	Louisiana Administrative Code
	Title 46 – Professional and Occupational Standards
	Part LIII: Pharmacists
Chap	pter 24. Limited Service Providers
Subc	chapter E. Marijuana Pharmacy
8744	0. Preamble; Warning; Consultation Suggested
	ursuant to Act 261 of the Regular Session of the 2015 Legislature as well as subsequent amendments, the
	oard of Pharmacy was directed to:
+	- develop an annual, nontransferable specialty license for a pharmacy to dispense recommended marijuana
	for therapeutic use, to limit the number of such licenses to a maximum of 10, and to adopt rules regardin
2	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 therapeuti
	marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for
	period of one month, including amount for topical treatments;
	e. standards, procedures, and protocols to ensure all recommended therapeutic marijuana dispensed, w
	the exception of raw or crude marijuana product, is consistently pharmaceutical grade.
	f. standards and procedures for the revocation, suspension, and nonrenewal of licenses;
	g. other licensing, renewal, and operational standards deemed necessary by the Board of Pharmacy;
	h. standards and procedures for testing recommended therapeutic marijuana samples for levels of
	tetrahydrocannabinols (THC) or other testing parameters deemed appropriate by the Board of
	Pharmacy;
	i. standards for the protection of health, safety, and security for dispensers of recommended therapeut
	marijuana;
	j. standards for the licensure of dispensers of recommended therapeutic marijuana; and
	k. standards for financial capacity to operate a marijuana pharmacy.
	 limitations on dispensing of raw or crude marijuana.
	farijuana is classified as a schedule I controlled substance by the U.S. Department of Justice, Drug
	nforcement 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
	violation of federal law.
2	. Neither Louisiana law nor this Part can preempt federal law. Therefore, the provisions of this Subchapte
	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 fi
	and forfeitures, as well as administrative consequences such as forfeiture of federal controlled substance
	registrations and exclusion from Medicare and other federal payer programs.
C.F	or the foregoing reasons, pharmacists and other persons credentialed by the board may wish to consult with
	wn legal counsel as well as any health care facility, private or governmental payor with which they are
	ted, professional liability insurers, and financial institutions with which they maintain depository relationsh
	engaging in the activities described herein.
AUTH	ORITY NOTE: Promulgated in accordance with R.S. 40:1046.

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

59 §2441. Definitions

60 A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section: 61 *Administer* - the direct application of marijuana to the body of a qualifying patient by ingestion or any other means. 62 Advertisement all representations disseminated in any manner or by any means, other than by labeling, for the 63 purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana, excluding 64 information of an educational nature designed to inform citizens of the nature and form of the state's therapeutic 65 marijuana program and its legally permitted products. 66 Agent - an authorized person who acts on behalf of or at the direction of another person. It does not include a 67 common or contract carrier, public warehouseman, or employee of the carrier or warehouseman. 68 Approved Safe - a safe which conforms to or exceeds all of the following standards: 69 a. shall have the following specifications or the equivalent: 70 i. 30 man minutes against surreptitious entry; 71 ii. 10 man minutes against forced entry; 72 iii. 20 man hours against lock manipulation; and 73 iv. 20 man hours against radiological techniques; b. if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way it cannot be readily 74 75 removed; and 76 e. is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly 77 to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-78 hour control station operated by the licensee, or such other protection as the board or its designee may 79 approve. Approved Vault 80 a. a vault constructed before, or under construction on, September 1, 1971, which is of substantial construction 81 82 with a steel door, combination or key lock, and an alarm system; or 83 b. a vault constructed after September 1, 1971: 84 the walls, floors, and ceilings of which are constructed of at least 8 inches of reinforced concrete or other 85 substantial masonry, reinforced vertically and horizontally with one half inch steel rods tied 6 inches on 86 center, or the structural equivalent to such reinforced walls, floors, and ceilings; 87 ii. the door and frame unit of which vault shall conform to the following specifications or the equivalent: 88 (a). thirty man minutes against surreptitious entry; 89 (b). ten man minutes against forced entry; 90 (c). twenty man hours against lock manipulation; and 91 (d). twenty man hours against radiological techniques; 92 iii. which vault, if operations require it to remain open for frequent access, is equipped with a "day gate" 93 which is self closing and self locking or the equivalent, for use during the hours of operation in which 94 the vault door is open; 95 iv. the walls or perimeter of which are equipped with an alarm which, upon unauthorized entry, shall 96 transmit a signal directly to a central station protection company, or a local or state police agency which 97 has a legal responsibility to respond, or a 24 hour control station operated by the licensee, or such other 98 protection as the board or its designee may approve, and if necessary, alarm buttons at strategic points of 99 entry to the perimeter area of the vault; 100 v. the door of which shall be equipped with one or more contact switches; and 101 vi. which vault has one of the following: (a). complete electrical lacing of the walls, floor and ceiling; 102 103 (b). sensitive ultrasonic equipment within the vault: 104 (c). sensitive sound accumulator system; or (d). such other device designed to detect illegal entry as may be approved by the board. 105 106 Authorized Clinician – means licensed health professionals authorized pursuant to R.S. 40:1046. Board - the Louisiana Board of Pharmacy. 107 108 *CFR* - Code of Federal Regulations.

109 Deliver or Delivery - the actual, constructive or attempted transfer from one person to another of marijuana, whether

110 or not there is an agency relationship.

- 111 *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
- 113 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.
- 115 *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.
- 117 *LDAF* the Louisiana Department of Agriculture and Forestry.
- 118 *LDH* the Louisiana Department of Health.
- 119 Louisiana Medical Marijuana Tracking System (LMMTS) the required seed-to-sale tracking system that tracks
- 120 medical marijuana from either the seed or immature plant stage until the product is sold to a pharmacy or is 121 destroyed.
- 122 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.
- 125 *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
- 127 person does not exceed five per cent of the total ownership or interest rights in such pharmacy and such person does
- 128 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.
- **133** *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 approved by the commissioner of the
 Department of Agriculture and Forestry. reviewed by the Louisiana Department of Health.
- 143 *Pharmacist* an individual currently licensed by the board to engage in the practice of pharmacy.
- 144 *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.
- Physician an individual currently licensed by the state Board of Medical Examiners to engage in the practice of
 medicine.
- *Prescription Monitoring Program (PMP)* the electronic prescription drug monitoring program established by R.S.
 40:1001 et seq.
- *Producer* a person licensed by the <u>Louisiana</u> Department of <u>Agriculture and Forestry</u> <u>Health</u> to cultivate marijuana
 for therapeutic use.
- 152 *Production or Produce* the manufacture, planting, preparation, cultivation, growing, harvesting, propagation,
- 153 compounding, conversion or processing of marijuana, either directly or indirectly by extraction from substances of
- 154 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 Agriculture and Forestry Health has issued a producer license.
- 159 whom the <u>Louisiana</u> Department of <u>Agriculture and Porestry Hearm</u> has issued a producer incense.
 160 Sale any form of delivery, which includes barter, exchange or gift, or offer therefor, and each such transaction
- 160 *Sale* any form of derivery, which includes barter, exchange of gift, or offer therefor, and each such 161 made by any person whether as principal, proprietor, agent, servant, or employee.
- 161 made by any person whether as principal, proprietor, agent, servant, or employee.
- 162 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.
- and roots of the marijuana pla
- **166** AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

