

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

Subchapter E. Marijuana Pharmacy

§2440. Preamble; warning; consultation suggested

- A. Pursuant to Act 261 of the Regular Session of the 2015 Louisiana Legislature as well as the subsequent amendment found in Act 96 of the Regular Session of the 2016 Louisiana Legislature, the Louisiana 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 ten, 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 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 Louisiana 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 Louisiana 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.
- 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 the board’s rules 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.

- 53 C. For the foregoing reasons, pharmacists and other persons credentialed by the board may wish to
54 consult with their own legal counsel as well as any health care facility, private or governmental payor
55 with which they are affiliated, professional liability insurers, and financial institutions with which they
56 maintain depository relationships before engaging in the activities described herein.
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58 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

59 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
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61 §2441. Definitions

- 62 A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this
63 Section:
- 64 1. *Administer* means the direct application of marijuana to the body of a qualifying patient by
65 ingestion or any other means.
 - 66 2. *Advertisement* means all representations disseminated in any manner or by any means, other than
67 by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the
68 purchase of marijuana.
 - 69 3. *Agent* means an authorized person who acts on behalf of or at the direction of another person. It
70 does not include a common or contract carrier, public warehouseman, or employee of the carrier
71 or warehouseman.
 - 72 4. *Approved safe* means a safe which conforms to or exceeds all of the following standards:
 - 73 a. Shall have the following specifications or the equivalent: 30 man-minutes against
74 surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock
75 manipulation, and 20 man-hours against radiological techniques;
 - 76 b. If it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way it
77 cannot be readily removed; and
 - 78 c. Depending upon the quantities stored, is equipped with an alarm system which, upon
79 attempted unauthorized entry, shall transmit a signal directly to a central protection company
80 or a local or state police agency which has a legal duty to respond, or a 24-hour control station
81 operated by the licensee, or such other protection as the board or its designee may approve.
 - 82 5. *Approved vault* means:
 - 83 a. A vault constructed before, or under construction on, September 1, 1971, which is of
84 substantial construction with a steel door, combination or key lock, and an alarm system; or
 - 85 b. A vault constructed after September 1, 1971:
 - 86 i. The walls, floors, and ceilings of which are constructed of at least eight inches of
87 reinforced concrete or other substantial masonry, reinforced vertically and horizontally
88 with one-half inch steel rods tied six inches on center, or the structural equivalent to such
89 reinforced walls, floors, and ceilings;
 - 90 ii. The door and frame unit of which vault shall conform to the following specifications or
91 the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against
92 forced entry, 20 man-hours against lock manipulation, and 20 man-hours against
93 radiological techniques;
 - 94 iii. Which vault, if operations require it to remain open for frequent access, is equipped with
95 a "day gate" which is self-closing and self-locking or the equivalent, for use during the
96 hours of operation in which the vault door is open;
 - 97 iv. The walls or perimeter of which are equipped with an alarm which, upon unauthorized
98 entry, shall transmit a signal directly to a central station protection company, or a local or
99 state police agency which has a legal responsibility to respond, or a 24-hour control
100 station operated by the licensee, or such other protection as the board or its designee may
101 approve, and if necessary, alarm buttons at strategic points of entry to the perimeter area
102 of the vault;
 - 103 v. The door of which shall be equipped with one or more contact switches; and
 - 104 vi. Which vault has one of the following:
 - 105 (a) Complete electrical lacing of the walls, floor and ceiling;
 - 106 (b) Sensitive ultrasonic equipment within the vault;

- 107 (c) Sensitive sound accumulator system; or
108 (d) Such other device designed to detect illegal entry as may be approved by the
109 board.
- 110 6. *Board* means the Louisiana Board of Pharmacy.
111 7. *CFR* means Code of Federal Regulations.
112 8. *Deliver or delivery* means the actual, constructive or attempted transfer from one person to another
113 of marijuana, whether or not there is an agency relationship.
114 9. *Financial interest* means any actual, or a future right to, ownership, investment or compensation
115 arrangement with another person, either directly or indirectly, through business, investment or
116 immediate family. Financial interest does not include ownership of investment securities in a
117 publicly-held corporation that is traded on a national exchange or over-the-counter market,
118 provided the investment securities held by such person do not exceed five per cent of the total
119 number of shares issued by the corporation.
- 120 10. *Immediate family* shall have the same meaning as provided in La. R.S. 42:1102, i.e., his children
121 and the spouses of his children, his brothers and their spouses, his sisters and their spouses, his
122 parents, his spouse, and the parents of his spouse.
123 11. *LDAF* means the Louisiana Department of Agriculture and Forestry.
124 12. *LDH* means the Louisiana Department of Health.
125 13. *Louisiana Medical Marijuana Tracking System (LMMTS)* means the required seed-to-sale tracking
126 system that tracks medical marijuana from either the seed or immature plant stage until the
127 product is sold to a pharmacy or is destroyed.
128 14. *Marijuana* means all parts of plants of the genus *Cannabis*, whether growing or not, the seeds
129 thereof, the resin extracted from any part of such plant, and every compound, manufacture, salt,
130 derivative, mixture, or preparation of such plant, its seeds or resin, but shall not include the mature
131 stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such
132 plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature
133 stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant
134 which is incapable of germination.
135 15. *Marijuana pharmacy* means that area within a facility where marijuana is stored, dispensed, and
136 sold. If a facility does not offer any products or services other than marijuana and/or related
137 supplies, the entire facility is a marijuana pharmacy for the purposes of this Subchapter.
138 16. *Marijuana pharmacy owner* means any person with an ownership interest in a marijuana
139 pharmacy, except the term does not include a person with an investment interest through a
140 publicly-held company provided the interest held by such person does not exceed five per cent of
141 the total ownership or interest rights in such pharmacy and such person does not participate
142 directly or indirectly in the control, management, or operation of the pharmacy.
143 17. *Marijuana product* means any product containing marijuana, including raw materials, that requires
144 no further processing and that is packaged for sale to pharmacies, qualifying patients and primary
145 caregivers.
146 18. *Owner's managing officer* means the person designated by the organization owning the pharmacy
147 to be responsible to the board for the proper operation of the pharmacy in compliance with all
148 applicable laws and regulations.
149 19. *Pharmaceutical grade marijuana* means marijuana or marijuana products that are not adulterated
150 and are:
151 a. Processed, packaged and labeled according to the United States Food & Drug
152 Administration's "*Current Good Manufacturing Practice in Manufacturing, Packaging,*
153 *Labeling, or Holding Operations for Dietary Supplements*" as found in 21 CFR 111 or its
154 successor;
155 b. Labeled with the results of an active ingredient analysis, a microbiological contaminants
156 analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue
157 analysis which have been completed on a batch basis by a laboratory; and
158 c. Where each step of the production, cultivating, trimming, curing, manufacturing, processing,
159 and packaging method has been documented by using standard operation procedures
160 approved by the Commissioner of the Louisiana Department of Agriculture and Forestry.

