Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 24. Limited Service Providers

Subchapter A. Durable Medical Equipment

§2401. Definitions

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

"Durable medical equipment" (DME) – technologically sophisticated medical devices that may be used in a residence, including the following:

a. Oxygen and oxygen delivery system;
b. Ventilators;
c. Respiratory disease management devices;
d. Continuous positive airway pressure (CPAP) devices;
e. Electronic and computerized wheelchairs and seating systems;
f. Apnea monitors;
g. Transcutaneous electrical nerve stimulator (TENS) units;
h. Low air loss cutaneous pressure management devices;
i. Sequential compression devices;
j. Feeding pumps;
k. Home phototherapy devices;
l. Infusion delivery devices;
m. Distribution of medical gases to end users for human consumption;
n. Hospital beds;
o. Nebulizers; and
p. Other similar equipment as determined by rule.

"Legend device" – an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician" and/or "Rx Only", or any other designation required under federal law.

"Legend drug" –

a. Any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or animals;
b. Any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or animals; or
c. Any substance other than food intended to affect the structure or any function of the body of humans or other animals.

"Medical gas" – compressed oxygen and liquid oxygen intended for human consumption.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:502 (March 2013).

§2403. Durable Medical Equipment (DME) Permit

A. No person or other entity shall sell, rent or provide, or offer to sell, rent or provide, directly or indirectly, to consumers in this state any durable medical equipment, legend devices, and/or medical gas until such person has obtained a Durable Medical Equipment (DME) permit from the board.

B. A DME permit shall authorize the permit holder to procure, possess and provide legend devices to the patient or end user; however, the DME permit shall not authorize the permit holder to procure, possess, or provide any prescription medications.

C. The board shall not issue a DME permit to any person or other entity that has not registered with the Louisiana Secretary of State to conduct business within the state.

D. Licensing Procedures
   1. A person or other entity desiring to obtain a DME permit shall complete the application form supplied by the board and submit it with any required attachments and the application fee to the board.
   2. The applicant shall provide a complete street address reflecting the location where the applicant will hold the equipment and engage in the activity for which the permit is acquired. The board shall not issue more than one permit for the same physical space.
   3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
   4. A person or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2).
   5. Once issued, the DME permit shall expire on August 31 of every year. No person or other entity shall engage in the provision of DME with an expired DME permit.

E. Maintenance of Permit
   1. A DME permit shall be valid only for the person or other entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a DME permit be valid for any premises other than the physical location for which it was issued.
   2. The DME permit holder shall inform the board in writing of any and all changes to its business location within 10 calendar days, with such notice to include both the previous and new addresses.
   3. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall not serve or be used as an additional or second permit.
   4. A DME provider changing ownership shall notify the board in writing 15 calendar days prior to the transfer of ownership.
      a. A change of ownership shall be evident under any of the following circumstances:
         i. Sale;
         ii. Death of a sole proprietor;
         iii. The addition or deletion of one or more partners in a partnership;
         iv. Bankruptcy sale; or
         v. A fifty (50) percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original DME permit
      b. The new owner shall submit a properly completed application form with all required attachments and appropriate fee to the board.

F. Renewal and Reinstatement of Permit
   1. The renewal of an active DME permit shall require the submission of a completed application form supplied by the board supplemented with any required attachments and appropriate fee, prior to the expiration date of the permit.
   2. The reinstatement of an expired DME permit shall require the submission of a completed application form supplied by the board supplemented with any required attachments as well as the renewal and reinstatement fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:502 (March 2013).

§2405. Standards of Practice

A. The DME provider shall not furnish any legend device or medical gas to a patient without a prescription or medical order from a licensed practitioner with prescriptive authority.

B. General Requirements
   1. The provider shall establish a suitable facility to house the equipment, allow for equipment maintenance work space, and contain sufficient space for the storage and retrieval of all required records.
   2. The provider shall maintain the facility in a clean, orderly and sanitary condition at all times.
   3. The facility shall be equipped with a functioning lavatory with hot and cold running water, or in the alternative, hand washing appliances or waterless hand cleaner are available.
   4. The facility shall comply with all local and state building laws and fire codes.
   5. The provider shall comply with all requirements from the United States Pharmacopeia (USP), the federal Food and Drug Administration (FDA), federal Department of Transportation (DOT) and Occupational Safety and Health Administration (OSHA) relative to the storage, packaging, labeling and shipping of DME including medical gases.

6. The provider shall staff the facility with an adequate number of qualified personnel to properly render DME services in the manner prescribed by law.
7. The provider shall make services continuously available without interruption when such services are essential to the maintenance of life or when the lack of services might reasonably cause harm.
8. The provider shall implement and maintain written procedures for handling complaints, and further, shall maintain a complaint file documenting all complaints and their resolution.