167 168			CICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended 473 (October 2019), LR 46:1227 (September 2020), <u>amended LR</u>
169	87	112	Marijuana Products
170			. Marijuana Products
171	А.		clusive Source
172		1.	The exclusive source of marijuana products shall be the producers licensed for that activity by <u>LDH</u> . the
173 174		2	Department of Agriculture and Forestry (LDAF).
		2.	Licensed producers shall prepare pharmaceutical grade marijuana products as well as raw marijuana
175 176		2	products for distribution to marijuana pharmacies licensed by the board.
177		3.	Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be
			distributed to any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed
178	D	Lal	by any marijuana pharmacy.
179 180	D.		poratory Testing — Prior to manufacturing any marijuana product, the producer shall segregate all harvested marijuana into
180		1.	homogenized batches.
181		2	A producer shall make available each such batch at the production facility for testing by a laboratory
183		Ζ.	approved by LDAF. The laboratory employee shall select a random sample from each such batch.
184			a. Medical marijuana concentrate shall not be used to produce any final product until it has passed all
185			a. An entry and the share not be used to produce any multiproduct until it has passed and analysis limits for:
185			i. active ingredient analysis for characterization of potency;
187			ii. pesticide active ingredients, including but not limited to, the most recent list of targeted
188			pesticides published by LDAF;
189			iii. residual solvents;
190			iv. heavy metals; and
191			v. mycotoxins.
192			b. Product shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has
193			passed all concentrate analysis limits for:
194			i. microbiological contaminants;
195			ii. active ingredient analysis for accuracy of potency; and
196			iii. homogeneity.
197			c. Final products not produced from concentrate, e.g., dried and cured flower, shall not be released for
198			delivery to a marijuana pharmacy for sale or consumption until it has passed all analysis limits for:
199			i. active ingredient analysis for characterization of potency;
200			ii. pesticide active ingredients, including but not limited to the most recent list of targeted pesticides
201			published by LDAF;
202			iii. heavy metals;
203			iv. mycotoxins;
204			v. microbiological contaminants; and
205			vi. homogeneity.
206			d. LDAF personnel may select a random sample at any point in the process for the purpose of analysis for
207			anything the LDAF deems necessary.
208			e. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for
209			the analyses being conducted.
210		3.	From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging
211			and sale to a pharmacy until the laboratory provides the results from its tests and analyses, the producer
212			shall segregate and withhold from use the entire batch with the exception of the samples removed by the
213			laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in
214			a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its
215			efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a
216			pharmacy prior to the time the laboratory has completed its testing and analysis and provided those results,
217			in written or electronic form, to the producer or the producer's designated employee.
218		4.	-Testing Specifications
219			a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if it
220			satisfies the recommended microbial and fungal limits for cannabis products as follows:
221			i. total yeast and mold: < 10,000 colony forming units per gram (CFU/g); and
222			ii. E. coli (pathogenic strains) and Salmonella spp: < 1 CFU/g.

	b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it meets the
224	following standards:
225	i. aflatoxin b1 < 20 parts per billion (ppb);
226	ii. aflatoxin b2 < 20 ppb;
	**
227	$\frac{\text{iii.} \text{aflatoxin gl} < 20 \text{ ppb;}}{100000000000000000000000000000000000$
228	iv. aflatoxin g2 < 20 ppb; and
229	v. – ochratoxin < 20 ppb.
230	c. With respect to the heavy metals test, a marijuana sample shall be deemed to have passed if it meets
231	the following standards:
232	i. arsenic < 10 parts per million (ppm);
233	ii. cadmium < 4.1 ppm;
234	iii. lead < 10 ppm; and
235	iv. mercury < 2 ppm.
236	d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to have passed
237	if it does not contain any residues appearing on LDAF's approved list and any approved residues
238	present are less than the limits allowed by LDAF.
239	e. With respect to the residual solvent test, a marijuana sample shall be deemed to have passed if the
240	following solvents are below the listed limits:
241	i. butanes < 800 ppm;
242	ii. heptanes < 500 ppm;
243	iii. benzene < 1 ppm;
244	iv. toluene < 1 ppm;
245	v. hexanes < 10 ppm;
246	
-	vi. total xylenes < 1 ppm; and
247	vii. ethanol < 5,000 ppm.
248	f. With respect to the test for homogeneity, a marijuana sample shall be deemed passed if each aliquot
249	tested is within plus or minus 15 percent of the total aliquots average finding for potency for each
250	labeled active ingredient. Any solid product will be considered not homogenous if 10 percent of the
251	product contains more than 20 percent of the total active ingredient.
252	
252	g. Every sample shall undergo an active ingredient analysis or potency analysis.
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279		d. In the event a product fails the potency or homogeneity testing, then, with prior approval of LDAF, the
280		product can be re sized and tested again. The reformulated product shall be tested again in duplicate
281		and pass all required tests before it can be released for sale or consumption. If either duplicate fails any
282		test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF.
283	6	In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such test result
284	0.	at the same time it transmits those results to the producer. In addition, the laboratory shall maintain the
285		laboratory test results including all relevant chromatograms and quality control documentation for at least
286		five years and make them available to LDAF at its request.
287	7.	The laboratory shall dispose of any remaining medical marijuana concentrate or product samples no sooner
288		than 60 days following the completion of any testing, in compliance with the disposal rules promulgated by
289		LDAF.
290	1. 8.	A producer shall provide the laboratory test results to the The marijuana pharmacy shall obtain the
291		laboratory test results from the producer for each batch of marijuana used in a product acquired by the
292		marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients,
293		
		caregivers, and physicians <u>authorized clinicians</u> who recommended such marijuana products dispensed to
294	~ ~	their patients.
295		oduct Dosage Forms
296	1.	The producer marijuana pharmacy shall limit their production dispensing of pharmaceutical grade
297		marijuana products to the following dosage forms:
298		a. oils, extracts, tinctures, or sprays;
299		b. solid oral dosage forms, e.g., capsules or pills;
300		c. liquid oral dosage forms, e.g., solutions or suspensions;
301		d. gelatin-based or pectin-based chewables;
		U I
302		e. topical applications, oils or lotions;
303		f. transdermal patches;
304		g. suppositories; or
305		h. metered-dose inhalers
306		i. bulk raw product.
307	2.	The producer marijuana pharmacy may produce dispense other products from raw or crude marijuana.
307 308	<mark>2.</mark>	The producer <u>marijuana pharmacy</u> may produce <u>dispense</u> other products from raw or crude marijuana, including dried flower, buds, and other plant material, intended for the following methods of
308	<mark>2.</mark>	including dried flower, buds, and other plant material, intended for the following methods of
308 309	2.	including dried flower, buds, and other plant material, intended for the following methods of administration:
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308 309 310 311		 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.
308 309 310 311 312	2. 3.	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. No marijuana product shall:
308 309 310 311 312 313		 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. No marijuana product shall: a. include alcoholic liquor, dietary supplements, or any drug, except for marijuana. For purposes of this
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336		i. shall not specifically target individuals under the age of 18 years;
337		ii. shall not bear any resemblance to a trademarked, characteristic or product specialized packaging
338		of any commercially available candy, snack, baked good or beverage;
339		iii. shall not use the words "candy" or "candies";
340		iv. shall not use a cartoon, color scheme, image, graphic or feature that might make the package
340 341		attractive to children; and
342		
		v. shall not use a seal, flag, crest, coat of arms or other insignia that could reasonably lead any person
343		to believe the product has been endorsed, manufactured by, or used by any state, parish,
344	-	municipality, or any agent thereof.
345	$\frac{2}{2}$	Labeling
346		a. Each product shall be labeled by the producer prior to its sale to the marijuana pharmacy.
347		b. Each label shall be securely affixed to the package and shall comply with labeling standards for
348		marijuana products promulgated by LDAF.
349		c. The label for each product shall bear a product identification code registered with the board.
350		d. The producer may utilize a two dimensional quick response (QR) code or a package insert which is
351		enclosed or attached to the product container to provide the information required in this Section. If the
352		producer elects to use such supplementary labeling, the label affixed to the outer surface of the product
353		container shall contain the following information, at a minimum:
354		i. the batch or lot number;
355		ii. the potency of any THC or CBD contained therein;
356		iii. the net weight;
357		iv. the expiration date; and
358		v. any caution statements.
359	E. Dis	tribution of Marijuana Products to Marijuana Pharmacies
360		The producer shall maintain complete inventory records in the Louisiana medical marijuana tracking
361		system (LMMTS), as required and delineated in rules promulgated by LDAF.
362	2	The producer shall maintain comprehensive records in LMMTS of all marijuana products distributed to the
363	2.	marijuana pharmacies, whether by transport and delivery to the pharmacy or by transfer to the agent of the
364	2	pharmacy at the production facility.
365	3.	In the event the producer delivers the products to the pharmacy, such activities must be in compliance with
366		the rules for that activity promulgated by LDAF.
367	4.	-In the event the pharmacy elects to send an agent to the production facility to retrieve products ordered by
368		the pharmacy, the personnel at the production facility shall verify the identity and credentials of the
369		pharmacy's agent before releasing the products to the agent.
370		a. The producer shall provide a copy of the transport manifest generated by LMMTS, which shall contain
371		the following information:
372		i. the name and address of the producer selling the product;
373		ii. the name and address of the pharmacy purchasing the product;
374		iii. the name and quantity (by weight or unit) of marijuana products included in the delivery;
375		
		iv. the date of transport and time of departure from the production facility;
376		v. the make, model, and license plate number of the delivery vehicle;
377		vi. the date and time of arrival at the pharmacy; and
378		vii. the name and signature of the pharmacy's agent.
379		b. The pharmacy's agent shall compare the transport manifest to the products transferred to his
380		possession, and when correct, shall return a signed copy of the manifest to the producer before
381		departing from the production facility.
382		c. The pharmacy's agent shall place the products in a locked, safe, and secure storage compartment that is
383		part of the motor vehicle, or in the alternative, in a locked storage container that has a separate key or
384		combination pad, and further, the product shall not visible or recognizable from outside the vehicle,
385		and further, the vehicle shall not bear the name of the pharmacy or any markings to indicate the vehicle
386		contains marijuana.
387		
		d. The pharmacy's agent shall maintain physical control of the vehicle at all times during the transport,
388		and shall not leave the vehicle unattended at any time.
389		e. The pharmacy's agent shall have access to a secure form of communication with the pharmacy as well
390		as the ability to contact law enforcement through the 911 emergency system.
391		f. Upon arrival at the pharmacy, the pharmacy's agent shall deliver the product to a pharmacist for
392		verification of receipt; the pharmacist shall time, date, and sign the delivery manifest.