- 161 20. *Pharmacist* means an individual currently licensed by the board to engage in the practice of
 162 pharmacy.
 163 21. *Pharmacy technician* means an individual who assists in the practice of pharmacy under the direct
 164 and immediate supervision of a licensed pharmacist and is currently certified to do so by the
 165 board.
 166 22. *Physician* means an individual currently licensed by the Louisiana State Board of Medical
 167 Examiners to engage in the practice of medicine.
 168 23. *Prescription monitoring program (PMP)* means the electronic prescription drug monitoring
 169 program established by La. R.S. 40:1001 *et seq.*
 170 24. *Producer* means a person licensed by the Louisiana Department of Agriculture and Forestry to
 171 cultivate marijuana for therapeutic use.
 172 25. *Production or produce* means the manufacture, planting, preparation, cultivation, growing,
 173 harvesting, propagation, compounding, conversion or processing of marijuana, either directly or
 174 indirectly by extraction from substances of natural origin, or independently by means of chemical
 175 synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging
 176 or repackaging of the substance or labeling or relabeling of its container, except that this term does
 177 not include the preparation or compounding of marijuana by a patient or caregiver for the patient's
 178 use.
 179 26. *Production facility* means a secure, indoor facility where the production of marijuana occurs and
 180 that is operated by a person to whom the Louisiana Department of Agriculture and Forestry has
 181 issued a producer license.
 182 27. *Sale* is any form of delivery, which includes barter, exchange or gift, or offer therefor, and each
 183 such transaction made by any person whether as principal, proprietor, agent, servant, or employee.
 184 28. *Usable marijuana* means the dried leaves and flowers of the marijuana plant, and any mixtures or
 185 preparations of such leaves and flowers, that are appropriate for the therapeutic use of marijuana,
 186 but does not include the seeds, stalks, and roots of the marijuana plant.

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

189 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
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191 §2443. Marijuana products

- 192 A. Exclusive Source.
 193 1. The exclusive source of marijuana products shall be the producer licensed for that activity by the
 194 Louisiana Department of Agriculture and Forestry (LDAF).
 195 2. That producer shall prepare pharmaceutical grade marijuana products for distribution to the
 196 marijuana pharmacies licensed by the board.
 197 3. Marijuana products from any other source shall be deemed misbranded and/or adulterated and
 198 shall not be distributed to any marijuana pharmacy, nor may such misbranded and/or adulterated
 199 products be dispensed by any marijuana pharmacy.
 200 B. Laboratory Testing.
 201 1. Prior to manufacturing any marijuana product, the producer shall segregate all harvested
 202 marijuana into homogenized batches.
 203 2. A producer shall make available each such batch at the production facility for testing by a
 204 laboratory approved by LDAF. The laboratory employee shall select a random sample from each
 205 batch. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy
 206 metals, pesticide chemical residue, residual solvents, homogeneity, and for the purpose of
 207 conducting an active ingredient analysis.
 208 3. From the time that a batch of marijuana has been homogenized for sample testing and eventual
 209 packaging and sale to a pharmacy until the laboratory provides the results from its tests and
 210 analyses, the producer shall segregate and withhold from use the entire batch with the exception of
 211 the samples removed by the laboratory for testing. During this period of segregation, the producer
 212 shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana
 213 from becoming contaminated or losing its efficacy. Under no circumstances shall a producer
 214 include marijuana in a marijuana product or sell it to a pharmacy prior to the time the laboratory

- 215 has completed its testing and analysis and provided those results, in written or electronic form, to
216 the producer or the producer's designated employee.
- 217 4. The laboratory shall immediately return or dispose of any marijuana upon the completion of any
218 testing, use, or research. When the laboratory disposes of marijuana, the laboratory shall comply
219 with the marijuana disposal rules promulgated by LDAF.
- 220 5. In the event a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal,
221 pesticide chemical residue, residual solvent, or homogeneity test based on the standards set forth
222 in this Section, the producer shall dispose of the entire batch from which the sample was taken, in
223 compliance with the marijuana disposal rules promulgated by LDAF.
- 224 a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if
225 it satisfies the standards set forth in *Chapter 1111 – Microbiological Examination of*
226 *Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances*
227 *for Pharmaceutical Use of the United States Pharmacopeia* (USP), available at www.usp.org.
- 228 b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it
229 meets the following standards:
- 230 i. Aflatoxin B1 < 20 parts per billion (ppb);
231 ii. Aflatoxin B2 < 20 ppb;
232 iii. Aflatoxin G1 < 20 ppb;
233 iv. Aflatoxin G2 < 20 ppb; and
234 v. Ochratoxin A < 20 ppb.
- 235 c. With respect to the heavy metals test, a marijuana sample shall be deemed to have passed if it
236 meets the following standards:
- 237 i. Arsenic < 10 parts per million (ppm);
238 ii. Cadmium < 4.1 ppm;
239 iii. Lead < 10 ppm; and
240 iv. Mercury < 2 ppm
- 241 d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to
242 have passed if it satisfies the most stringent acceptable standard for a pesticide chemical
243 residue in any food item as set forth in Subpart C of the United States Environmental
244 Protection Agency's "*Tolerances and Exemptions for Pesticide Chemical Residues in Food*",
245 as found in 40 CFR 180 or its successor.
- 246 e. With respect to the residual solvent test, a marijuana sample shall be deemed to have passed if
247 the following solvents are below the listed limits:
- 248 i. Butanes < 800 ppm;
249 ii. Heptanes < 500 ppm;
250 iii. Benzene < 1 ppm;
251 iv. Toluene < 1 ppm;
252 v. Hexanes < 10 ppm; and
253 vi. Total Xylenes < 1 ppm.
- 254 f. With respect to the test for homogeneity, a marijuana sample shall be deemed to have failed if
255 ten percent of the sample contains more than twenty percent of the total active ingredient.
- 256 g. With respect to the analysis of active ingredients, the following substances, when present,
257 shall be identified and measured. The maximum variance permitted is fifteen percent from
258 the labeled amount. For example, a product labeled as containing 10 milligrams of
259 tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than
260 11.5 milligram THC.
- 261 i. THC (tetrahydrocannabinol);
262 ii. THCA (tetrahydrocannabinolic acid);
263 iii. CBD (cannabidiol); and
264 iv. CBDA (cannabidiolic acid).
- 265 6. If a sample of marijuana passes the microbiological, mycotoxin, heavy metal, pesticide chemical
266 residue, residual solvent, and homogeneity tests, the laboratory shall release the entire batch for
267 immediate manufacturing, packaging, and labeling for sale to a marijuana pharmacy.

