

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII. Pharmacists

Chapter 24. Limited Service Providers

Subchapter E. Marijuana Pharmacy

§2441. Definitions

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

Administer—the direct application of marijuana to the body of a qualifying patient by ingestion or any other means.

Agent—an authorized person who acts on behalf of or at the direction of another person. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

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

Board—the Louisiana Board of Pharmacy.

CFR—Code of Federal Regulations.

Deliver or Delivery—the actual, constructive or attempted transfer from one person to another of marijuana, whether or not there is an agency relationship.

Financial Interest—any actual, or a future right to, ownership or investment, either directly or indirectly, through business, investment or immediate family. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by such person do not exceed 5 percent of the total number of shares issued by the corporation.

Immediate Family—R.S. 42:1102; i.e., his children and the spouses of his children, his brothers and their spouses, his sisters and their spouses, his parents, his spouse, and the parents of his spouse.

LDH—the Louisiana Department of Health.

Louisiana Medical Marijuana Tracking System (LMMTS)—the required seed-to-sale tracking system that tracks medical marijuana from either the seed or immature plant stage until the product is sold to a pharmacy or is destroyed.

Marijuana Pharmacy—that area within a facility where marijuana is stored, dispensed, and sold. If a facility does not offer any products or services other than marijuana and/or related supplies, the entire facility is a marijuana pharmacy for the purposes of this Subchapter.

Marijuana Pharmacy Owner—any person with an ownership interest in a marijuana pharmacy, except the term does not include a person with an investment interest through a publicly-held company provided the interest held by such person does not exceed five per cent of the total ownership or interest rights in such pharmacy and such person does not participate directly or indirectly in the control, management, or operation of the pharmacy.

Marijuana Product—any product containing marijuana, including raw materials, that requires no further processing and that is packaged for sale to pharmacies, qualifying patients and primary caregivers.

Owner's Managing Officer—the person designated by the organization owning the pharmacy to be responsible to the board for the proper operation of the pharmacy in compliance with all applicable laws and regulations.

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

a. processed, packaged and labeled according to the United States Food and Drug Administration’s “current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements,” as found in 21 CFR 111 or its successor;

b. labeled with the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue analysis which have been completed on a batch basis by a laboratory; and

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

Pharmacist—an individual currently licensed by the board to engage in the practice of pharmacy.

Pharmacy Technician—an individual who assists in the practice of pharmacy under the direct and immediate supervision of a licensed pharmacist and is currently certified to do so by the board.

Prescription Monitoring Program (PMP)—the electronic prescription drug monitoring program established by R.S. 40:1001 et seq.

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

Production or *Produce*—the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by a patient or caregiver for the patient’s 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 Health has issued a producer license.

Sale—any form of delivery, which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant, or employee.

Usable Marijuana—the dried leaves and flowers of the marijuana plant, and any mixtures or preparations of such leaves and flowers that are appropriate for the therapeutic use of marijuana, but does not include the seeds, stalks, and roots of the marijuana plant.

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 49:1719 (October 2023).

§2443. Marijuana Products

A. Exclusive Source

1. The exclusive source of marijuana products shall be the producers licensed for that activity by LDH.

2. Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be received by any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed by any marijuana pharmacy.

B. Laboratory Testing

1. The marijuana pharmacy shall have access to the laboratory test results from the producer for each final product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and authorized clinicians who recommended such marijuana products dispensed to their patients.

C. Product Dosage Forms

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

- a. oils, extracts, tinctures, or sprays;
- b. solid oral dosage forms, e.g., capsules or pills;
- c. liquid oral dosage forms, e.g., solutions or suspensions;
- d. gelatin-based or pectin-based chewables;
- e. topical applications, oils or lotions;
- f. transdermal patches;
- g. suppositories; or
- h. metered-dose inhalers

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

- a. combustible forms for inhalation, including but not limited to pre-rolls; and
- b. edible forms for ingestion.