393		
394		THORITY NOTE: Promulgated in accordance with R.S. 40:1046.
395		TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR
396		473 (October 2019), amended LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:1902
397	(Jul	y 2022), <u>amended LR</u>
398	0.3	
399		445. Marijuana Pharmacy Permit
400	А.	The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.
401	В.	The dispensing of marijuana for therapeutic purposes shall be limited to those pharmacies holding a marijuana
402		pharmacy permit issued by the board, and only when that permit is in active or restricted status.
403	C.	When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy in
404		compliance with the provisions of this Subchapter.
405	D.	When the permit is issued, it shall be valid only for the owner and the specific location noted on the application
406		and recorded on the permit.
407	E.	A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event
408		the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership
409		will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy
410		permit owner continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or
411		more without obtaining a new marijuana pharmacy permit shall be deemed undergo disciplinary review by the
412		board to determine if it is guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.
413	F.	Although a change of ownership of less than 50 percent shall not require a new pharmacy permit, any proposed
414		change of ownership shall require prior notice to the board, and further, approval by the board.
415	G	The board shall not have more than 10 active marijuana pharmacy permits at any given time. To facilitate
416	0.	compliance with that legislative restriction, the board recognizes the nine regions previously declared by the
417		Department of Health, to wit:
418		1. metropolitan, composed of the parishes of Jefferson, Orleans, Plaquemines, and St. Bernard;
419		2. capitol, composed of the parishes of Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe
420		Coupee, West Baton Rouge, and West Feliciana;
421		3. Teche, composed of the parishes of Assumption, Lafourche, St. Charles, St. James, St. John, St. Mary, and
422		Terrebonne;
423		4. Acadian, composed of the parishes of Acadia, Evangeline, Iberia, Lafayette, St. Landry, St. Martin, and
424		Vermilion;
425		5. southwest, composed of the parishes of Allen, Beauregard, Calcasieu, Cameron, and Jefferson Davis;
426		6. central, composed of the parishes of Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon,
427		and Winn;
428		7. northwest, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red
429		River, Sabine, and Webster;
430		8. northeast, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison,
430		-a. — northeast, composed of the parishes of cardwen, East Carron, Frankmi, Jackson, Encom, Madison, Morehouse, Ouachita, Richland, Tensas, Union, and West Carroll; and
431		9. southeast, composed of the parishes of Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington.
432		To achieve an equitable distribution of the marijuana pharmacy permits across the state, the board shall reserve
433	11.	one marijuana pharmacy permit for each of the nine regions identified above. In the event the board is
434		
435		convinced of the need for a second permit in one region, it may issue that permit following the procedures
430 437	сī	identified in this Subchapter. Further expansion will require a legislative amendment of the original restriction.
437 438	<u>G</u> +	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
439		effect. Such notice shall include, but not be limited to:
440		1. the maximum number of permits to be awarded;
441		2. information on how to obtain an application;
442		3. the deadline for receipt of applications;
443		4. acceptable methods for submitting an application;
444		5. the preferred locations, if any, for the marijuana pharmacy permits; and
445		6. the criteria that shall be considered in awarding the marijuana pharmacy permits.
446	<u>H</u> J	Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted
447		application and award marijuana pharmacy permits on a competitive basis based on the criteria set out in the

448 notice for applications. In the event the board determines there are an insufficient number of qualified