- 268 7. In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such
269 test result at the same time it transmits those results to the producer.
- 270 8. The laboratory shall comply with all rules applicable to the testing of marijuana promulgated by
271 LDAF.
- 272 9. A producer shall provide the laboratory test results to the marijuana pharmacy for each batch of
273 marijuana used in a product acquired by the marijuana pharmacy. The pharmacy shall make such
274 testing results available upon request to their patients, caregivers, and physicians who
275 recommended such marijuana products dispensed to their patients.
- 276 C. Product Dosage Forms.
- 277 1. The producer shall limit their production of pharmaceutical grade marijuana products to the
278 following dosage forms:
- 279 a. Oils, extracts, tinctures, or sprays;
280 b. Capsules or pills;
281 c. Topical applications, oils or lotions;
282 d. Transdermal patches; or
283 e. Suppositories.
- 284 2. No marijuana product shall:
- 285 a. Include alcoholic liquor, dietary supplements, or any drug, except for pharmaceutical grade
286 marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or
287 solid containing less than one-half of one percent of alcohol by volume, or ethanol-based
288 tinctures;
- 289 b. Be manufactured or sold as a beverage or confectionary;
- 290 c. Be manufactured or sold in a form or with a design that:
- 291 i. Is obscene or indecent;
292 ii. May encourage the use of marijuana for recreational purposes;
293 iii. May encourage the use of marijuana for a condition other than a debilitating medical
294 condition; or
295 iv. Is customarily associated with persons under the age of eighteen; or
- 296 d. Have had pesticide chemicals or organic solvents used during the production or
297 manufacturing process other than those which may be approved by the Commissioner of
298 LDAF.
- 299 3. Any marijuana product not in compliance with the provisions of this Paragraph shall be deemed
300 adulterated.
- 301 D. Packaging and Labeling Requirements.
- 302 1. Packaging.
- 303 a. The producer shall ensure every product intended for dispensing to a patient is placed within a
304 child-resistant, light-resistant, tamper-evident container prior to sale or transport to the
305 pharmacy.
- 306 i. A package shall be deemed child-resistant if it satisfies the standard for ‘special
307 packaging’ as set forth in the United States Consumer Product Safety Commission’s
308 *Poison Prevention Packaging* as found in 16 CFR 1700.1(b)(4) or its successor.
- 309 ii. A package shall be deemed light-resistant if it satisfies the standard set forth in *Chapter*
310 *671 – Containers: Performance Testing of the United States Pharmacopeia (USP)*.
- 311 iii. A package shall be deemed tamper-evident if it clearly indicates prior access to the
312 container.
- 313 b. Any product containing pharmaceutical grade marijuana or its principal psychoactive
314 constituent tetrahydrocannabinol (THC) shall be packaged so that one dose contains no more
315 than 10 milligrams of THC.
- 316 c. If it is not intended for the entire product to be used at a single time, the packaging must be re-
317 sealable in a manner that maintains its child-resistant property for multiple openings. Single
318 doses may be placed in a package with other single doses; however, the total amount of active
319 THC contained within the larger packaging shall not exceed 100 milligrams.
- 320 d. No single container shall contain more than a one month supply of marijuana.
- 321 e. Packaging selected by the producer shall be subject to the following restrictions.

- 322 i. Shall not specifically target individuals under the age of 21 years;
- 323 ii. Shall not bear any resemblance to a trademarked, characteristic or product-specialized
- 324 packaging of any commercially available candy, snack, baked good or beverage;
- 325 iii. Shall not use the words “candy” or “candies”;
- 326 iv. Shall not use a cartoon, color scheme, image, graphic or feature that might make the
- 327 package attractive to children; and
- 328 v. Shall not use a seal, flag, crest, coat of arms or other insignia that could reasonably lead
- 329 any person to believe the product has been endorsed, manufactured by, or used by any
- 330 state, parish, municipality, or any agent thereof.
- 331 2. Labeling.
- 332 a. Each product shall be labeled by the producer prior to its sale to the marijuana pharmacy.
- 333 Each label shall be securely affixed to the package and shall include, at a minimum:
- 334 i. The batch or lot number assigned by the producer to the marijuana plant(s) from which
- 335 the marijuana used in the product was harvested;
- 336 ii. A complete list of solvents, chemicals, and pesticides used in the creation of any
- 337 marijuana concentrate;
- 338 iii. A complete list of all ingredients used to manufacture the product, which may include a
- 339 list of any potential allergens contained within, or used in the manufacture of, a product;
- 340 iv. The potency of the THC and CBD in the product, expressed in milligrams for each
- 341 cannabinoids;
- 342 v. The net weight, using a standard of measure compatible with the LMMTS, of the
- 343 product prior to its placement in the shipping container;
- 344 vi. A product expiration date, upon which the product will no longer be fit for use. Once a
- 345 label with an expiration date has been affixed to a product, the producer shall not
- 346 alter that date or affix a new label with a later date; and
- 347 vii. A statement the product has been tested for contaminants, that there were no adverse
- 348 findings, and the date of such testing.
- 349 b. The labeling text on any marijuana product shall not make any false or misleading statements
- 350 regarding health or physical benefits to the consumer. Further, each label shall include all of
- 351 the following statements:
- 352 i. “Contains Marijuana. For Medical Use Only. KEEP OUT OF THE REACH OF
- 353 CHILDREN.”
- 354 ii. “Marijuana can impair concentration, coordination, and judgment. Do not operate a
- 355 vehicle or machinery under the influence of this drug.”
- 356 iii. “There may be additional health risks associated with the consumption of this product
- 357 for women who are pregnant, breastfeeding, or planning to become pregnant.”
- 358 iv. A statement that it is illegal for any person to possess or consume the contents of the
- 359 package other than the patient for whom it was recommended.
- 360 c. The labeling text required by this Section shall be no smaller than 1/16 of an inch, shall be
- 361 printed in English, and must be unobstructed and conspicuous.
- 362 E. Distribution of Marijuana Products to Marijuana Pharmacies.
- 363 1. The producer shall maintain complete inventory records in the Louisiana Medical Marijuana
- 364 Tracking System (LMMTS), as required and delineated in rules promulgated by LDAF.
- 365 2. The producer shall maintain comprehensive records in LMMTS of all marijuana products
- 366 distributed to the marijuana pharmacies, whether by transport and delivery to the pharmacy or by
- 367 transfer to the agent of the pharmacy at the production facility.
- 368 3. In the event the producer delivers the products to the pharmacy, such activities must be in
- 369 compliance with the rules for that activity promulgated by LDAF.
- 370 4. In the event the pharmacy elects to send an agent to the production facility to retrieve products
- 371 ordered by the pharmacy, the personnel at the production facility shall verify the identity and
- 372 credentials of the pharmacy’s agent before releasing the products to the agent.
- 373 a. The producer shall provide a copy of the transport manifest generated by LMMTS, which
- 374 shall contain the following information:
- 375 i. The name and address of the producer selling the product;

- 376 ii. The name and address of the pharmacy purchasing the product;
- 377 iii. The name and quantity (by weight or unit) of marijuana products included in the
- 378 delivery;
- 379 iv. The date of transport and time of departure from the production facility;
- 380 v. The make, model, and license plate number of the delivery vehicle;
- 381 vi. The date and time of arrival at the pharmacy; and
- 382 vii. The name and signature of the pharmacy's agent.
- 383 b. The pharmacy's agent shall compare the transport manifest to the products transferred to his
- 384 possession, and when correct, shall return a signed copy of the manifest to the producer before
- 385 departing from the production facility.
- 386 c. The pharmacy's agent shall place the products in a locked, safe, and secure storage
- 387 compartment that is part of the motor vehicle, or in the alternative, in a locked storage
- 388 container that has a separate key or combination pad, and further, the product shall not visible
- 389 or recognizable from outside the vehicle, and further, the vehicle shall not bear the name of
- 390 the pharmacy or any markings to indicate the vehicle contains marijuana
- 391 d. The pharmacy's agent shall maintain physical control of the vehicle at all times during the
- 392 transport, and shall not leave the vehicle unattended at any time.
- 393 e. The pharmacy's agent shall have access to a secure form of communication with the
- 394 pharmacy as well as the ability to contact law enforcement through the 911 emergency
- 395 system.
- 396 f. Upon arrival at the pharmacy, the pharmacy's agent shall deliver the product to a pharmacist
- 397 for verification of receipt; the pharmacist shall time, date, and sign the delivery manifest.
- 398