C. Requirements for Providers of Medical Gas, Oxygen and Respiratory Equipment

1. The provider shall comply with the following:
   a. When transporting medical gas or oxygen in cylinder or liquid form, comply with all current DOT rules;
   b. When trans-filling medical oxygen systems, comply with FDA and all state agency requirements regarding trans-filling and repackaging;
   c. Demonstrate that medical gas and oxygen provided in cylinder or liquid form meet minimum purity standards for medical grade gas or medical grade oxygen; and
   d. Adhere to the following safety inspection requirements:
      i. Demonstrate that each piece of oxygen or respiratory equipment has been checked, is free of defects, and operates within the manufacturer's specifications;
      ii. Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
      iii. Maintain all electrical components so they do not present fire or shock hazard; and
      iv. Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
2. The provider shall comply with the following recall procedures:
   a. Ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
   b. Maintain a tracking system for all medical gas and oxygen delivered;
   c. Document all equipment serial numbers and model numbers to ensure that equipment can be retrieved in the event a recall is initiated; and
   d. Maintain records for equipment that requires FDA tracking.
3. The provider shall comply with the following maintenance and cleaning requirements:
   a. Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set-up;
   b. Maintain and established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
   c. Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
   d. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment;
   e. Clean and disinfected equipment according to manufacturers' specifications;
   f. Instruct the patient or caregiver on proper cleaning techniques as specified by the manufacturer; and
   g. Ensure that all medical gas, oxygen and respiratory equipment are properly identified by a tag or label as to its current status of use, i.e., out-of-order or ready for use.
4. The provider shall implement a comprehensive preventive maintenance program which shall include the following:
   a. Procedures for problem reporting, tracking, recall, and resolution;
   b. Performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
   c. Routine inspection, service, and maintenance of equipment located in the patient's home according to the manufacturer's specifications.
5. The provider shall maintain repair logs to document repair and maintenance of equipment, and such logs shall contain the following information:
   a. Type of equipment;
   b. Manufacturer;
   c. Model;
   d. Serial number;
   e. Date of repair;
   f. Specific repair made; and
   g. Name of person or company performing the repair.

6. The provider shall maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.
7. The provider shall utilize client orientation checklists to review the following information with the patient or caregiver:
    a. Instructions for use of the equipment;
    b. Safety precautions;
    c. Cleaning procedures;
    d. Maintenance procedures;
    e. Return demonstration on back-up oxygen systems delivered;
    f. Instruction for emergency and routine contact procedures; and
    g. Delivery and review of written instruction materials to ensure the patient receives adequate information to properly operate the equipment.
8. A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, an assessment of the safety of the home environment, the ability of the patient or caregiver to comply with the prescription or medical order, and the ability of the patient or caregiver to operate and clean the equipment as instructed.

D. Requirements for Providers of Other Durable Medical Equipment
1. Providers who sell, rent or furnish DME or legend devices shall comply with the following:
    a. Provide proper training to personnel for the safe delivery and use of any DME or legend devices;
    b. Ensure that all manufacturer's recommended assembly and maintenance procedures are followed; and
    c. Adhere to the following safety inspection measures:
        i. Demonstrate that each piece of DME or legend device has been checked, is free of defect and operates within the manufacturer's specifications;
        ii. Refrain from modifying equipment to the extent that the modification might reasonably cause harm;
        iii. Maintain all electrical components so they do not present fire or shock hazard; and
        iv. Ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
2. The provider shall comply with the following maintenance and cleaning requirements:
    a. Maintain documentation demonstrating that a function and safety check of equipment was performed prior to set-up;
    b. Maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
    c. Maintain a Material Safety Data Sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
    d. Maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment;
    e. Clean and disinfect equipment according to manufacturers' specifications; and
    f. Instruct the patient or caregiver on proper cleaning techniques as specified by the manufacturer.

E. Records Management for All DME Providers
1. An electronic record keeping system shall be implemented and maintained by the provider. The system shall provide adequate safeguards against unauthorized access, manipulation or alteration, and further, shall be susceptible to reconstruction in the event of electronic or computer malfunction or an unforeseen accident resulting in the destruction of the system or the information contained therein.
2. All records required in this Chapter shall be retained for a minimum of two years from the last transaction.
3. All records required in this Chapter shall be available and readily retrievable upon request for board inspection and review. In particular, such records shall be produced within 72 hours of the request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:503 (March 2013).

§2407. Exemptions

A. The credentialing requirements of this Subchapter shall not apply to the following persons or entities unless such persons or entities have separate business entities engaged in the business of providing DME to patients at their home:
1. Chiropractors;

2. Dentists;
3. Occupational therapists;
4. Optometrists;
5. Physical therapists;
6. Physicians;
7. Podiatrists;
8. Respiratory therapists;
9. Speech pathologists;
10. Veterinarians;
11. Distributors;
12. Home health agencies;
13. Hospice programs;
14. Hospitals;
15. Long term care facilities;
16. Manufacturers; and
17. Pharmacies.

B. Pharmacies, long term care facilities and hospitals, although excluded from the credentialing requirements of this Subchapter, shall be subject to and comply with the standards of practice identified herein.

C. Nothing in this Subchapter shall be construed to prohibit the pre-hospital emergency administration of oxygen by licensed healthcare providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

AUTHORITY NOE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:504 (March 2013).

§2409. (Reserved)

Subchapter B. Special Event Pharmacy Permit

§2411. Special Event Pharmacy Permit

A. For good cause shown, the board may issue a special event pharmacy permit when the scope, degree, or type of pharmacy practice or service to be provided is of a special, limited, or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions as requested by the applicant and imposed by the board in cases where certain requirements or standards of practice may be waived.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1223.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:100 (January 2015).