449	app	licants to award all of the marijuana pharmacy permits the board has determined are desirable, the board
450	may	y republish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.
451	IK. The	e board shall have the right to amend the notice of open applications prior to the deadline for submitting an
452		lication. Such amended notice shall be published in the same manner as the original notice of open
453		lications.
454		The board shall have the right to cancel a notice of open applications prior to the award of a marijuana
455		urmacy permit.
456	pna	innacy permit.
457	AUTHO	RITY NOTE: Promulgated in accordance with R.S. 40:1046.
458		ICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1543 (August 2017).
459	IIISTOK	TCAL NOTE. I folindigated by the Department of Health, Board of Finannacy, ER 45.1545 (August 2017).
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460		. Licensing Procedures
461	A. App	plication for Initial Issuance of Permit
462	1.	The board shall develop an application form suitable for the marijuana pharmacy permit. The board may
463		revise that application form on its own initiative in order to collect the information it deems necessary to
464		properly evaluate an applicant.
465	2.	The board shall not process applications received by facsimile, or that are incomplete, or submitted with the
466		incorrect fee.
467	3.	The applicant shall fully disclose the ownership of the entity that will own the permit as well as any
468	5.	additional holding companies that may exist, such that any natural person with any ownership interest shall
469		be fully identified.
470	4.	In the event any person holding any ownership interest in the entity submitting an application for a
	4.	
471		marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified
472		and the board shall not issue a marijuana pharmacy permit to that applicant:
473		a. within the two-year period preceding the date of the application, the person or any member of the
474	_	person's immediate family served as a member of the board or its staff.
475	5.	The applicant shall provide a complete street address reflecting the location at which the applicant proposes
476		to operate the marijuana pharmacy.
477	6.	The applicant shall provide the following information and records in the application process:
478		a. a detailed description of any other services or products to be offered by the marijuana pharmacy;
479		b. details regarding the applicant's plans to maintain adequate control against the diversion, theft, or loss
480		of marijuana;
481		c. documents or information sufficient to establish the applicant is authorized to conduct business in
482		Louisiana and that all applicable state and local building, fire and zoning requirements, and local
483		ordinances will be met;
484		d. text and graphic materials showing the exterior appearance of the proposed marijuana pharmacy and its
485		site compatibility with commercial or residential structures already constructed or under construction
485		within the immediate neighborhood;
487		
488		i. the square footage of the area which will constitute the prescription department;
489		ii. the square footage of the overall marijuana pharmacy;
490		iii. the square footage and location of areas used as storerooms or stockrooms;
491		iv. the size of the counter that will be used for the dispensing and sale of marijuana;
492		v. the location of the marijuana pharmacy sink and refrigerator, if any;
493		vi. the location of all approved safes and vaults that will be used to store marijuana;
494		vii. the location of the toilet facilities;
495		viii. the location of the break room and location of lockers for personal belongings;
496		ix. the location and size of the patient counseling area(s);
497		x. the location(s) where any other products or services will be offered; and
498		xi. the location of all areas that may contain marijuana showing the location of walls, partitions,
499		counters, and all areas of ingress and egress;
500		f. —such other documents and information reasonably required by the board to determine the applicant's
501		suitability for permitting or to protect the public's health and safety.
502	7.	The owner's managing officer and the pharmacist-in-charge shall be fully identified within the application
502	/.	and they both shall sign and date the application form.
505	8.	
	٥.	The applicant shall direct the following persons to submit to the criminal history record check process used
505		by the board, at the applicant's expense:

 b. the pharmacist-in-charge; and c. any person holding any share of ownership in the entity; provided however that any person not holding any share of ownership but holding a corporate officer position in the entity may be required to submit to the criminal history record check. 9. The requirement for a criminal history record check may be waived by the board in the event the person has a lendy completed that process for the board within the two-year period prior to the date of the applicant's financial capacity to properly operate a marijuana plannacy-including but not limited to, evidence of his exerce mecount, letter of credit, or surely bond of at least \$100,000 in a financial institution headpartered in the ownership but not like plannacy's \$100,000 occurs account, letter of credit, or surely bond that head \$120,000 in a financial institution headpartered in the event the board determines after a due process learing that the pharmacy in sompliance with the provisions of this Subchapter. b. The board ball permit the pharmacy's screw account, letter of credit, or surely bond to be reduced by \$252,000 upon the successful whereare to f and of the following millionnes: i. a determination by the board dift pharmacy is screw account, letter of credit, and adult to commence and has begun dispensing of marijuana as provided in this Subchapter. i. a determination by the board that the pharmacy is fully operational and whole commence and has begun dispensing of marijuan as provided in this Subchapter. ii. a determination by violation of law or signation of a second end without substantial interruption and without my violation of law or signation and without substantial interruption and without my violation of law or signation of a second end without substantial interruption and without my violation of law or signation of a second end without adviolating interruption with signation of a second end without substantial interruption with the application of law or sign	506		a. the owner's managing officer;
 any share of ownership but holding a corporate officer position in the entity may be required to submit to the criminal history record check may be waived by the board in the event the person has afready completed that process for the board within the two-year period prior to the date of the application. The applicant shall supplement the application form with sufficient documentation of the application. The applicant shall supplement the application form with sufficient documentation of the application. The applicant letter of credit, or surety bond of at least 1500,000 in a financial institution headplatatteed in the working. The applicant head the construction of the application is a sufficient to the pharmacy is strong to the pharmacy in the pharmacy is a strong the strong th	507		b. the pharmacist-in-charge; and
 to the criminal history record check. 9. The requirement for a criminal history record check may be waived by the board in the event the person has already completed that process for the board within the two-year period prior to the date of the application. 10. The applicant shall supplement the application form with sufficient documentation of the applicant's financial capacity to properly operate a marginana pharmacy-in-subality but and time to the vent the board determines after a due process hearing that the pharmacy has failed to timely and successfully complete the construction of the pharmacy or to operate such pharmacy in compliance with the provisions of this Subchupter. b. The board shull permit the pharmacy's earway account, letter of credit, or surety bond to be to commence and has begin disponted by the board that the pharmacy is faily operational and able to commence and has begin disponting of marijuma as provided in this Subchupter. b. The board shull permit the pharmacy is early a constrained operational and without substantial interruption and without any violation of law or regulation for a second and without substantial interruption and without any violation of a wor are pharmacy and and without substantial interruption and without any violation of law or accound, nearly and direct and the substantial interruption and without any violation of law or accound, nearly on differ a minimum of \$25,2000 for the creating of its operation. c. In the event a pharmacy voluntarily chooses not to reave the pharmacy permit and follows proper closed and interruption and without any violation of law or accound and without substantial interruption and without any violation or accound and without substantial interruption and without any violation of a source accound and without substantial interruption and without any violation of a source accound and without substantial interruption and without any violation or accound and an without substantial interrupt	508		c. any person holding any share of ownership in the entity; provided however that any person not holding
 The requirement for a criminal history record check may be waived by the board in the event the person has already completed that process for the board within the two-year period prior to the date of the application. The applicant shall supplement the application form with sufficient documentation of the applicant's financial capacity to properly operate a marijuana pharmacy including but not limited to evidence of his earrow account, letter of eredit, or surely bond shall be payable to the board in the origin of the pharmacy in compliance with the pharmacy in a surely bond shall be payable to the board in the event the horned determines after a due process hearing that the pharmacy in compliance with the provisions of this Subchapter. The payle and shall permit the pharmacy is earrow account, letter of credit, or surely bond to be reduced by \$25,000 upon the successful achievement of each of the following millectones: a determination by the board that the pharmacy is early bard without aubstantial interprism and without any violation of law or regulation for a one-gare period, and the begun dispensing of mariyuma as provided in this Subchapter. a determination by the board that the pharmacy remained operational and without abdsmittil interprism and without any violation of law or regulation for a one-gare period. and the begun dispensing of mariyuma as provided in this Subchapter. a determination by the board that the pharmacy remained operational and without aubstantial interprism and without any violation of law or regulation for a one-gare period. and interprism and without any violation of law or regulation for a second one year period. Summary and without any violation of law or regulation for a second one year period. Summary and the second and the application and accounce and has begun the application of a second and year period. Sumany as a second one and the period is the ordit withor the viol	509		any share of ownership but holding a corporate officer position in the entity may be required to submit
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562			i. its proximity to previously approved marijuana pharmacies or locations of proposed marijuana
563			pharmacies with pending applications;
564			ii. whether the patient population in the area proposed by the marijuana pharmacy permit applicant
565			justifies the need for a marijuana pharmacy, or an additional marijuana pharmacy, in that area;
566			iii. whether the proximity of the proposed marijuana pharmacy will have a detrimental effect upon
567			any place used primarily for religious worship, public or private school, convent, charitable
568			institution, whether supported by private or public funds, hospital or veterans' home or any camp
569			or military establishment; or
570			iv. whether the number of marijuana pharmacies in the locality is such that the granting of a permit is
571			detrimental to the public interest. In reaching a conclusion in this respect, the board may consider
572			the population of, the number of like permits and number of all permits existent in, the particular
573			municipality and the immediate neighborhood concerned, the effect that a new permit may have
574			on such town or neighborhood or on like permits existent in such municipality or neighborhood;
575			c. the applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana;
576			d. the applicant's ability to maintain the knowledge, understanding, judgment, procedures, security
577			controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and
578			e. the extent to which the applicant or any of the applicant's owners have a financial interest in any other
579			permittee, licensee, registrant, or other applicant currently or previously credentialed by the board; and
580			f. Any other reason provided by any federal law or rule or state law or rule that is not inconsistent with
581			R.S. 40:1046 or 40:1047 or this Subchapter.
582		16.	Following their evaluation of the applications for a marijuana pharmacy permit, the committee shall
583			develop a recommendation for presentation to the board at the board's next meeting. The board may accept
584			the committee's recommendation, select an alternative applicant, reject all of the applicants, or return all
585			the applicants to the committee for their reconsideration.
586		17.	The board may disqualify any applicant who:
587			a. submits an incomplete, false, inaccurate, or misleading application;
588			b. fails to submit an application by the published deadline; or
589			c. fails to pay all applicable fees.
590		18.	The decision of the board to award or not to award a marijuana pharmacy permit to an applicant shall be
591			final.
592		19.	Upon the approval of an application, the board shall award the marijuana pharmacy permit and state
593			controlled dangerous substance license to the applicant. Upon completion of a satisfactory inspection of the
594			pharmacy premises, the board shall issue the marijuana pharmacy permit and state controlled dangerous
595			substance license to the applicant awarded the permit.
596		20.	If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such
597			pharmacy within 310 days of being notified of the marijuana pharmacy permit award, the board may, in the
598			board's discretion, rescind such marijuana pharmacy permit, unless such delay was caused by force
599			majeure. A marijuana pharmacy shall be deemed to have commenced operation if the pharmacy is capable
600			of operating in accordance with the applicant's approved application. In the event a marijuana pharmacy
601			permit is rescinded pursuant to this Subsection, the board shall award a marijuana pharmacy permit by
602			selecting among the qualified applicants who applied for the marijuana pharmacy permit that was
603			rescinded. If no other qualified applicant applied for such marijuana pharmacy permit or satisfied the
604			criteria for awarding a permit, the board shall publish, in accordance with this Section, a notice of open
605	P		applications for marijuana pharmacy permits.
606	В.		plication for Renewal of Permit
607		1.	All marijuana pharmacy permits expire at midnight on December 31 of every year, regardless of the date of
608		~	its initial issuance.
609		2.	The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall complete,
610			sign and date a permit renewal application form supplied by the board, and further, shall include all
611			information requested on the form and attach the pharmacy permit renewal fee and state controlled
612			dangerous substance license renewal fee authorized in R.S. 37:1184 LAC 46:LIII.115 and the prescription
613			monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application
614		2	package to the board office prior to the expiration date of the pharmacy permit.
615		3.	The board shall not process applications received by facsimile, or that are incomplete, or submitted with the
616		4	incorrect fees.
617		4.	In the event the pharmacy does not submit a properly completed renewal application form and fee to the
618			board prior to the expiration of the permit, the permit shall be rendered null and void. A marijuana