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

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

401

402 **§2445. Marijuana pharmacy permit**

- 403 A. The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.
- 404 B. The dispensing of marijuana for therapeutic purposes shall be restricted to those pharmacies holding a
- 405 marijuana pharmacy permit issued by the board, and only when that permit is in active or restricted
- 406 status.
- 407 C. When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy
- 408 in compliance with the provisions of this Subchapter.
- 409 D. When the permit is issued, it shall be valid only for the owner and the specific location noted on the
- 410 application and recorded on the permit.
- 411 E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in
- 412 the event the ownership of the organization that acquired the permit changes by fifty percent or more,
- 413 then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy
- 414 permit. A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its
- 415 ownership has changed by fifty percent or more without obtaining a new marijuana pharmacy permit
- 416 shall be deemed guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.
- 417 F. Although a change of ownership of less than fifty percent shall not require a new pharmacy permit, any
- 418 proposed change of ownership shall require prior notice to the board, and further, approval by the
- 419 board.
- 420 G. The board shall not have more than ten active marijuana pharmacy permits at any given time. To
- 421 facilitate compliance with that legislative restriction, the board recognizes the nine regions previously
- 422 declared by the Department of Health, to wit:
- 423 1. *Metropolitan*, composed of the parishes of Jefferson, Orleans, Plaquemines, and St. Bernard;
- 424 2. *Capitol*, composed of the parishes of Ascension, East Baton Rouge, East Feliciana, Iberville,
- 425 Pointe Coupee, West Baton Rouge, and West Feliciana;
- 426 3. *Teche*, composed of the parishes of Assumption, Lafourche, St. Charles, St. James, St. John, St.
- 427 Mary, and Terrebonne;
- 428 4. *Acadian*, composed of the parishes of Acadia, Evangeline, Iberia, Lafayette, St. Landry, St.
- 429 Martin, and Vermilion;

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

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

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

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469 **§2447. Licensing procedures**

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- A. Application for Initial Issuance of Permit
 1. The board shall develop an application form suitable for the marijuana pharmacy permit. The board may revise that application form on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.
 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
 3. The applicant shall fully disclose the ownership of the entity that will own the permit as well as any additional holding companies that may exist, such that any natural person with any ownership interest shall be fully identified.
 4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:

- 482 a. Within the five year period preceding the date of the application, has made a contribution to a
483 candidate in a Louisiana election governed by the provisions of the Campaign Finance
484 Disclosure Act [R.S. 14:1481]; or
485 b. Within the two year period preceding the date of the application, the person or any member of
486 the person's immediate family held a position in state service, including but not limited to, a
487 legislator, statewide public official, state employee, or member of the board.
- 488 5. The applicant shall provide a complete street address reflecting the location at which the applicant
489 proposes to operate the marijuana pharmacy.
- 490 6. The applicant shall provide the following information and records in the application process:
- 491 a. A detailed description of any other services or products to be offered by the marijuana
492 pharmacy;
- 493 b. Details regarding the applicant's plans to maintain adequate control against the diversion,
494 theft, or loss of marijuana;
- 495 c. Documents or information sufficient to establish the applicant is authorized to conduct
496 business in Louisiana and that all applicable state and local building, fire and zoning
497 requirements, and local ordinances will be met;
- 498 d. Text and graphic materials showing the exterior appearance of the proposed marijuana
499 pharmacy and its site compatibility with commercial or residential structures already
500 constructed or under construction within the immediate neighborhood;
- 501 e. A blueprint of the proposed marijuana pharmacy which shall, at a minimum, show and
502 identify:
- 503 i. The square footage of the area which will constitute the prescription department;
- 504 ii. The square footage of the overall marijuana pharmacy;
- 505 iii. The square footage and location of areas used as storerooms or stockrooms;
- 506 iv. The size of the counter that will be used for the dispensing and sale of marijuana;
- 507 v. The location of the marijuana pharmacy sink and refrigerator, if any;
- 508 vi. The location of all approved safes and vaults that will be used to store marijuana;
- 509 vii. The location of the toilet facilities;
- 510 viii. The location of the break room and location of lockers for personal belongings;
- 511 ix. The location and size of the patient counseling area(s);
- 512 x. The location(s) where any other products or services will be offered; and
- 513 xi. The location of all areas that may contain marijuana showing the location of walls,
514 partitions, counters, and all areas of ingress and egress.
- 515 f. Such other documents and information reasonably required by the board to determine the
516 applicant's suitability for permitting or to protect the public's health and safety.
- 517 7. The owner's managing officer and the pharmacist-in-charge shall be fully identified within the
518 application and they both shall sign and date the application form.
- 519 8. The applicant shall direct the following persons to submit to the criminal history record check
520 process used by the board, at the applicant's expense:
- 521 a. The owner's managing officer;
- 522 b. The pharmacist-in-charge; and
- 523 c. Any person holding any share of ownership in the entity; provided however that any person
524 not holding any share of ownership but holding a corporate officer position in the entity may
525 be required to submit to the criminal history record check.
- 526 9. The requirement for a criminal history record check may be waived by the board in the event the
527 person has already completed that process for the board within the two year period prior to the
528 date of the application.
- 529 10. The applicant shall supplement the application form with sufficient documentation of the
530 applicant's financial capacity to properly operate a marijuana pharmacy, including but not limited
531 to, evidence of his escrow account, letter of credit, or surety bond of at least one million dollars in
532 a financial institution headquartered in Louisiana.
- 533 a. The pharmacy's one million dollar escrow account, letter of credit, or surety bond shall be
534 payable to the board in the event the board determines after a due process hearing that the
535 pharmacy has failed to timely and successfully complete the construction of the pharmacy or

- 536 to operate such pharmacy in compliance with the provisions of this Subchapter.
537
538 b. The board shall permit the pharmacy's escrow account, letter of credit, or surety bond to be
539 reduced by two hundred fifty thousand dollars upon the successful achievement of each of the
540 following milestones:
541 i. A determination by the board that the pharmacy is fully operational and able to commence
542 and has begun dispensing of marijuana as provided in this Subchapter;
543 ii. A determination by the board that the pharmacy remained operational and without
544 substantial interruption and without any violation of law or regulation for a one year
545 period; and
546 iii. A determination by the board that the pharmacy remained operational and without
547 substantial interruption and without any violation of law or regulation for a second one
548 year period.
549 iv. The pharmacy shall maintain the escrow account, letter of credit, or surety bond for a
550 minimum of two hundred fifty thousand dollars for the remainder of its operation.
551 c. In the event a pharmacy voluntarily chooses not to renew the pharmacy permit and follows
552 proper closure procedures, the board shall extinguish the obligations under the escrow
553 account, letter of credit, or surety bond at the end of the permit's term.
- 554 11. In the event any information contained in the application or accompanying documents changes
555 after being submitted to the board, the applicant shall immediately notify the board in writing and
556 provide corrected information in a timely manner so as not to disrupt the application processing or
557 permit selection process.
- 558 12. The board may verify information contained in each application and accompanying documentation
559 in order to assess the applicant's character and fitness to operate a marijuana pharmacy. The
560 board may verify the information and assess the applicant's character and fitness by, among other
561 actions:
562 a. Contacting the applicant by telephone, electronic mail, mail, or such other means as is
563 reasonable under the circumstances;
564 b. Conducting one or more on-site visits of the location for the proposed marijuana pharmacy, or
565 other pharmacies associated with the applicant or any of the applicant's owners;
566 c. Conducting background checks or contacting references of the applicant, its managing officer,
567 any of the corporate officers, or any shareholder, as well as the pharmacist-in-charge;
568 d. Contacting state regulators in any other states where the applicant, the applicant's owners or
569 corporate officers, or its pharmacist-in-charge are engaged in, or have sought to be engaged
570 in, any aspect of that state's medical marijuana program; or
571 e. Requiring a personal meeting with the owner's managing officer and the pharmacist-in-charge
572 and the submission of additional information or documents.
- 573 13. The application shall be accompanied by payment of the permit fees and administrative hearing
574 fee authorized by La. R.S. 37:1184 and 40:1013.
- 575 14. When the staff has determined an entity's application package is complete, the application shall be
576 referred to the board's Application Review Committee, and further, the applicant shall be properly
577 notified at least thirty days prior to the committee's hearing during which their application will be
578 considered.
- 579 15. During the hearing held by the board's Application Review Committee, the members shall
580 consider, but are not limited to, the following criteria when evaluating an application for a
581 marijuana pharmacy permit:
582 a. The character and fitness of the owner's managing officer, the pharmacist-in-charge, any of
583 the owners and any other person who may have control or influence over the operation of the
584 proposed marijuana pharmacy;
585 b. The location for the proposed marijuana pharmacy including, but not limited to:
586 i. Its proximity to previously approved marijuana pharmacies or locations of proposed
587 marijuana pharmacies with pending applications;
588 ii. Whether the patient population in the area proposed by the marijuana pharmacy permit
589 applicant justifies the need for a marijuana pharmacy, or an additional marijuana
pharmacy, in that area;

