provide a narrative explanation of the costs or savings shown in "A. 1.", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

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 $2000 in FY 2023 and $2000 in FY 2024.

There may be additional costs associated with inspections of additional pharmacies due to the elimination of the ten permit limit. The maximum number of marijuana pharmacies authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. Compliance inspections cost approximately $300 and are conducted approximately every 18 months. The annual cost of inspections will depend upon the number of marijuana pharmacies in operation and is indeterminable. These costs will be funded through self-generated revenues from application fees.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 23	FY 24	FY 25
State General Fund Agency Self-Generated Dedicated Federal Funds Other (Specify)	$2000	INCREASE	SEE BELOW
TOTAL	$2000	INCREASE	SEE BELOW

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

LBP has sufficient self-generated funds available to implement the proposed rule changes.

B. COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

The proposed rule changes will not result in costs or savings to local governmental units.

2. Indicate the sources of funding of the local governmental unit, which will be affected by these costs or savings.

The proposed rule changes will not affect sources of funding of local governmental units.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

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

REVENUE INCREASE/DECREASE	FY 23	FY 24	FY 25
State General Fund			
Agency Self-Generated		SEE BELOW	SEE BELOW
Dedicated Funds*			
Federal Funds			
Local Funds			
TOTAL	None	SEE BELOW	SEE BELOW

*Specify the particular fund being impacted.

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A." Describe all data, assumptions, and methods used in calculating these increases or decreases.

LBP may realize additional revenues through pharmacy permit application fees associated with the elimination of the ten permit limit. The maximum number of marijuana pharmacies authorized by RS 40:1046 is thirty, though the actual number of marijuana pharmacies that will be in operation at any given time is indeterminable. The application fees total $550 ($500 for the application plus the annual $25 Controlled Dangerous Substance license fee and the annual $25 Prescription Monitoring Program fee), and annual fees total $250. The annual revenues realized will depend upon the number of marijuana pharmacies in operation and is indeterminable.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

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

A. What persons, small businesses, or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule change in Section 2451, which was a result of Act 491 (2022RS), will benefit consumers by requiring home delivery to patients in each zip code at least once per month, resulting in increased access to care. There will be a cost to marijuana pharmacies to provide delivery services, the amount of which is indeterminable.

The proposed rule changes benefit marijuana pharmacies by reducing the number of regulations to align with ordinary community pharmacy permit requirements more closely. The reduction in regulations, specifically security requirements, should provide an economic benefit for marijuana pharmacies, particularly for new permits.

The proposed rule changes also address recent legislative changes, including changing the licensing of contractors who cultivate, extract, process, produce, and transport therapeutic marijuana to LDH.

B. Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to these groups.

The proposed rule changes will have no impact on receipts and/or income to these groups.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed changes eliminate the rule which limits the number of marijuana pharmacy permits to ten. Under current law, the maximum number of allowed marijuana pharmacies in the state is thirty. The opening of additional marijuana pharmacies will increase both competition and employment opportunities at marijuana pharmacies opened around the state.