619 pharmacy shall not operate with an expired permit. Evidence it has done so will provide sufficient basis for 620 the board to discipline the permit for violation of R.S. 37:1241(12). 621 5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the 622 board office no later than 30 days after the expiration date of the permit may be processed by the board staff, provided the appropriate delinquent fee authorized in R.S. 37:1184 LAC 46:LIII.115 is included with 623 624 the application. 625 6. A marijuana pharmacy permit not renewed by 30 days after the expiration date shall be automatically 626 terminated by the board. 627 7. An application for the reinstatement of a terminated marijuana pharmacy permit shall be referred to the 628 board's reinstatement committee for its consideration. 629 C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits 630 1. The applicant shall complete an application form for this specific purpose supplied by the board; the 631 application shall require the inclusion of the annual renewal fee, the delinquent fee, the administrative hearing fee, and the reinstatement fees authorized in R.S. 37:1184 LAC 46:LIII.115 and the program fee 632 633 authorized in R.S. 40:1013. 634 2. An application for the reinstatement of a marijuana pharmacy permit previously terminated, suspended or 635 revoked by the board may only be approved following a preliminary hearing to determine whether the 636 reinstatement of the permit is in the public's best interest. 637 D. Maintenance of Marijuana Pharmacy Permit 638 A marijuana pharmacy permit is valid only for the entity or person to whom it is issued and shall not be 639 subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any 640 premises other than the business location recorded thereon. 641 A duplicate or replacement permit shall be issued upon the written request of the licensee and payment of 642 the fee authorized in R.S. 37:1184. A duplicate or replacement license shall not serve or be used as an 643 additional or second license. 644 2.3. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the permit shall 645 notify the board and request approval of the contemplated name or trade name. The board shall reasonably 646 accommodate such requests, unless there is cause not to do so (e.g., duplicative or misleading names). The 647 marijuana pharmacy shall not change its name or trade name until approved by the board. 3.4. Prior to any modification, remodeling, expansion, reduction, or other physical, non-cosmetic alteration of 648 649 the marijuana pharmacy, the owner of the permit shall notify the board and request approval of the 650 contemplated change(s). The board shall reasonably accommodate such request, unless there is cause not to 651 do so (e.g., inconsistent with operating requirements). The marijuana pharmacy shall not make such 652 changes until approved by the board. 653 4.5. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit an 654 application form for that purpose supplied by the board and pay the appropriate fee authorized in R.S. 655 37:1184 LAC 46:LIII.115. The board may require an inspection of the new location prior to the issuance of 656 the permit for the new location. No marijuana pharmacy shall commence operation in a new location until 657 approved by the board. 658 5.6. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the 659 pharmacist-in-charge for the marijuana pharmacy permit. 6.7. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the 660 661 owner's managing officer for the marijuana pharmacy permit. 662 7.8. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall notify 663 the board in accordance with the rules governing the permanent closure of a pharmacy as described in 664 Chapter 11 of this Part. 665

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).

- 670 §2449. Marijuana Pharmacy Personnel
- 671 A. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.
- B. 1. The PIC shall insure and document the initial and continuing competency of the entire professional staff to
- 673 provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the PIC shall provide
 674 access to education and training in the following domains:

675		a. policies and procedures of the pharmacy, especially those relating to the tasks and functions that
676		employee is expected to perform;
677		b. professional conduct, ethics, and patient confidentiality; and
678		c. developments in the therapeutic use of marijuana.
679		2. Further, the PIC shall document such education and training, provide such records to the board when
680		requested, and retain such records for at least two years after the employee disassociates with the
681		requested, and retain such records for at least two years after the employee disassociates with the pharmacy.
682	C	
	U.	The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy interns)
683	р	and Chapter 9 (pharmacy technicians) of this Part.
684	D.	In addition to the scope of practice limitations found in Chapter 9 of this Part, pharmacy technicians practicing
685		in a marijuana pharmacy shall not:
686		1. consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before or after
687		marijuana has been dispensed, or regarding any medical information contained in a patient medication
688		record;
689		2. consult with the physician <u>authorized clinician</u> who issued the recommendation/prescription/order for
690		marijuana to the patient, or the physician's authorized clinician's agent, regarding a patient or any medical
691		information pertaining to the patient's marijuana or any other drug the patient may be taking;
692		3. interpret the patient's clinical data or provide medical advice;
693		4. perform professional consultations with physicians authorized elinicians, nurses, or other health care
694		professionals or their authorized agents; or
695		5. determine whether a different brand or formulation of marijuana should be dispensed for the marijuana
696		product or formulation recommended/prescribed/ordered by the physician authorized clinician or requested
697		by the patient or his caregiver.
698		
699	AU	HORITY NOTE: Promulgated in accordance with R.S. 40:1046.
700		TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1546 (August 2017), amended LR
701		2103 (August 2022).
702		
703	§2 4	451. Operation of Marijuana Pharmacy
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731		Such procedures may include, but are not limited to, telephone system messages and conspicuously posted
732		signs.
733 734		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.
735	K.	A marijuana pharmacy shall provide information to patients and caregivers regarding the possession and use of
736	к.	marijuana. Such informational material shall include information related to:
737		1. limitations on the right to possess and use marijuana pursuant to R.S. 40:1046;
738		 safe techniques for proper use of marijuana and paraphernalia;
739		 alternative methods and forms of consumption by which one can use marijuana;
740		4. signs and symptoms of substance abuse; and
741		5. opportunities to participate in substance abuse programs.
742	L.	The marijuana pharmacy shall establish, implement and adhere to a written alcohol free, drug free and smoke
743		free work place policy, which shall be available to the board upon request.
744	M.	The receipt of all deliveries from producers shall be carried out under the direct supervision of a pharmacist
745		who shall be present to accept the delivery. Upon delivery, the marijuana shall immediately be placed in an
746		approved safe or approved vault within the pharmacy where marijuana is stored.
747	<u>N.M.</u>	No marijuana pharmacy shall acquire, possess or dispense any controlled substance other than medical
748		marijuana products authorized by R.S. 40:1046.
749	<u> </u>	No marijuana shall be administered on the premises of a marijuana pharmacy, except during patient counseling,
750	D	education or training.
751	<u>Р. О</u> .	No person associated with a marijuana pharmacy shall enter into any agreement with a physician an authorized
752		<u>clinician</u> or health care facility concerning the provision of services or equipment that may adversely affect any
753 754	Q. <u>Р</u>.	person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase marijuana. Delivery of Dispensed Marijuana Products.
755	. <u>.</u>	1. A marijuana pharmacy shall dispense a marijuana product to a patient or his caregiver in the marijuana
756		pharmacy. At the patient's request, the caregiver may deliver a dispensed marijuana product to the patient's
757		location.
758		2. Each marijuana pharmacy shall offer home delivery to patients in each zip code within its region at least
759		once per month.
760		3. At the patient or caregiver's request, the marijuana pharmacy may deliver or facilitate the delivery of a
761		dispensed marijuana product to the patient's location.
762		4. The delivery of a dispensed marijuana product is subject to the following requirements:
763		1. a. The marijuana pharmacy shall not deliver or facilitate the delivery of a marijuana product to a
764		location outside the state.
765		2. <u>b.</u> The marijuana pharmacy shall ensure the physical integrity and security of the marijuana product
766		while in transit.
767		3. c. In the event the delivery of the marijuana product is not completed, the marijuana product shall be
768		returned to the marijuana pharmacy from which it was dispensed.
769		4. <u>d.</u> In the event the pharmacist-in-charge of the marijuana pharmacy cannot assure the integrity and
770 771	P O	security of a returned marijuana product, the pharmacy shall dispose of the marijuana product. No marijuana shall be sold when the marijuana pharmacy is closed and not open for business.
772		Board representatives, local law enforcement or other federal, state or local government officials may enter any
773	<u>.</u>.	area of a marijuana pharmacy if necessary to perform their governmental duties.
774	T-S	Right of Inspection. The board, or its agent, representative, or designee, is authorized:
775	1. <u>5.</u>	1. to enter a marijuana pharmacy at any time during its hours of operation, or any other place, including a
776		vehicle, wherein marijuana is held, dispensed, sold, or otherwise disposed of;
777		2. to inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment,
778		finished and unfinished material, containers and labeling, and all things therein, including records, files,
779		financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls
780		and facilities; and
781		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.
782		
783	₩. <u>T</u> .	Inspection of Records. Every person required to prepare, obtain or keep records, logs, reports or other
783 784	U . <u>T</u> .	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
783	U . <u>T</u> .	Inspection of Records. Every person required to prepare, obtain or keep records, logs, reports or other

787 with this Section, no person shall use a foreign language or codes or symbols to designate marijuana types or 788 persons in the keeping of any required document. 789

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

791 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1547 (August 2017), amended LR 792 46:1227 (September 2020), amended LR 47:590 (May 2021), LR 48:2103 (August 2022), amended LR

794 §2453. Security Requirements for Marijuana Pharmacies

795 A. A marijuana pharmacy shall:

793

- 796 1. store all marijuana in an approved safe or vault, as defined in this Subchapter, and in such a manner as to 797 prevent diversion, theft, or loss;
- 798 2. maintain all marijuana in a secure area or location accessible only to specifically authorized employees, 799 which shall include only the minimum number of employees essential for efficient operation;
- 800 3. not permit any person less than eighteen years of age to enter the prescription department, with the 801 exception of patients being counseled by the pharmacist;
- 4. keep all approved safes and vaults securely locked and protected from entry, except for the actual time 802 803 required to remove or replace marijuana, provided that during hours of operation the pharmacist in charge 804 may authorize the placement of a limited quantity of dispensing stock outside such safes or vaults but 805 within the secure prescription department.
- 806 5. keep all locks and security equipment in good working order;
- 807 6. not allow keys to be left in the locks and not store or place keys in a location accessible to persons other 808 than specifically authorized employees;
- 809 7. not allow other security measures, such as combination numbers, passwords or electronic or biometric 810 security systems, to be accessible to persons other than specifically authorized employees; 811
 - 8. keep the pharmacy securely locked and protected from entry by unauthorized employees;
- 812 9. keep the outside perimeter of the pharmacy premises well lit; and
- 813 10. post a sign at all entry ways into any area of the pharmacy containing marijuana, including a room with an 814 approved safe or vault, which sign shall be a minimum of 12 inches in height and 12 inches in width which 815 shall state: "Do Not Enter Limited Access Area Access Limited to Authorized Employees Only" in lettering no smaller than 1/2 inch in height. 816

817 B. All pharmacies shall have an adequate security system to prevent and detect diversion, theft or loss of marijuana 818 utilizing commercial grade equipment, which shall include at a minimum:

819 1. a perimeter alarm;

- 820 2. motion detector;
- 821 3. video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be 822 appropriate for the normal lighting conditions of the area under surveillance. The pharmacy shall direct 823 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 824 825 allow for the capture of clear and certain identification of any person entering or exiting the pharmacy;
- 826 24 hour recordings from all video cameras, which the pharmacy shall make available for immediate 4 827 viewing by the board or its authorized representative upon request and shall retain for at least 30 days. If a 828 pharmacy is aware of a pending criminal, civil, or administrative investigation or legal proceeding for 829 which a recording may contain relevant information, the pharmacy shall retain an unaltered copy of the 830 recording until the investigation or proceeding is closed or the entity conducting the investigation or 831 proceeding notifies the pharmacy that it is not necessary to retain the recording:
- 832 a. all video recordings shall allow for the exporting of still images in an industry standard image format, 833 including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary 834 format that ensures authentication of the video and guarantees that no alteration of the recorded image 835 has taken place. Exported video shall also have the ability to be saved in an industry standard file 836 format that can be played on a standard computer operating system. A pharmacy shall erase all 837 recordings prior to disposal or sale of the pharmacy;

838 -duress alarm, which for purposes of this Subsection means a silent security alarm system signal generated 5 839 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; 840