3. No marijuana product shall:

a. include alcoholic liquor, dietary supplements, or any drug, except for marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than 0.5 percent of alcohol by volume, or ethanol-based tinctures.

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

- i. is obscene or indecent;
- ii. may encourage the use of marijuana for recreational purposes;
- iii. may encourage the use of marijuana for a condition other than a debilitating medical condition; or
- iv. is customarily associated with persons under the age of 18 years; or

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 LDH.

4. Any marijuana product not in compliance with the provisions of this Section shall be deemed adulterated.

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 49:1719 (October 2023).

113 **§2445. Marijuana Pharmacy Permit**

114 A. The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.

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

117 C. When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy in
118 compliance with the provisions of this Subchapter.

119 D. When the permit is issued, it shall be valid only for the owner and the specific location noted on the application
120 and recorded on the permit.

121 E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event
122 the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership will be
123 deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy permit owner
124 continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or more without obtaining
125 a new marijuana pharmacy permit shall be subject to disciplinary review by the board.

126 F. Although a change of ownership of less than 50 percent shall not require a new pharmacy permit, any proposed
127 change of ownership shall require prior notice to the board, and further, approval by the board.

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

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

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

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

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

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

147 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1543 (August 2017), amended
148 LR 49:1720 (October 2023).

149

150 **§2447. Licensing Procedures**

151 A. Application for Initial Issuance of Permit

152 1. The board shall develop an application form suitable for the marijuana pharmacy permit. The board may
153 revise that application form on its own initiative in order to collect the information it deems necessary to properly
154 evaluate an applicant.

155 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the
156 incorrect fee.

157 3. The applicant shall fully disclose the ownership of the entity that will own the permit as well as any additional
158 holding companies that may exist, such that any natural person with any ownership interest shall be fully identified.

159 4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana
160 pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not
161 issue a marijuana pharmacy permit to that applicant:

162 a. within the two-year period preceding the date of the application, the person or any member of the person's
163 immediate family served as a member of the board or its staff.

164 5. The applicant shall provide a complete street address reflecting the location at which the applicant proposes
165 to operate the marijuana pharmacy.

166 6. The applicant shall provide the following information and records in the application process:

167 a. a detailed description of any other services or products to be offered by the marijuana pharmacy;

168 b. details regarding the applicant's plans to maintain adequate control against the diversion, theft, or loss of
169 marijuana;

170 c. documents or information sufficient to establish the applicant is authorized to conduct business in
171 Louisiana and that all applicable state and local building, fire and zoning requirements, and local ordinances will be
172 met;

173 d. text and graphic materials showing the exterior appearance of the proposed marijuana pharmacy and its
174 site compatibility with commercial or residential structures already constructed or under construction within the
175 immediate neighborhood;

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

178 7. The owner's managing officer and the pharmacist-in-charge shall be fully identified within the application
179 and they both shall sign and date the application form.

180 8. The applicant shall direct the following persons to submit to the criminal history record check process used
181 by the board, at the applicant's expense:

182 a. the owner's managing officer;

183 b. the pharmacist-in-charge; and

184 c. any person holding any share of ownership in the entity; provided however that any person not holding
185 any share of ownership but holding a corporate officer position in the entity may be required to submit to the criminal
186 history record check.

187 9. The requirement for a criminal history record check may be waived by the board in the event the person has
188 already completed that process for the board within the two-year period prior to the date of the application.

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

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

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

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

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

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

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

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

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

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

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

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

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

219 f. Any other reason provided by any federal law or rule or state law or rule that is not inconsistent with R.S.
220 40:1046 or 40:1047 or this Subchapter.

221 14. Following their evaluation of the applications for a marijuana pharmacy permit, the committee shall develop
222 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.

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.

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

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.

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 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. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

4. In the event the pharmacy does not submit a properly completed renewal application form and fee to the board prior to the expiration of the permit, the permit shall be rendered null and void. A marijuana pharmacy shall not operate with an expired permit. Evidence it has done so will provide sufficient basis for the board to discipline the permit for violation of R.S. 37:1241(12).