- 590 iii. Whether the proximity of the proposed marijuana pharmacy will have a detrimental
591 effect upon any place used primarily for religious worship, public or private school,
592 convent, charitable institution, whether supported by private or public funds, hospital or
593 veterans' home or any camp or military establishment; or
594 iv. Whether the number of marijuana pharmacies in the locality is such that the granting of a
595 permit is detrimental to the public interest. In reaching a conclusion in this respect, the
596 board may consider the population of, the number of like permits and number of all -
597 permits existent in, the particular municipality and the immediate neighborhood
598 concerned, the effect that a new permit may have on such town or neighborhood or on
599 like permits existent in such municipality or neighborhood.
- 600 c. The applicant's ability to maintain adequate control against the diversion, theft and loss of
601 marijuana;
602 d. The applicant's ability to maintain the knowledge, understanding, judgment, procedures,
603 security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale
604 of marijuana; and
605 e. The extent to which the applicant or any of the applicant's owners have a financial interest in
606 any other permittee, licensee, registrant, or other applicant currently or previously
607 credentialed by the board; and
608 f. Any other reason provided by any federal law or rule or state law or rule that is not
609 inconsistent with the Act.
- 610 16. Following their evaluation of the applications for a marijuana pharmacy permit, the committee
611 shall develop a recommendation for presentation to the board at the board's next meeting. The
612 board may accept the committee's recommendation, select an alternative applicant, reject all of the
613 applicants, or return all the applicants to the committee for their reconsideration.
- 614 17. The board may disqualify any applicant who:
615 a. Submits an incomplete, false, inaccurate, or misleading application;
616 b. Fails to submit an application by the published deadline; or
617 c. Fails to pay all applicable fees.
- 618 18. The decision of the board to award or not to award a marijuana pharmacy permit to an applicant
619 shall be final.
- 620 19. Upon the approval of an application, the board shall issue the marijuana pharmacy permit and state
621 controlled dangerous substance license to the applicant.
- 622 20. If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation
623 of such pharmacy within 180 days of being notified of the marijuana pharmacy permit award, the
624 board may, in the board's discretion, rescind such marijuana pharmacy permit, unless such delay
625 was caused by force majeure. A marijuana pharmacy shall be deemed to have commenced
626 operation if the pharmacy is capable of operating in accordance with the applicant's approved
627 application. In the event a marijuana pharmacy permit is rescinded pursuant to this subsection, the
628 board shall award a marijuana pharmacy permit by selecting among the qualified applicants who
629 applied for the marijuana pharmacy permit that was rescinded. If no other qualified applicant
630 applied for such marijuana pharmacy permit or satisfied the criteria for awarding a permit, the
631 board shall publish, in accordance with this section, a notice of open applications for marijuana
632 pharmacy permits.
- 633 B. Application for Renewal of Permit
634 1. All marijuana pharmacy permits expire at midnight on December 31 of every year, regardless of
635 the date of its initial issuance.
636 2. The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall
637 complete, sign and date a permit renewal application form supplied by the board, and further, shall
638 include all information requested on the form and include the pharmacy permit renewal fee and
639 state controlled dangerous substance license renewal fee authorized in R.S. 37:1184 prior to the
640 expiration the pharmacy permit.
641 3. The board shall not process applications received by facsimile, or that are incomplete, or
642 submitted with the incorrect fees.

- 643 4. In the event the pharmacy does not submit a properly completed renewal application form and fee
 644 to the board prior to the expiration of the permit, the permit shall be rendered null and void. A
 645 marijuana pharmacy shall not operate with an expired permit. Evidence it has done so will
 646 provide sufficient basis for the board to discipline the permit for violation of R.S. 37:1241(12).
 647 5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is
 648 received in the board office no later than thirty days after the expiration date of the permit may be
 649 processed by the board staff, provided the appropriate delinquent fee authorized in R.S. 37:1184 is
 650 included with the application.
 651 6. A marijuana pharmacy permit not renewed by thirty days after the expiration date shall be
 652 automatically terminated by the board.
 653 7. An application for the reinstatement of a terminated marijuana pharmacy permit shall be referred
 654 to the board's Reinstatement Committee for its consideration.
- 655 C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits
 656 1. The applicant shall complete an application form for this specific purpose supplied by the board;
 657 the application shall require the inclusion of the annual renewal fee, the delinquent fee, the
 658 administrative hearing fee, and the reinstatement fees authorized in R.S. 37:1184 and the program
 659 fee authorized in R.S. 40:1013.
 660 2. An application for the reinstatement of a marijuana pharmacy permit previously terminated,
 661 suspended or revoked by the board may only be approved following a preliminary hearing to
 662 determine whether the reinstatement of the permit is in the public's best interest.
- 663 D. Maintenance of Marijuana Pharmacy Permit
 664 1. A marijuana pharmacy permit is valid only for the entity or person to whom it is issued and shall
 665 not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit
 666 be valid for any premises other than the business location recorded thereon.
 667 2. A duplicate or replacement permit shall be issued upon the written request of the licensee and
 668 payment of the fee authorized in R.S. 37:1184. A duplicate or replacement license shall not serve
 669 or be used as an additional or second license.
 670 3. Prior to any person affiliating with a marijuana pharmacy, including any change in the ownership
 671 of the permit, such person shall comply with the credentialing requirements of the board. No
 672 person shall commence their affiliation with a marijuana pharmacy until approved by the board.
 673 4. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the
 674 permit shall notify the board and request approval of the contemplated name or trade name. The
 675 board shall reasonably accommodate such requests, unless there is cause not to do so, e.g.,
 676 duplicative or misleading names. The marijuana pharmacy shall not change its name or trade
 677 name until approved by the board.
 678 5. Prior to any modification, remodeling, expansion, reduction, other physical, non-cosmetic
 679 alteration of the marijuana pharmacy, the owner of the permit shall notify the board and request
 680 approval of the contemplated change(s). The board shall reasonably accommodate such request,
 681 unless there is cause not to do so, e.g., inconsistent with operating requirements. The marijuana
 682 pharmacy shall not make such changes until approved by the board.
 683 6. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit
 684 an application form for that purpose supplied by the board and pay the appropriate fee authorized
 685 in R.S. 37:1184. The board may require an inspection of the new location prior to the issuance of
 686 the permit for the new location. No marijuana pharmacy shall commence operation in a new
 687 location until approved by the board.
 688 7. The owner of the pharmacy permit shall notify the board no later than ten days following a change
 689 in the pharmacist-in-charge for the marijuana pharmacy permit.
 690 8. The owner of the pharmacy permit shall notify the board no later than ten days following a change
 691 in the owner's managing officer for the marijuana pharmacy permit.
 692 9. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall
 693 notify the board in accordance with the rules governing the permanent closure of a pharmacy as
 694 described in Chapter 11 of the board's rules.
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AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