841 6. panic alarm, which for purposes of this Subsection means an audible security alarm system signal 842 generated by the manual activation of a device intended to signal a life threatening or emergency situation 843 requiring a law enforcement response;

	7. holdup alarm, which for purposes of this Subsection means a silent alarm signal generated by the manual
	activation of a device intended to signal a robbery in progress;
	8. automatic voice dialer, which for purposes of this Subsection means any electrical, electronic, mechanical,
	or other device capable of being programmed to send a prerecorded voice message, when activated, over a
	telephone line, radio or other communication system, to a law enforcement, public safety or emergency
	services agency requesting dispatch;
	9. a failure notification system that provides an audible, text or visual notification of any failure in the
	surveillance system. The failure notification system shall provide an alert to the pharmacy within five
	minutes of the failure, either by telephone, email, or text message;
	10. the ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera
	image (live or recorded);
	11. a date and time stamp embedded on all recordings. The date and time shall be synchronized and set
	correctly and shall not significantly obscure the picture; and
	12. the ability to remain operational during a power outage.
<u>C.</u>	A pharmacy shall maintain all security system equipment and recordings in a secure location so as to prevent
	theft, loss, destruction, or alterations.
	1. A pharmacy shall keep all on site surveillance rooms locked and shall not use such rooms for any other
	function.
	2. A pharmacy shall limit access to surveillance areas to persons that are essential to surveillance operations,
	law enforcement agencies, security system service employees, and the board's authorized representative.
	3. A pharmacy shall make available to the board upon request a current list of authorized employees and
	service employees that have access to the surveillance room.
D.	A pharmacy shall keep all security equipment in good working order and shall test such equipment no less than
2.	two times per year.
F	When a pharmacy presents special security issues, such as an extremely large stock of marijuana, exposed
L.	handling or unusual vulnerability to, or actual, diversion, theft or loss, the board may require additional
F	safeguards, including but not limited to, a supervised watchman service.
F.	Any marijuana not stored in compliance with this Section, or stored at a location other than that for which the
	pharmacy permit was issued, shall be subject to embargo or seizure by the board.
G.	In the event any marijuana pharmacy permit is revoked, suspended, or not renewed, the pharmacy shall dispose
	of its entire stock of marijuana in accordance with the disposal provisions in this Subchapter.
H.	If a pharmacy has provided other safeguards which can be regarded in total as an adequate substitute for some
	element of protection required of the pharmacy, such added protection may be taken into account by the board
	in evaluating overall required security measures.
AU	FHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
	THORITY NOTE: Promulgated in accordance with R.S. 40:1046. TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR
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HIS 48:1	TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 903 (July 2022), <u>amended LR</u>
нія 48:1 §2 4	TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 903 (July 2022), <u>amended LR</u>
HIS 48:1 §2 4	 TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 903 (July 2022), <u>amended LR</u> I55. Reportable Security Events Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized
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HIS 48:1 §2 4	 TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 903 (July 2022), <u>amended LR</u> 455. Reportable Security Events Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana, or of any loss or unauthorized alternation of records related to marijuana or patients, a pharmacy shall immediately notify:
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HIS 48:1 §2 4 A. B.	 TORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 903 (July 2022), <u>amended LR</u> 455. Reportable Security Events Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana, or of any loss or unauthorized alternation of records related to marijuana or patients, a pharmacy shall immediately notify: appropriate law enforcement authorities; and the board. 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.
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900	Ð.	Ap	harmacy shall maintain and shall make available all documentation related to an occurrence that is				
901			ortable.				
902							
903	AU	AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.					
904	HIS	TOR	ICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017).				
905							
906	824	157.	Standards of Practice				
907			vironmental Standards				
908		1.	The prescription department shall be of sufficient size commensurate with the nature and scope of practice.				
909		1.	The space occupied by the prescription department shall be restricted to authorized personnel only, as				
910			determined by the pharmacist-in-charge, and shall not be accessible to the general public. <u>A marijuana</u>				
911			pharmacy shall not permit any person less than eighteen years of age to enter the prescription department,				
912			with the exception of patients being counseled by the pharmacist.				
913		2.	The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with				
914		2.	the nature and scope of practice for that pharmacy.				
915		3.	The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom				
916		5.	facilities, with approved sewage disposal.				
917		4.	All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained at				
918		4.	temperatures which will ensure the integrity of drugs during their storage and prior to their dispensing as				
919			stipulated by the United States Pharmacopeia and/or manufacturer's or distributor's product labeling unless				
920			otherwise indicated by the board.				
921		5.	The prescription department shall be secured by one or more physical barriers with suitable locks and a				
922		5.	monitored alarm system capable of detecting unauthorized entry., and further, complies with security				
923			requirements identified elsewhere in this Subchapter.				
924		6.	Prescription and other patient healthcare information shall be maintained in a manner that protects the				
925		0.	integrity and confidentiality of such information.				
926	B.	Mir	nimum Staffing Requirements				
927	D.	1.	There shall be at least one pharmacist on duty at all times the pharmacy is open for business.				
928		2.	Every pharmacist practicing in the pharmacy shall possess a Louisiana pharmacist license in active status as				
929		2.	well as access privileges to the state prescription monitoring program.				
930		3.	A pharmacy intern, pharmacy technician or pharmacy technician candidate may assist the pharmacist in the				
931		5.	prescription department, but only when in possession of valid credentials issued by the board. The				
932			supervising pharmacist may establish a delegate credential in the state prescription monitoring program for				
933			any licensed pharmacy personnel affiliated with that pharmacy.				
934		4.	Additional clerical personnel may also be present at the pharmacy.				
935			No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.				
936	C		erational Standards				
937	C.	1.	The marijuana pharmacy shall comply with the provisions of Chapters 11, 25, 27, 29, and 31 of this Part				
938		1.	except when this Subchapter grants exceptions or imposes more stringent requirements.				
939		2.	In the event the marijuana pharmacy intends to close permanently, the pharmacist-in-charge (PIC) shall				
940		2.	comply with the pharmacy closure procedures described in Chapter 11 of this Part, and further, the owner				
941			of the pharmacy permit shall not prevent or interfere with the PIC's performance of those tasks.				
942			a. In addition to the other closure requirements, the closing pharmacy shall include in its notice to the				
943			board and to the public the identification of the destination pharmacy where the closing pharmacy's				
944			prescription records will be transferred. That destination pharmacy shall be the marijuana pharmacy				
945			nearest the closing pharmacy, unless otherwise approved by the board.				
946	р	Rec	cordkeeping Requirements				
947	р.	1.	When the pharmacy receives a request for marijuana from a recommending physician authorized clinician				
948		1.	in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging				
949			system in compliance with Section 1123 of this Part.				
950		2.	Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at least two				
951		2.	years after the date of dispensing, and further, shall be readily retrievable upon request by the board.				
952		3.	Inventory of Marijuana Product				
953		5.	a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana products				
954			acquired, held, dispensed, and disposed by the pharmacy.				
955			b. The pharmacy shall access the LMMTS and enter all acquisitions and product transfer transactions in				
956			that system.				
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957			c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product inventory
958			from the production facility, the pharmacist shall verify the agent is at least 21 years of age and is
959			eligible to drive on public roadways.
960			d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the possession
961			of the pharmacy on any date which is within one year of the previous annual inventory, and further,
962			shall conduct additional inventory counts on the following occasions:
963 964			 arrival of a new pharmacist-in-charge; discovery of any significant loss, disappearance, or theft of marijuana product;
964 965			 ii. discovery of any significant loss, disappearance, or theft of marijuana product; iii. departure of a pharmacist-in-charge; and
966			iv. permanent closure of the pharmacy.
967			e. Inventory records shall be retained on the pharmacy's premises for at least two years after the most
968			recent entry.
969		4.	The pharmacy shall develop and maintain sufficient records to fully reveal the business transactions related
970			to marijuana products, including their procurement and sale, for the current tax year as well as the two
971			immediately preceding tax years, all of which shall be made available to the board upon request.
972		5.	The board may require any pharmacy or its owners to furnish such information as the board considers
973			necessary for the proper administration of R.S. 40:1046, and may require a financial audit of the business
974			of any marijuana pharmacy, and the expense thereof shall be paid by the marijuana pharmacy.
975	E.	Pro	fessional Practice Standards
976		1.	Recommendation / opinion (hereinafter, "request") for Therapeutic Marijuana
977			a. The pharmacist may accept any request for a marijuana product which has been:
978			i. issued by a physician an authorized clinician in possession of a current and unrestricted license to
979			practice in this state medicine from the Louisiana State Board of Medical Examiners as well as a
980			current and unrestricted state controlled substance license with therapeutic marijuana privileges
981			from the board; and
982			ii. received directly from the physician authorized clinician and not from the patient or any third
983			party other than the entity transmitting the request, either by electronic means conforming with the
984			provisions of 21 CFR 1311 or its successor, or in the alternative, by facsimile bearing a
985			handwritten or digital signature of the physician <u>authorized clinician</u> .
986			b. The request shall disclose the following information at a minimum:
987			i. name, address, telephone number, and national provider identifier (NPI) number of the physician
988 989			authorized clinician issuing the request;
989 990			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;
991			iv. type of marijuana product requested;
992			v. date request was issued;
993			vi. self-certification the physician <u>authorized clinician</u> holds a current and unrestricted license to
994			practice in this state medicine issued by the Louisiana State Board of Medical Examiners; and
995			vii. signature of the physician authorized clinician issuing the recommendation, excluding any proxy
996			or agent.
997			c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of
998			time is indicated by the physician authorized clinician. A pharmacist shall not dispense marijuana
999			product pursuant to an expired request.
1000			d. Requests for raw or crude marijuana products intended for persons under 21 years of age shall
1001			specifically indicate a recommendation for raw or crude forms of marijuana for such persons.
1002			e. A marijuana pharmacy shall transfer an unexpired request for marijuana product to another marijuana
1003			pharmacy when requested by the patient or his caregiver.
1004		2.	Upon request by the patient or caregiver and prior to dispensing any marijuana product to a patient, the
1005			pharmacist shall provide product testing results available to the pharmacist for the product contemplated for
1006			dispensing.
1007		3.	Dispensing Marijuana Products
1008			a. Prior to dispensing any marijuana product to a patient, the pharmacist shall review the patient's records
1009			in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in
1010			that review by consultation with the recommending physician <u>authorized clinician</u> .
1011			b. Dispensing Limitations
1012			i. A pharmacist shall not dispense more than two and one-half ounces, or 71 grams, of raw or crude
1013			marijuana every 14 days to any person.