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 LAC 46:LIII.115 is included with the application.

6. A marijuana pharmacy permit not renewed by 30 days after the expiration date shall be automatically terminated by the board.

7. An application for the reinstatement of a terminated marijuana pharmacy permit shall be referred to the board's reinstatement committee for its consideration.

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 LAC 46:LIII.115 and the program fee authorized in R.S. 40:1013.

2. An application for the reinstatement of a marijuana pharmacy permit previously terminated, suspended or revoked by the board may only be approved following a preliminary hearing to determine whether the reinstatement of the permit is in the public's best interest.

D. Maintenance of Marijuana Pharmacy Permit

1. A marijuana pharmacy permit is valid only for the entity or person to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the business location recorded thereon.

2. 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.

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.

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 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.

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.

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.

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 49:1720 (October 2023).

§2451. Operation of Marijuana Pharmacy

A. No person may operate a marijuana pharmacy without a marijuana pharmacy permit issued by the board, and further, that permit shall be in active or restricted status. A pharmacist shall be on duty at all times during the regular open hours of the marijuana pharmacy.

B. A marijuana pharmacy shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Louisiana.

C. A marijuana pharmacy shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:

1. it may acquire marijuana from an authorized producer pursuant to the provisions of R.S. 40:1046; and
2. it may dispense and sell marijuana to a patient with a recommendation/prescription/order for such marijuana or the patient's caregiver.

D. No person at a marijuana pharmacy shall provide marijuana samples.

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

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

G. A marijuana pharmacy shall place all products sold to the patient or caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.

H. A marijuana pharmacy shall not permit any person to enter the prescription department unless that person's responsibilities necessitate access to the department and then for only as long as necessary to perform the person's job duties.

I. While inside the pharmacy, all pharmacy employees shall wear name tags or similar forms of identification that clearly identify them to the public, including their position at the pharmacy.

J. A marijuana pharmacy shall be open for qualifying patients and primary caregivers to purchase marijuana products for a minimum of 10 hours per week.

1. A marijuana pharmacy that closes during its normal hours of operation shall implement procedures to notify patients and caregivers of when the marijuana pharmacy will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs.

2. In the event the pharmacist on duty leaves the prescription department, the prescription department shall comply with the provisions of §1109 (temporary absence) or §1111 (closure) of this Part.

K. A marijuana pharmacy shall provide information to patients and caregivers regarding the possession and use of marijuana. Such informational material shall include information related to:

1. limitations on the right to possess and use marijuana pursuant to R.S. 40:1046;
2. safe techniques for proper use of marijuana and paraphernalia;

3. alternative methods and forms of consumption by which one can use marijuana;
4. signs and symptoms of substance abuse; and
5. opportunities to participate in substance abuse programs.

L. 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.

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

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

O. No person associated with a marijuana pharmacy shall enter into any agreement with 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.

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:

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

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

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.

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.

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

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

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.

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 49:1720 (October 2023).

§2455. Reportable Security Events

A. Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana, or of any loss or unauthorized alteration of records related to marijuana or patients, a pharmacy shall immediately notify:

1. appropriate law enforcement authorities; and
2. the board.

B. A pharmacy shall provide the written notice to the board by way of a signed statement which details the circumstances of the event, including an accurate inventory of the quantity and brand names of the marijuana diverted, stolen, lost, destroyed, or damaged, along with confirmation that the local law enforcement authorities were notified. A pharmacy shall make such notice no later than 24 hours after discovery of the event.

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 49:1721 (October 2023).

§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. The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.

3. The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal.

4. All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained at temperatures which will ensure the integrity of drugs during their storage and prior to their dispensing as stipulated

by the *United States Pharmacopeia* and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board.

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.

6. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.

B. Minimum Staffing Requirements

1. There shall be at least one pharmacist on duty at all times the pharmacy is open for business.

2. Every pharmacist practicing in the pharmacy shall possess a Louisiana pharmacist license in active status as well as access privileges to the state prescription monitoring program.