§2413. General Requirements

A. Authority and Limitation

1. A special event pharmacy permit shall authorize the permit holder to procure and possess prescription and non-prescription drugs and devices, and hold such items for immediate administration directly to a patient and/or dispense such items to a patient for later use upon the order of a practitioner with prescriptive authority.
2. In the absence of a Louisiana controlled dangerous substance (CDS) license, the holder of a special event pharmacy permit shall not procure or possess any controlled dangerous substances.

B. Licensing Procedure

1. A person or other entity desiring to obtain a special event pharmacy permit shall complete the application form supplied by the board and submit it with any required attachments and the application fee to the board.
2. The applicant shall provide a complete physical address reflecting the location where the applicant will hold the drugs and devices and engage in the activity for which the permit is acquired. The board shall not issue more than one permit for the same physical space.
3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.

4. A person or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2).
5. Once issued, the special event pharmacy permit shall expire 30 days thereafter. No person or other entity shall operate s special event pharmacy with an expired permit; the continued operation of a special event pharmacy with an expired permit shall constitute a violation of R.S. 37:1241(A)(12). Upon written request to the board, and with the concurrence of the board's president and executive director, the expiration date of the special event pharmacy permit may be extended up to an additional 30 days. No special event pharmacy permit shall be valid for more than 60 days.

C. Maintenance of Permit
1. A special event pharmacy permit shall be valid only for the person or other entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a special event pharmacy permit be valid for any premises other than the physical location for which it is issued.
2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall not serve or be used as an additional or second permit.

D. Closure of Permit
1. At the conclusion of the special event, the permit holder shall terminate the dispensing and/or distribution of drugs and/or devices from the pharmacy.
2. Disposition of Inventory
   a. Controlled Dangerous Substances Listed in Schedule II. These drugs shall be either returned to the supplier or transferred to an authorized registrant accompanied by an executed DEA Form 222, or its successor. Alternatively, these drugs shall be inventoried on the DEA Form 41 (registrant's inventory of drugs surrendered), or its successor, and then either returned to the regional DEA office or destroyed, but only pursuant to permission from the DEA or agent of the board. The permit holder shall retain triplicate copies of returns, transfers, and/or destruction.
   b. Controlled Dangerous Substances Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by appropriate inventory records. Alternatively, these drugs shall be inventoried on the DEA Form 41, or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board.
   c. All Other Prescription and Non-prescription Drugs and/or Devices. These items shall be returned to the supplier, transferred to another registrant, or destroyed.
3. Surrender of Credentials and Board Notice
   a. When all drugs, devices, prescription records and/or other pharmacy records have been removed from the premises, the permit holder shall prepare and render a final closure notice to the board. The notice shall contain the following:
      i. disposition and destination of all drugs and/or devices held by the pharmacy;
      ii. disposition and destination of all prescriptions and medical orders dispensed or administered to patients;
      iii. disposition and destination of all other pharmacy records, including acquisition, inventory, and disposition records for all drugs and/or devices;
      iv. the commitment to store such records for no less than two years following the closure of the pharmacy, and further, to make such records available for inspection by the board no later than 72 hours following a request from the board.
      v. the certification that all signage indicating the presence of a pharmacy has been removed from the premises;
      vi. the confirmation of the surrender of any federal DEA registration held by the pharmacy to the regional DEA office; and
      vii. the original and all duplicate copies of the special event pharmacy permit, and if applicable, Louisiana CDS license.
   b. The pharmacist-in-charge of the special event pharmacy permit has the primary responsibility for the proper closure of the pharmacy permit. However, in the event the pharmacist-in-charge fails to complete the task, then the permit holder shall be responsible for the proper closure of the pharmacy permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:100 (January 2015).

§2415. Standards of Practice

A. General Requirements

1. The special event pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment, and supplies commensurate with the scope of practice for that pharmacy, provided:
    a. The pharmacy shall be of sufficient size to allow for the safe and proper storage of prescription drugs and, if applicable, controlled dangerous substances;
    b. 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 prior to their dispensing as stipulated by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board;
    c. The pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the pharmacist is not present; and
    d. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.
2. The pharmacist-in-charge of the special event pharmacy shall be responsible for all pharmacy operations including supervision of all pharmacy personnel.
3. The pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times the pharmacy is open for the transaction of business.
4. The pharmacy shall have a sufficient number of pharmacists and/or other pharmacy personnel on duty to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
5. When the pharmacy is closed or there is no pharmacist on duty, other individuals shall not have access to the pharmacy except for the temporary absences as provided for in Chapter 11 of these rules.
6. The special event pharmacy shall comply with the recordkeeping requirements identified in Chapter 11 of these rules.
7. The compounding of preparations in a special event pharmacy shall be accomplished in compliance with the current federal standards applicable to such practices: USP Chapter 795, or its successor, for the compounding of non-sterile preparations and USP Chapter 797, or its successor, for the compounding of sterile preparations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:101 (January 2015).

Subchapter C. Telepharmacy Services

§2421. Purpose

A. As market forces continue to adversely impact community pharmacies, some pharmacies have or will close permanently. In certain parts of the state, such closures create critical access issues for citizens in need of pharmacy services.