697 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
698

699 **§2449. Marijuana pharmacy personnel; therapeutic marijuana designation**

- 700 A. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth
701 birthday.
- 702 B. The owner's managing officer and all persons holding a professional credential from the board shall
703 first obtain a Therapeutic Marijuana (TM) designation from the board before affiliating with a
704 marijuana pharmacy.
- 705 C. The board may issue a TM designation to a person who has filed the application for that designation
706 supplied by the board and has completed a criminal background check for the board within the two
707 year period prior to the date of the application for the TM designation, and that person:
- 708 1. Has been listed as an owner's managing officer on an application for a marijuana pharmacy
709 permit, or on a request to become a replacement owner's managing officer for an existing
710 marijuana pharmacy permit; or
 - 711 2. Holds one of the following professional credentials issued by the board – pharmacist, pharmacy
712 intern, or certified pharmacy technician – and further, that professional credential was issued by
713 the board at least two years prior to the date of the application for the TM designation, is in active
714 status and has not been disciplined by the board within the two year period prior to the date of the
715 application for the TM designation.
- 716 D. The board may restrict, suspend, or revoke a TM designation for cause, but only pursuant to the
717 Administrative Procedure Act.
- 718 E. No pharmacist, pharmacy intern, or certified pharmacy technician may practice within a marijuana
719 pharmacy in the absence of an active professional credential, an active TM designation, as well as
720 access privileges to the state prescription monitoring program. A pharmacist may elect to not allow a
721 pharmacy intern or pharmacy technician to function as his delegate with respect to access privileges to
722 the state prescription monitoring program, but the pharmacist shall have such access. A pharmacy
723 technician candidate shall not practice in a marijuana pharmacy.
- 724 F. A pharmacist shall first acquire a Pharmacist-in-Charge (PIC) privilege, as described in §1105 of the
725 board's rules, and the TM designation, as described in this Section, before accepting an appointment as
726 the PIC of a marijuana pharmacy.
- 727 1. The PIC of the marijuana pharmacy shall comply with the requirements of §1105 of the board's
728 rules.
 - 729 2. The PIC shall be responsible for notice to the board of all pharmacists, pharmacy interns, and
730 pharmacy technicians practicing at the marijuana pharmacy. The PIC shall cause such notice to be
731 received in the board office in written form (mail, fax, or electronic mail) no later than ten days
732 after the arrival or departure of the pharmacist, pharmacy intern, or pharmacy technician.
- 733 G. The PIC shall insure and document the initial and continuing competency of the entire professional
734 staff to provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the
735 PIC shall provide access to education and training in the following domains:
- 736 1. Policies and procedures of the pharmacy, especially those relating to the tasks and functions that
737 employee is expected to perform;
 - 738 2. Professional conduct, ethics, and patient confidentiality; and
 - 739 3. Developments in the therapeutic use of marijuana.
- 740 Further, the PIC shall document such education and training, provide such records to the board when
741 requested, and retain such records for at least two years after the employee disassociates with the
742 pharmacy.
- 743 H. The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy
744 interns) and Chapter 9 (pharmacy technicians) of the board's rules.
- 745 I. In addition to the scope of practice limitations found in Chapter 9 of the board's rules, pharmacy
746 technicians practicing in a marijuana pharmacy shall not:
- 747 1. Consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before
748 or after marijuana has been dispensed, or regarding any medical information contained in a patient
749 medication record;

- 750 2. Consult with the physician who issued the recommendation/prescription/order for marijuana to the
 751 patient, or the physician's agent, regarding a patient or any medical information pertaining to the
 752 patient's marijuana or any other drug the patient may be taking;
 753 3. Interpret the patient's clinical data or provide medical advice;
 754 4. Perform professional consultations with physicians, nurses, or other health care professionals or
 755 their authorized agents; or
 756 5. Determine whether a different brand or formulation of marijuana should be dispensed for the
 757 marijuana product or formulation recommended/prescribed/ordered by the physician or requested
 758 by the patient or his caregiver.
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760 AUHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

761 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
 762

763 §2451. Operation of marijuana pharmacy

- 764 A. No person may operate a marijuana pharmacy without a marijuana pharmacy permit issued by the
 765 board, and further, that permit shall be in active or restricted status. A pharmacist shall be on duty at
 766 all times during the regular open hours of the marijuana pharmacy.
 767 B. A marijuana pharmacy shall not dispense marijuana from, obtain marijuana from, or transfer marijuana
 768 to, a location outside of the state of Louisiana.
 769 C. A marijuana pharmacy shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana
 770 except:
 771 1. It may acquire marijuana from an authorized producer pursuant to the provisions of R.S. 40:1046;
 772 and
 773 2. It may dispense and sell marijuana to a patient with a recommendation/prescription/order for such
 774 marijuana or the patient's caregiver.
 775 D. No person at a marijuana pharmacy shall provide marijuana samples.
 776 E. A marijuana pharmacy shall sell marijuana products only in the original sealed containers
 777 or packaging as delivered by the producer, except that a pharmacist may remove the marijuana product
 778 from the producer's child-resistant container or package and place the marijuana product in a non-
 779 child-resistant, secure and light-resistant container upon a written request from the patient or caregiver
 780 so long as all original labeling is maintained with the product.
 781 F. Only a pharmacist may dispense marijuana, and only a pharmacist, pharmacy intern, or pharmacy
 782 technician may sell marijuana to patients and caregivers. A pharmacy intern or pharmacy technician
 783 may assist, under the direct supervision of a pharmacist, in the dispensing of marijuana.
 784 G. A marijuana pharmacy shall place all products sold to the patient or caregiver in an opaque package
 785 that shall not indicate the contents of the package, the originating facility or in any other way cause
 786 another person to believe that the package may contain marijuana.
 787 H. A marijuana pharmacy shall not permit any person to enter the prescription department unless that
 788 person's responsibilities necessitate access to the department and then for only as long as necessary to
 789 perform the person's job duties.
 790 I. While inside the pharmacy, all pharmacy employees shall wear name tags or similar forms of
 791 identification that clearly identify them to the public, including their position at the pharmacy.
 792 J. A marijuana pharmacy shall be open for qualifying patients and primary caregivers to purchase
 793 marijuana products for a minimum of 10 hours per week.
 794 1. A marijuana pharmacy that closes during its normal hours of operation shall implement
 795 procedures to notify patients and caregivers of when the marijuana pharmacy will resume normal
 796 hours of operation. Such procedures may include, but are not limited to, telephone system
 797 messages and conspicuously posted signs.
 798 2. In the event the pharmacist on duty leaves the prescription department, the prescription department
 799 shall comply with the provisions of §1109 (temporary absence) or §1111 (closure) of the board's
 800 rules.
 801 K. A marijuana pharmacy shall provide information to patients and caregivers regarding the possession
 802 and use of marijuana. Such informational material shall include information related to:

- 803 1. Limitations on the right to possess and use marijuana pursuant to R.S. 40:1046;
 804 2. Safe techniques for proper use of marijuana and paraphernalia;
 805 3. Alternative methods and forms of consumption by which one can use marijuana;
 806 4. Signs and symptoms of substance abuse; and
 807 5. Opportunities to participate in substance abuse programs.
- 808 L. The marijuana pharmacy shall establish, implement and adhere to a written alcohol-free,
 809 drug-free and smoke-free work place policy, which shall be available to the board upon request.
- 810 M. The receipt of all deliveries from producers shall be carried out under the direct supervision of a
 811 pharmacist who shall be present to accept the delivery. Upon delivery, the marijuana shall immediately
 812 be placed in an approved safe or approved vault within the pharmacy where marijuana is stored.
- 813 N. No marijuana pharmacy shall sell anything other than marijuana products; however, the pharmacy may
 814 elect to sell over-the-counter (OTC) medications and/or durable medical equipment (DME) from the
 815 same premises but outside the prescription department.
- 816 O. No marijuana shall be administered on the premises of a marijuana pharmacy, except during patient
 817 counseling, education or training.
- 818 P. No person associated with a marijuana pharmacy shall enter into any agreement with a physician or
 819 health care facility concerning the provision of services or equipment that may adversely affect any
 820 person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase
 821 marijuana.
- 822 Q. No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside
 823 of a marijuana pharmacy, except that a caregiver may deliver marijuana to the caregiver's patient.
- 824 R. No marijuana shall be sold when the marijuana pharmacy is closed and not open for business.
- 825 S. Board representatives, local law enforcement or other federal, state or local government officials may
 826 enter any area of a marijuana pharmacy if necessary to perform their governmental duties.
- 827 T. Right of inspection. The board, or its agent, representative, or designee, is authorized:
 828 1. To enter a marijuana pharmacy at any time during its hours of operation, or any other place,
 829 including a vehicle, wherein marijuana is held, dispensed, sold, or otherwise disposed of;
 830 2. To inspect within reasonable limits and in a reasonable manner, such place and all pertinent
 831 equipment, finished and unfinished material, containers and labeling, and all things therein,
 832 including records, files, financial data, sales data, shipping data, pricing data, employee data,
 833 research, papers, processes, controls and facilities; and
 834 3. To inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana
 835 product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished
 836 material.
- 837 U. Inspection of records. Every person required to prepare, obtain or keep records, logs, reports or other
 838 documents, and every person in charge, or having custody, of such documents shall maintain such
 839 documents in an auditable format for no less than two years. Upon request, such person shall make
 840 such documents immediately available for inspection and copying by the board or its authorized
 841 representative. In complying with this Section, no person shall use a foreign language or codes or
 842 symbols to designate marijuana types or persons in the keeping of any required document.

843
 844 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

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

846
 847 **§2453. Security requirements for marijuana pharmacies**

- 848 A. A marijuana pharmacy shall:
 849 1. Store all marijuana in an approved safe or vault, as defined in this Subchapter, and in such a
 850 manner as to prevent diversion, theft, or loss;
 851 2. Maintain all marijuana in a secure area or location accessible only to specifically authorized
 852 employees, which shall include only the minimum number of employees essential for efficient
 853 operation;
 854 3. Not permit any person less than eighteen years of age to enter the prescription department, with
 855 the exception of patients being counseled by the pharmacist;

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4. Keep all approved safes and vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana;
 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 twelve inches in height and twelve inches in width which shall state: *“Do Not Enter – Limited Access Area – Access Limited to Authorized Employees Only”* in lettering no smaller than one-half 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. Twenty-four 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 thirty 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;

- 909 10. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from
 910 any camera image (live or recorded);
 911 11. A date and time stamp embedded on all recordings. The date and time shall be synchronized and
 912 set correctly and shall not significantly obscure the picture; and
 913 12. The ability to remain operational during a power outage.
 914 C. A pharmacy shall maintain all security system equipment and recordings in a secure location so as to
 915 prevent theft, loss, destruction, or alterations.
 916 1. A pharmacy shall keep all on-site surveillance rooms locked and shall not use such rooms for any
 917 other function.
 918 2. A pharmacy shall limit access to surveillance areas to persons that are essential to surveillance
 919 operations, law enforcement agencies, security system service employees, and the board's
 920 authorized representative.
 921 3. A pharmacy shall make available to the board upon request a current list of authorized employees
 922 and service employees that have access to the surveillance room.
 923 D. A pharmacy shall keep all security equipment in good working order and shall test such equipment no
 924 less than two times per year.
 925 E. When a pharmacy presents special security issues, such as an extremely large stock of marijuana,
 926 exposed handling or unusual vulnerability to, or actual, diversion, theft or loss, the board may require
 927 additional safeguards, including but not limited to, a supervised watchman service.
 928 F. Any marijuana not stored in compliance with this Section, or stored at a location other than that for
 929 which the pharmacy permit was issued, shall be subject to embargo or seizure by the board.
 930 G. In the event any marijuana pharmacy permit is revoked, suspended, or not renewed, the pharmacy shall
 931 dispose of its entire stock of marijuana in accordance with the disposal provisions in this Subchapter.
 932 H. If a pharmacy has provided other safeguards which can be regarded in total as an adequate substitute
 933 for some element of protection required of the pharmacy, such added protection may be taken into
 934 account by the board in evaluating overall required security measures.
 935

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

937 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR
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939 **§2455. Reportable security events**

- 940 A. Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or
 941 unauthorized destruction of any marijuana, or of any loss or unauthorized alternation of records related
 942 to marijuana or patients, a pharmacy shall immediately notify:
 943 1. Appropriate law enforcement authorities; and
 944 2. The board.
 945 B. A pharmacy shall provide the written notice to the board by way of a signed statement which details
 946 the circumstances of the event, including an accurate inventory of the quantity and brand names of the
 947 marijuana diverted, stolen, lost, destroyed, or damaged, along with confirmation that the local law
 948 enforcement authorities were notified. A pharmacy shall make such notice no later than twenty-four
 949 hours after discovery of the event.
 950 C. A pharmacy shall notify the board no later than the next business day, followed by written notification
 951 no later than ten business days, of any of the following:
 952 1. An alarm activation or other event that requires response by public safety personnel;
 953 2. A breach of security;
 954 3. The failure of the security alarm system due to a loss of electrical support or mechanical
 955 malfunction that is expected to last longer than eight hours; and
 956 4. Corrective measures taken, if any.
 957 D. A pharmacy shall maintain and shall make available all documentation related to an occurrence that is
 958 reportable.
 959

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

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

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§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.
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, and further, complies with security requirements identified elsewhere in this Subchapter.
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, a Therapeutic Marijuana designation, and access privileges to the state prescription monitoring program.
3. A pharmacy intern may assist the pharmacist in the prescription department, but only when in possession of a Louisiana pharmacy intern registration in active status as well as a Therapeutic Marijuana designation. The supervising pharmacist may establish a delegate credential for the pharmacy intern in the state prescription monitoring program.
4. A pharmacy technician may assist the pharmacist in the prescription department, but only when in possession of a Louisiana pharmacy technician certificate in active status as well as a Therapeutic Marijuana designation. The supervising pharmacist may establish a delegate credential for the pharmacy technician in the state prescription monitoring program.
5. No pharmacy technician candidate may practice in a marijuana pharmacy.
6. Additional clerical personnel may also be present at the pharmacy.