3. A pharmacy intern, pharmacy technician or pharmacy technician candidate may assist the pharmacist in the prescription department, but only when in possession of valid credentials issued by the board. The supervising pharmacist may establish a delegate credential in the state prescription monitoring program for any licensed pharmacy personnel affiliated with that pharmacy.

4. Additional clerical personnel may also be present at the pharmacy.

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

C. Operational Standards

1. The marijuana pharmacy shall comply with the provisions of Chapters 11, 25, 27, 29, and 31 of this Part except when this Subchapter grants exceptions or imposes more stringent requirements.

2. In the event the marijuana pharmacy intends to close permanently, the pharmacist-in-charge (PIC) shall comply with the pharmacy closure procedures described in Chapter 11 of this Part, and further, the owner of the pharmacy permit shall not prevent or interfere with the PIC's performance of those tasks.

a. In addition to the other closure requirements, the closing pharmacy shall include in its notice to the board and to the public the identification of the destination pharmacy where the closing pharmacy's prescription records will be transferred. That destination pharmacy shall be the marijuana pharmacy nearest the closing pharmacy, unless otherwise approved by the board.

D. Recordkeeping Requirements

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

2. Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at least two years after the date of dispensing, and further, shall be readily retrievable upon request by the board.

3. Inventory of Marijuana Product

a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana products acquired, held, dispensed, and disposed by the pharmacy.

b. The pharmacy shall access the LMMTS and enter all acquisitions and product transfer transactions in that system.

c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product inventory from the production facility, the pharmacist shall verify the agent is at least 21 years of age and is eligible to drive on public roadways.

d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the possession of the pharmacy on any date which is within one year of the previous annual inventory, and further, shall conduct additional inventory counts on the following occasions:

- i. arrival of a new pharmacist-in-charge;
- ii. discovery of any significant loss, disappearance, or theft of marijuana product;
- iii. departure of a pharmacist-in-charge; and
- iv. permanent closure of the pharmacy.

e. Inventory records shall be retained on the pharmacy's premises for at least two years after the most recent entry.

4. The pharmacy shall develop and maintain sufficient records to fully reveal the business transactions related to marijuana products, including their procurement and sale, for the current tax year as well as the two immediately preceding tax years, all of which shall be made available to the board upon request.

5. The board may require any pharmacy or its owners to furnish such information as the board considers necessary for the proper administration of R.S. 40:1046, and may require a financial audit of the business of any marijuana pharmacy, and the expense thereof shall be paid by the marijuana pharmacy.

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 an authorized clinician in possession of a current and unrestricted license to practice in this state as well as a current and unrestricted state controlled substance license with therapeutic marijuana privileges from the board; and

ii. received directly from the 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 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 authorized clinician 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 authorized clinician holds a current and unrestricted license to practice in this state;

and

vii. signature of the 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 authorized clinician. A pharmacist shall not dispense marijuana product pursuant to an expired request.

d. Requests for raw or crude marijuana products intended for persons under 21 years of age shall specifically indicate a recommendation for raw or crude forms of marijuana for such persons.

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

2. Upon request by the patient or caregiver and prior to dispensing any marijuana product to a patient, the pharmacist shall provide product testing results available to the pharmacist for the product contemplated for dispensing.

3. Dispensing Marijuana Products

a. Prior to dispensing any marijuana product to a patient, the pharmacist shall review the patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending 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 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 Subparagraph 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 Subparagraph 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 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. name and address of the pharmacy dispensing the product;

ii. telephone number or other contact information of the pharmacy dispensing the product;

iii. name of the recommending authorized clinician;

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

- ii. quantity of product disposed;
- iii. manner of disposal; and
- iv. signatures of the pharmacist-in-charge disposing the product plus at least one witness who is either a credentialed staff member of that pharmacy or an agent of the board.

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

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017), amended LR 45:1473 (October 2019), LR 47:246 (February 2021), LR 47:1111 (August 2021), LR 48:1903 (July 2022), LR 48:2103 (August 2022), amended LR 49:1721 (October 2023).