B. As the pharmacy workforce continues to evolve, with changing patterns of distribution of the workforce, certain parts of the state have experienced a shortage of pharmacists, which can adversely impact access to pharmacist care.

C. In an effort to improve access to pharmacist care and pharmacy services, the board has determined it appropriate to establish standards for the operation and regulation of telepharmacy services

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015).

§2423. Definitions

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

"Central pharmacy" – a permitted pharmacy in Louisiana that supervises a telepharmacy dispensing site.

"Still image capture" – a specific image captured electronically from a video or other image capture device.

"Store and forward" – a video or still image record which is saved electronically for future review.

"Telepharmacy dispensing site" – a permitted pharmacy supervised by a central pharmacy that offers pharmacy services using a telepharmacy system.

"Telepharmacy system" – a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

a. Audio and video;
b. Still image capture; and
c. Store and forward

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015).

§2425. Telepharmacy Dispensing Site

A. General Requirements
   1. At the time of its opening, there shall be no other pharmacies licensed by the board within 15 miles (driving distance) of the location of the telepharmacy dispensing site. This mileage restriction shall not apply if a demonstration of need is presented to the board and a waiver to the mileage restriction is deemed appropriate.
   2. A telepharmacy dispensing site permit shall authorize the permit holder to procure and possess prescription and non-prescription drugs and devices, and:
      a. hold such items for immediate administration directly to a patient pursuant to an order from a lawful prescriber;
      b. dispense such items to a patient for later use upon the order of a practitioner with prescriptive authority; or
      c. distribute such items to another entity with lawful authority to procure and possess such items.
   3. In the event the telepharmacy dispensing site intends to procure and possess any controlled substances, that pharmacy shall first obtain a Louisiana Controlled Dangerous Substance license as well as the federal registration from the U.S. Drug Enforcement Administration.
   4. The telepharmacy dispensing site shall operate using a telepharmacy system under the control of its supervising central pharmacy.
   5. A central pharmacy may supervise no more than two telepharmacy dispensing sites, and all such sites must be located within the state of Louisiana.
   6. The minimum staffing requirement for a telepharmacy dispensing site shall be a Louisiana-licensed certified pharmacy technician with at least two years of experience as a Louisiana-licensed certified pharmacy technician and with demonstrated proficiency in operating the telepharmacy system used in the telepharmacy dispensing site.
   7. A pharmacist shall approve each prescription before it is taken away from the telepharmacy dispensing site.

B. Licensing Procedure
   1. A person or other entity intending to operate a telepharmacy dispensing site shall complete the application form supplied by the board, and then submit it with any required attachments and the application fee to the board.
   2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
   3. A person or other entity who submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2) and shall be subject to disciplinary action by the board.
   4. If determined appropriate by the board, the applicant may be required to meet with a committee of the board or an agent of the board prior to the issuance of the permit.
   5. Regardless of the date issued, the pharmacy permit shall expire on December 31 of every year. No person or other entity may operate a telepharmacy dispensing site with an expired permit; the continued operation of a telepharmacy dispensing site with an expired permit shall substantiate a violation of R.S. 37:1241(A)(12).
   6. In the event a telepharmacy dispensing site is dispensing more than 100 prescriptions per day based on a six-month average, the telepharmacy dispensing site shall convert its permit to a community pharmacy permit prior to the expiration date of the telepharmacy dispensing site permit.

C. Maintenance of Permit
   1. A telepharmacy dispensing site permit shall be valid only for the person or other entity to whom it is issued, and it shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the physical location for which it was issued.

2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall be marked as such, and it shall not serve or be used as an additional or second permit.

D. Closure of Permit
   1. When the owner of the permit intends to close the telepharmacy dispensing site permanently, the owner's managing officer and the pharmacist-in-charge shall be accountable to the board for the proper closure of the pharmacy in compliance with Section 1133 of the board's rules.
   2. Unless approved by the board in advance, all remaining inventory and records shall be transferred to the central pharmacy supervising that telepharmacy dispensing site.