C. Operational Standards

1. The marijuana pharmacy shall comply with the provisions of Chapters 11, 25, 27, 29, and 31 of the board's rules 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 the board's rules, 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. Prescription/recommendation/order (hereinafter, "request") for marijuana
 - a. The pharmacy shall not accept a verbal request.
 - b. In the event the pharmacy receives a request in written form by facsimile, the pharmacy may begin the preparation of the product to be dispensed, but the pharmacist shall not dispense the product until the original form of the request is delivered to him in the pharmacy and he has compared it to the product prepared for dispensing.

- 1016 c. The written request shall bear the manual signature of the authorized prescriber. No other
1017 form of signature shall be valid, including (but not limited to) stamps, computer generated
1018 signatures, or signatures of anyone other than the authorized prescriber.
- 1019 d. A request generated, signed, and transmitted in electronic format which is compliant with the
1020 standards for electronic prescribing of controlled substances identified in 21 CFR 1311 (or its
1021 successor) shall be construed as a validly formatted request.
- 1022 2. When the pharmacy receives a request for marijuana from an authorized prescriber in written
1023 form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging
1024 system in compliance with §1123 of the board's rules.
- 1025 3. Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at
1026 least two years after the date of dispensing, and further, shall be readily retrievable upon request
1027 by the board.
- 1028 4. Inventory of marijuana product
- 1029 a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana
1030 products acquired, held, dispensed, and disposed by the pharmacy.
- 1031 b. The pharmacy shall access the LMMTS and enter all inventory-related transactions in that
1032 system.
- 1033 c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product
1034 inventory from the production facility, the pharmacist shall verify the agent is at least twenty
1035 one years of age and is eligible to drive on public roadways.
- 1036 d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the
1037 possession of the pharmacy on any date which is within one year of the previous annual
1038 inventory, and further, shall conduct additional inventory counts on the following occasions:
- 1039 i. arrival of a new pharmacist-in-charge;
- 1040 ii. discovery of any significant loss, disappearance, or theft of marijuana product;
- 1041 iii. departure of a pharmacist-in-charge; and
- 1042 iv. permanent closure of the pharmacy.
- 1043 e. Inventory records shall be retained on the pharmacy's premises for at least two years after the
1044 most recent entry.
- 1045 5. The pharmacy shall develop and maintain sufficient records to fully reveal the business
1046 transactions related to marijuana products, including their procurement and sale, for the current tax
1047 year as well as the two immediately preceding tax years, all of which shall be made available to
1048 the board upon request.
- 1049 6. The board may require any pharmacy or its owners to furnish such information as the board
1050 considers necessary for the proper administration of R.S. 40:1046, and may require a financial
1051 audit of the business of any marijuana pharmacy, and the expense thereof shall be paid by the
1052 marijuana pharmacy.
- 1053 E. Professional Practice Standards
- 1054 1. Prior to dispensing any marijuana product to a patient, the pharmacist shall review that patient's
1055 records in the state prescription monitoring program. The pharmacist shall resolve any concerns
1056 identified in that review by consultation with the recommending physician.
- 1057 2. Labeling of marijuana product dispensed
- 1058 a. The pharmacist shall not dispense any marijuana product that does not bear the producer label
1059 required by the LDAF, and further, the pharmacy dispensing label shall not overlay or obscure
1060 the producer label in any way.
- 1061 b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:
- 1062 i. Name and address of the pharmacy dispensing the product;
- 1063 ii. Telephone number or other contact information of the pharmacy dispensing the product;
- 1064 iii. Name of the authorized prescriber;
- 1065 iv. Name of the patient;
- 1066 v. Date the product was dispensed;
- 1067 vi. Prescription number, which shall be a unique identifier for that specific transaction;
- 1068 vii. Name of the marijuana product, including any concentration, strength, or other identifiers
1069 of the marijuana product;

- 1070 viii. Quantity of marijuana dispensed;
- 1071 ix. Directions for use of the product as included in the prescriber's request;
- 1072 x. Expiration date of the product, which shall not exceed the expiration date determined by
- 1073 the producer of the product; and
- 1074 xi. Other information selected by the dispensing pharmacist to inform the patient as to the
- 1075 best use of the product for the intended purpose.
- 1076 3. The pharmacist shall perform prospective drug utilization review and shall counsel every patient
- 1077 receiving marijuana product every time it is dispensed, in compliance with the rules on drug
- 1078 utilization review and patient counseling in Chapter 5 of the board's rules.
- 1079 4. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with
- 1080 the reporting requirements as found in Chapter 29 of the board's rules.
- 1081 5. Disposal of marijuana product.
- 1082 a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is
- 1083 determined to be misbranded, adulterated, expired, deteriorated, undesired, excess,
- 1084 unauthorized, or unfit for dispensing; however, once accepted by the pharmacy, no marijuana
- 1085 product may be returned to any producer.
- 1086 b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the
- 1087 product shall be removed from active dispensing stock and quarantined in the pharmacy
- 1088 pending its disposal, and further, the removal from active dispensing stock shall be recorded in
- 1089 the LMMTS.
- 1090 c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the
- 1091 waste with other ground materials so the resulting mixture is at least 50% non-marijuana waste
- 1092 by volume. Material used to grind with the waste may include:
- 1093 i. Yard waste;
- 1094 ii. Paper waste;
- 1095 iii. Cardboard waste;
- 1096 iv. Plastic waste; or
- 1097 v. Soil or sand
- 1098 d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable
- 1099 shall be disposed of by delivery to an approved solid waste facility for final disposition.
- 1100 Examples of acceptable permitted solid waste facilities include:
- 1101 i. Compost; anaerobic digester;
- 1102 ii. Landfill, incinerator; or
- 1103 iii. Waste-to-energy facility.
- 1104 e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain,
- 1105 at a minimum, the following information:
- 1106 i. Brand name and other specific identifiers of the marijuana product disposed;
- 1107 ii. Quantity of product disposed;
- 1108 iii. Manner of disposal; and
- 1109 iv. Signatures of the pharmacist-in-charge disposing the product plus at least one witness
- 1110 who is either a credentialed staff member of that pharmacy or an agent of the board.

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1112 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

1113 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

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1115 **§2459. Advertising**

- 1116 A. The marijuana pharmacy shall not advertise through any public medium, including but not limited to
- 1117 newspapers, billboards, television, radio, internet, social media, or any other means designed to market
- 1118 its products to the general public.
- 1119 B. The marijuana pharmacy may market its products through direct mail, brochures, or other means to
- 1120 Louisiana-licensed physicians, but only when such advertising is directed solely to the practitioner and
- 1121 is not available to the general public.
- 1122 C. Any advertisement permitted in Paragraph B of this Section shall not:
- 1123 1. Make any deceptive, false, or misleading assertions or statements regarding any product; or

- 1124 2. Assert that its products are safe because they are regulated by LDAF or the board. The pharmacy
1125 may advertise that its products have been tested by an approve laboratory, but shall not assert that
1126 its products are safe because they are tested by an approved laboratory.
1127 D. The marijuana pharmacy may attach a maximum of two separate signs to the exterior of the building
1128 which identify the business by its business or trade name, provided that neither sign exceeds the size
1129 limit of sixteen hundred square inches.
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1131 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

1132 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR

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