1014	ii. Subject to the above limitation on dispensing raw or crude marijuana products, a pharmacist may
1015	dispense marijuana products on multiple occasions as indicated by the physician authorized
1016	clinician and needed by the patient until the request expires; however, the pharmacist shall not
1017	dispense more than a 90-day supply of marijuana product at one time nor more than a one-year
1018	supply pursuant to a single request
1019	4. Dispensing Marijuana Products to Visiting Qualifying Patients
1020	a. A visiting qualifying patient may obtain medical marijuana from a marijuana pharmacy, subject to the
1021	dispensing limitations of paragraph (3)(b) of this subsection, upon producing evidence of his valid
1022	medical marijuana registry identification card, or its equivalent, which has been issued under the
1023	medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the
1024	United States and in compliance with LA R.S. 40:1046.4.
1025	5.4. Labeling of Marijuana Product Dispensed
1026	a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required
1027	by the LDAF LDH, and further, the pharmacy dispensing label shall not overlay or obscure the
1028	
	producer label in any way.
1029	b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:
1030	i. name and address of the pharmacy dispensing the product;
1031	ii. telephone number or other contact information of the pharmacy dispensing the product;
1032	iii. name of the recommending physician <u>authorized clinician</u> ;
1033	iv. name of the patient;
1034	v. date the product was dispensed;
1035	vi. prescription number, which shall be a unique identifier for that specific transaction;
1036	vii. name of the marijuana product, including any concentration, strength, or other identifiers of the
1037	marijuana product;
1038	viii. quantity of marijuana dispensed;
1039	ix. directions for use of the product;
1040	x. expiration date of the product, which shall not exceed the expiration date determined by the
1041	producer of the product; and
1042	xi. other information selected by the dispensing pharmacist to inform the patient as to the best use of
1043	the product for the intended purpose.
1044	6.5. The pharmacist shall comply with the rules on drug utilization review and patient counseling in Chapter 5
1045	of this Part.
1046	<u>7.6.</u> Reporting transactions to state prescription monitoring program. The pharmacy shall comply with the
1047	reporting requirements as found in Chapter 29 of this Part.
1048	<u>8.7.</u> Disposal of Marijuana Product
1049	a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is
1050	determined to be misbranded, adulterated, expired, deteriorated, undesired, excess, unauthorized, or
1051	unfit for dispensing.
1052	b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the product
1053	shall be removed from active dispensing stock and quarantined in the pharmacy pending its disposal
1054	c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the waste with
1055	other ground materials so the resulting mixture is at least 50 percent non-marijuana waste by volume.
1056	Material used to grind with the waste may include:
1057	i. yard waste;
1058	ii. paper waste;
1059	iii. cardboard waste;
1060	iv. plastic waste; or
1061	v. soil or sand.
1062	d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable shall be
1063	disposed of by delivery to an approved solid waste facility for final disposition.
1064	i. Examples of acceptable permitted solid waste facilities include:
1065	(a). compost; anaerobic digester;
1066	(b). landfill, incinerator; or
1067	(c). waste-to-energy facility.
1068	e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain, at a
1069	minimum, the following information:
1070	i. brand name and other specific identifiers of the marijuana product disposed;

- 1071 ii. quantity of product disposed; 1072
 - 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.
- 1075 1076 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

1077 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017), amended LR 1078 45:1473 (October 2019), LR 47:246 (February 2021), LR 47:1111 (August 2021), LR 48:1903 (July 2022), LR 48:2103 (August 1079 2022). 1080

§2459. Advertising 1081

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- 1082 A. The marijuana pharmacy shall not advertise through any public medium, including but not limited to 1083 newspapers, billboards, television, radio, internet, social media, or any other means designed to market its 1084 products to the general public.
- 1085 B. The marijuana pharmacy may market its products through direct mail, brochures, or other means to Louisiana-1086 licensed physicians, but only when such advertising is directed solely to the practitioner and is not available to 1087 the general public.
- 1088 C. Any advertisement permitted in Subsection B of this Section shall not:
- 1089 1. make any deceptive, false, or misleading assertions or statements regarding any product; or
- 1090 2. assert that its products are safe because they are regulated by LDAF or the board. The pharmacy may
- 1091 advertise that its products have been tested by an approved laboratory, but shall not assert that its products 1092 are safe because they are tested by an approved laboratory.
- 1093 D. The marijuana pharmacy may attach a maximum of two separate signs to the exterior of the building which 1094 identify the business by its business or trade name, provided that neither sign exceeds the size limit of 1,600 1095 square inches.
- 1097 AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
- 1098 HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1552 (August 2017), Repealed LR