E. Standards of Practice
   1. Environmental Standards
      a. The prescription department shall consist of an area at least 300 square feet in size; this space shall be restricted to authorized personnel only and not accessible to the general public.
      b. The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
      c. The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal.
      d. 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 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.
      e. The prescription department shall be secured by a physical barrier with suitable locks and a monitored alarm system capable of detecting unauthorized entry.
      f. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information; and
      g. The dispensing site shall be configured and equipped to sustain optimal operation of all the technological components of the telepharmacy system.
   2. Minimum Staffing Requirements
      a. The pharmacist-in-charge of the supervising central pharmacy shall be the pharmacist-in-charge of the telepharmacy dispensing site, and this requirement shall operate as an exception to the provisions of Section 1105.A.2 and Section 1105.K of the board's rules. However, the pharmacist-in-charge shall comply with the remaining provisions of Section 1105 of the board's rules.
      b. The telepharmacy dispensing site does not require the personal presence of a pharmacist, but it is permissible for a pharmacist to practice in that site.
      c. In the absence of a pharmacist, the site shall be staffed by one – and only one – Louisiana-licensed certified pharmacy technician. The technician present at the telepharmacy dispensing site shall be included with the other personnel at the supervising central pharmacy when calculating the ratio of pharmacists to technicians.
      d. A pharmacy intern may not practice at a telepharmacy dispensing site.
      e. Additional clerical personnel may also be present at the site.
   3. Operational Standards
      a. The telepharmacy dispensing site shall comply with the provisions of Chapters 11, 25, 27, and 29 of the board's rules except when this Subchapter grants exceptions or imposes more stringent requirements.
      b. The telepharmacy dispensing site shall be connected to its supervising central pharmacy using the telepharmacy system.
      c. In the event of an interruption in the proper operation of the telepharmacy system, the telepharmacy dispensing site must immediately cease operations. No prescription shall be dispensed during the interruption, and further, the staff shall post a sign at the entrance advising the public of an estimated date or time of resumption of services.
      d. The dispensing of prescriptions shall be construed as completed at the central pharmacy; therefore, the telepharmacy dispensing site shall use the central pharmacy's dispensing information system.
      e. The telepharmacy system shall permit prescription labels to be generated from the central pharmacy or the telepharmacy dispensing site.
         i. New prescriptions may be received and entered at the central pharmacy with a label printed at the telepharmacy dispensing site; or
         ii. New prescriptions received at the telepharmacy dispensing site may be entered by the technician with all verification, utilization review, and final check the responsibility of the pharmacist at the central pharmacy.

f. As part of the final check, the pharmacist shall verify the source container, prescription medication, and prescription label against the prescription form, using the technology in the telepharmacy system.
g. A pharmacist shall counsel the patient or patient's agent for all new prescriptions and refills, using the technology in the telepharmacy system.
h. The pharmacist-in-charge shall be responsible for routine inspection of the telepharmacy dispensing site. The policies and procedure shall identify the inspection criteria to be monitored. Each inspection shall be conducted no later than 30 days after the previous inspection. The inspection reports detailing the findings of each inspection shall be retained for at least two years, and further, shall be readily retrievable upon request by the board or its agent.

4. Recordkeeping Requirements
   a. The dispensing information system shall be capable of recording the names or initials of the pharmacist responsible for final verification of the prescription as well as the technician assisting in the dispensing process, and to print those identities on the prescription label.
   b. Prescriptions filled at the telepharmacy dispensing site shall be distinguishable on records from those filled at the central pharmacy.
   c. Records of activities at the telepharmacy dispensing site shall be distinguishable from the records of activities at the central pharmacy.
   d. Telepharmacy dispensing sites holding controlled substances shall maintain a perpetual inventory of controlled dangerous substances and drugs of concern.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 21:2149 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 46:586 (April 2020).

Subchapter D. Remote Processor Pharmacy

§2431. Purpose

A. The purpose of this Subchapter is to establish standards for the operation and regulation of remote processor pharmacies to be located within the state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2148 (October 2015).

§2433. Definitions

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

"On-Site Pharmacy" – a permitted pharmacy which utilizes remote processing services from a remote processor pharmacy.

"Remote Processing Services" – the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:

a. Receipt, interpretation, or clarification of an order;
b. Data entry and information transfer;
c. Interpretation of clinical data;
d. Performance of drug utilization review; and
e. Provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.

"Remote Processor" – a pharmacy holding a remote processor pharmacy permit and provides remote processing services for another permitted pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2148 (October 2015).

§2435. General Requirements

A. Authority and Limitations
   1. A remote processor pharmacy permit shall authorize the permit holder to engage in remote processing services.
   2. A remote processor pharmacy permit shall not authorize the procurement or possession of any prescription medications or any controlled substances.
   3. The holder of a remote processor pharmacy permit shall not be eligible to acquire a Louisiana Controlled Dangerous Substances license or a federal registration from the U.S. Drug Enforcement Administration.

B. Licensing Procedure
   1. A person or other entity intending to operate a remote processor pharmacy shall complete the application form supplied by the board, and then submit it with any required attachments and the application fee to the board.
   2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
   3. A person or other entity who submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2) and shall be subject to disciplinary action by the board.
   4. If determined appropriate by the board, the applicant may be required to meet with a committee of the board or an agent of the board prior to the issuance of the permit.
   5. Regardless of the date issued, the pharmacy permit shall expire on December 31 of every year. No person or other entity may operate a remote processor pharmacy with an expired permit; the continued operation of a remote processor pharmacy with an expired permit shall substantiate a violation of R.S. 37:1241(A)(12).

C. Maintenance of Permit
   1. A remote processor pharmacy permit shall be valid only for the person or other entity to whom it is issued, and it shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the physical location for which it was issued.
   2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall be marked as such, and it shall not serve or be used as an additional or second permit.

D. Closure of Permit
   1. When the owner of the permit intends to close the remote processor pharmacy permanently, the owner's managing officer and the pharmacist-in-charge shall be accountable to the board for the proper closure of the pharmacy in compliance with Section 1133 of the board's rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2148 (October 2015).

§2437. Standards of Practice

A. Environmental Standards
   1. The remote processor pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
   2. The pharmacy shall be well-lighted, well ventilated and in compliance with the Louisiana Sanitary Code.
   3. The pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry by unauthorized personnel.
   4. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.

B. Staffing Requirements
   1. The pharmacist-in-charge shall be a Louisiana-licensed pharmacist who is accountable to the board for compliance with the provisions of Section 1105 of the board's rules.
   2. The pharmacist-in-charge shall assemble and manage a staff of appropriately-credentialed people as necessary to perform its work in a safe manner.
   3. For those pharmacies using pharmacy interns, pharmacy technicians, and pharmacy technician candidates, the staffing ratios cited in the board's rules are applicable to those types of personnel.

C. Operations
   1. The remote processor pharmacy shall comply with the provisions of Section 1143 of the board's rules.
   2. The remote processor shall comply with the recordkeeping provisions of Section 1123 of the board's
   3. rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015).

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 Board of Pharmacy was directed to:
   1. Develop an annual, nontransferable specialty license for a pharmacy to dispense recommended marijuana for therapeutic use, to limit the number of such licenses to a maximum of 10, and to adopt rules regarding the geographical locations of dispensing pharmacies in the state; and
   2. Adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such rules to include, at a minimum, the following:
      a. Standards, procedures, and protocols for the effective use of recommended marijuana for therapeutic use as authorized by state law and related rules;
      b. Standards, procedures, and protocols for the dispensing and tracking of recommended therapeutic marijuana;
      c. Procedures and protocols to provide that no recommended therapeutic marijuana may be dispensed from, produced from, obtained from, sold to, or transferred to a location outside of this state;
      d. Standards, procedures, and protocols for determining the amount of usable recommended therapeutic marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amount for topical treatments;
      e. Standards, procedures, and protocols to ensure all recommended therapeutic marijuana dispensed is consistently pharmaceutical grade;
      f. Standards and procedures for the revocation, suspension, and nonrenewal of licenses;
      g. Other licensing, renewal, and operational standards deemed necessary by the Board of Pharmacy;
      h. Standards and procedures for testing recommended therapeutic marijuana samples for levels of tetrahydrocannabinols (THC) or other testing parameters deemed appropriate by the Board of Pharmacy;
      i. Standards for the protection of health, safety, and security for dispensers of recommended therapeutic marijuana;
      j. Standards for the licensure of dispensers of recommended therapeutic marijuana; and
      k. Standards for financial capacity to operate a marijuana pharmacy.

B. Marijuana is classified as a Schedule I controlled substance by the U.S. Department of Justice, Drug Enforcement Administration.
   1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing, distribution, dispensing, or administering of any Schedule I controlled substance, including marijuana, is a violation of federal law.
   2. Neither Louisiana law nor this Part can preempt federal law. Therefore, the provisions of this Subchapter notwithstanding, persons engaged in the activities described herein remain subject to the full force of federal law enforcement, including arrest and prosecution of criminal charges, the assessment of civil fines and forfeitures, as well as administrative consequences such as forfeiture of federal controlled substance registrations and exclusion from Medicare and other federal payer programs.

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017)

§2441. Definitions

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

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

Advertisement – all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana, excluding

information of an educational nature designed to inform citizens of the nature and form of the state's therapeutic marijuana program and its legally permitted products.

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

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

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

Approved Vault:

a. A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or
b. A vault constructed after September 1, 1971:
    i. The walls, floors, and ceilings of which are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
    ii. The door and frame unit of which vault shall conform to the following specifications or the equivalent:
        (a) 30 man-minutes against surreptitious entry;
        (b) 10 man-minutes against forced entry;
        (c) 20 man-hours against lock manipulation; and
        (d) 20 man-hours against radiological techniques;
    iii. Which vault, if operations require it to remain open for frequent access, is equipped with a "day gate" which is self-closing and self-locking or the equivalent, for use during the hours of operation in which the vault door is open;
    iv. The walls or perimeter of which are equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve, and if necessary, alarm buttons at strategic points of entry to the perimeter area of the vault;
    v. The door of which shall be equipped with one or more contact switches; and
    vi. Which vault has one of the following:
        (a) Complete electrical lacing of the walls, floor and ceiling;
        (b) Sensitive ultrasonic equipment within the vault;
        (c) Sensitive sound accumulator system; or
        (d) Such other device designed to detect illegal entry as may be approved by the board.

Board – the Louisiana Board of Pharmacy.

CFR – the Code of Federal Regulations.

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

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

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

LDAF – the Louisiana Department of Agriculture and Forestry.

LDH – the Louisiana Department of Health.

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

Marijuana – all parts of plants of the genus *Cannabis*, whether growing or not, the seeds thereof, the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of

such plant, its seeds or resin, but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination, or cannabidiol when contained in a drug product approved by the United States Food and Drug Administration.

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

Marijuana Pharmacy Owner – any person with an ownership interest in a marijuana pharmacy, except the term does not include a person with an investment interest through a publicly-held company provided the interest held by such person does not exceed 5 per cent of the total ownership or interest rights in such pharmacy and such person does not participate directly or indirectly in the control, management, or operation of the pharmacy.

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

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

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

a. Processed, packaged and labeled according to the United States Food & 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.

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

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

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 Department of Agriculture and Forestry to cultivate marijuana for therapeutic use.

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

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

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

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended LR 45:1473 (October 2019).

§2443. Marijuana Products

A. Exclusive Source.
   1. The exclusive source of marijuana products shall be the producer licensed for that activity by the Department of Agriculture and Forestry (LDAF).
   2. That producer shall prepare pharmaceutical grade marijuana products for distribution to the marijuana pharmacies licensed by the board.

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

B. Laboratory Testing.

1. Prior to manufacturing any marijuana product, the producer shall segregate all harvested marijuana into homogenized batches.
2. A producer shall make available each such batch at the production facility for testing by a laboratory approved by LDAF. The laboratory employee shall select a random sample from each batch.
   a. Medical marijuana concentrate shall not be used to produce any form of product until it has passed all analysis limits for:
      i. Active ingredient analysis for characterization of potency;
      ii. Pesticide active ingredients, including but not limited to, the most recent list of targeted pesticides published by LDAF;
      iii. Residual solvents;
      iv. Heavy metals; and
      v. Mycotoxins.
   b. Product shall not be released for delivery to a pharmacy for sale or consumption until it has passed all analysis limits for:
      i. Microbiological contaminants;
      ii. Active ingredient analysis for accuracy of potency; and
      iii. Homogeneity.
   c. LDAF personnel may select a random sample at any point in the process for the purpose of analysis for anything the LDAF deems necessary.
   d. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for the analyses being conducted.
3. From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a pharmacy until the laboratory provides the results from its tests and analyses, the producer shall segregate and withhold from use the entire batch with the exception of the samples removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a pharmacy prior to the time the laboratory has completed its testing and analysis and provided those results, in written or electronic form, to the producer or the producer's designated employee.
4. Testing Specifications
   a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the recommended microbial and fungal limits for cannabis products as follows:
      i. Total yeast and mold: < 10,000 colony-forming units per gram (CFU/g); and
      ii. E. coli (pathogenic strains) and Salmonella *spp*: < 1 CFU/g.
   b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it meets the following standards:
      i. Aflatoxin b1 < 20 parts per billion (ppb);
      ii. Aflatoxin b2 < 20 ppb;
      iii. Aflatoxin g1 < 20 ppb;
      iv. Aflatoxin g2 < 20 ppb; and
      v. Ochratoxin < 20 ppb.
   c. With respect to the heavy metals test, a marijuana sample shall be deemed to have passed if it meets the following standards:
      i. Arsenic < 10 parts per million (ppm);
      ii. Cadmium < 4.1 ppm;
      iii. Lead < 10 ppm; and
      iv. Mercury < 2 ppm
   d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the United States Environmental Protection Agency's "Tolerances and Exemptions for Pesticide Chemical Residues in Food", as found in 40 CFR 180 or its successor.
   e. With respect to the residual solvent test, a marijuana sample shall be deemed to have passed if the following solvents are below the listed limits:
      i. Butanes < 800 ppm;

ii. Heptanes < 500 ppm;
iii. Benzene < 1 ppm;
iv. Toluene < 1 ppm;
v. Hexanes < 10 ppm;
vi. Total Xylenes < 1 ppm; and
vii. Ethanol < 5,000 ppm.

f. With respect to the test for homogeneity, a marijuana sample shall be deemed to have failed if 10 percent of the sample contains more than 20 percent of the total active ingredient.

g. Every sample shall undergo an active ingredient analysis or potency analysis.

i. For medical marijuana concentrate samples, the potency test is to establish the presence of active ingredients and their concentrations for accurate calculations of amounts needed for the production of products. The analysis must identify the following substances:
(a) THC (tetrahydrocannabinol);
(b) THCA (tetrahydrocannabinolic acid);
(c) CBD (cannabidiol); and
(d) CBDA (cannabidiolic acid).

ii. For product samples, the potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing. The maximum variance permitted is 15 percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC.

5. Procedures for Sample Failures

a. In the event a medical marijuana concentrate sample fails testing for pesticides, heavy metals or mycotoxin, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

b. In the event a medical marijuana concentrate sample fails residual solvent testing, then, with prior approval of LDAF, the product may be subjected to an appropriate remedy, e.g., vacuum drying, reformulated and tested again. The reformulation must pass all required tests for a medical marijuana concentrate in duplicate before it can be released for use in products. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF. A batch of medical marijuana concentrate can only be reformulated once and only to remedy excessive residual solvents.

c. In the event a product fails the microbiological testing, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

d. In the event a product fails the potency or homogeneity testing, then, with prior approval of LDAF, the product can be re-sized and tested again. The reformulated product shall be tested again in duplicate and pass all required tests before it can be released for sale or consumption. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF.

6. In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such test result at the same time it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results including all relevant chromatograms and quality control documentation for at least five years and make them available to LDAF at its request.

7. The laboratory shall dispose of any remaining medical marijuana concentrate or product samples no sooner than 60 days following the completion of any testing, in compliance with the disposal rules promulgated by LDAF.

8. A producer shall provide the laboratory test results to the marijuana pharmacy for each batch of marijuana used in a product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and physicians who recommended such marijuana products dispensed to their patients.

C. Product Dosage Forms.

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

a. Oils, extracts, tinctures, or sprays;
b. Solid oral dosage forms, e.g., capsules or pills;
c. Liquid oral dosage forms, e.g., solutions or suspensions;
d. Gelatin-based chewables;
e. Topical applications, oils or lotions;
f. Transdermal patches;

g. Suppositories; or
h. Metered-dose inhalers.

2. No marijuana product shall:
   a. Include alcoholic liquor, dietary supplements, or any drug, except for pharmaceutical grade marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than 0.5 percent of alcohol by volume, or ethanol-based tinctures;
   b. Be manufactured or sold as a beverage;
   c. Be manufactured or sold in a form or with a design that:
      i. Is obscene or indecent;
      ii. May encourage the use of marijuana for recreational purposes;
      iii. May encourage the use of marijuana for a condition other than a debilitating medical condition; or
      iv. Is customarily associated with persons under the age of 18 years; or
   d. Have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved by the Commissioner of LDAF.
3. Any marijuana product not in compliance with the provisions of this Paragraph shall be deemed adulterated.

D. Packaging and Labeling Requirements.
1. Packaging.
   a. The producer shall ensure every product intended for dispensing to a patient is placed within a child-resistant, light-resistant, tamper-evident container prior to sale or transport to the pharmacy.
      i. A package shall be deemed child-resistant if it satisfies the standard for 'special packaging' as set forth in the United States Consumer Product Safety Commission's "Poison Prevention Packaging" as found in 16 CFR 1700.1(b)(4) or its successor.
      ii. A package shall be deemed light-resistant if it satisfies the standard set forth in "Chapter 671 – Containers: Performance Testing" of the *United States Pharmacopeia* (USP).
      iii. A package shall be deemed tamper-evident if it clearly indicates prior access to the container.
   b. No single container shall contain more than a one-month supply of marijuana.
   c. Packaging selected by the producer shall be subject to the following restrictions.
      i. Shall not specifically target individuals under the age of 18 years;
      ii. Shall not bear any resemblance to a trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;
      iii. Shall not use the words "candy" or "candies";
      iv. Shall not use a cartoon, color scheme, image, graphic or feature that might make the package attractive to children; and
      v. Shall not use a seal, flag, crest, coat of arms or other insignia that could reasonably lead any person to believe the product has been endorsed, manufactured by, or used by any state, parish, municipality, or any agent thereof.
2. Labeling.
   a. Each product shall be labeled by the producer prior to its sale to the marijuana pharmacy. Each label shall be securely affixed to the package and shall include, at a minimum:
      i. The batch or lot number assigned by the producer to the marijuana plant(s) from which the marijuana used in the product was harvested;
      ii. A complete list of solvents, chemicals, and pesticides used in the creation of any marijuana concentrate;
      iii. A complete list of all ingredients used to manufacture the product, which may include a list of any potential allergens contained within, or used in the manufacture of, a product;
      iv. The potency of the THC and CBD in the product, expressed in milligrams for each cannabinoid;
      v. The net weight, using a standard of measure compatible with the LMMTS, of the product prior to its placement in the shipping container;
      vi. A product expiration date, upon which the product will no longer be fit for use. Once a label with an expiration date has been affixed to a product, the producer shall not alter that date or affix a new label with a later date; and
      vii. A statement the product has been tested for contaminants, that there were no adverse findings, and the date of such testing.
      viii. A product identification code registered with the board.
   b. The labeling text on any marijuana product shall not make any false or misleading statements regarding health or physical benefits to the consumer. Further, each label shall include all of the following statements:

i. “Contains Marijuana. For Medical Use Only. KEEP OUT OF THE REACH OF CHILDREN.”
ii. “Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug.”
iii. “There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning to become pregnant.”
iv. A statement that it is illegal for any person to possess or consume the contents of the package other than the patient for whom it was recommended.

c. The labeling text required by this Section shall be no smaller than 1/16 of an inch, shall be printed in English, and must be unobstructed and conspicuous.

d. The producer may utilize a package insert which is enclosed or attached to the product container to provide the information required in this Section. If the producer elects to use such supplementary labeling, the label affixed to the outer surface of the product container shall contain the following information, at a minimum
i. the batch or lot number referenced at Clause D.2.a.i of this Section;
ii. the potency of the THC and CBD referenced at Clause D.2.a.iv of this Section;
iii. the net weight referenced at Clause D.2.a.v of this Section;
iv. the expiration date referenced at Clause D.2.a.vi of this Section; and
v. the caution statement referenced at Clause D.2.b.i of this Section.

E. Distribution of Marijuana Products to Marijuana Pharmacies.

1. The producer shall maintain complete inventory records in the Louisiana Medical Marijuana Tracking System (LMMTS), as required and delineated in rules promulgated by LDAF.
2. The producer shall maintain comprehensive records in LMMTS of all marijuana products distributed to the marijuana pharmacies, whether by transport and delivery to the pharmacy or by transfer to the agent of the pharmacy at the production facility.
3. In the event the producer delivers the products to the pharmacy, such activities must be in compliance with the rules for that activity promulgated by LDAF.
4. In the event the pharmacy elects to send an agent to the production facility to retrieve products ordered by the pharmacy, the personnel at the production facility shall verify the identity and credentials of the pharmacy’s agent before releasing the products to the agent.
   a. The producer shall provide a copy of the transport manifest generated by LMMTS, which shall contain the following information:
      i. The name and address of the producer selling the product;
      ii. The name and address of the pharmacy purchasing the product;
      iii. The name and quantity (by weight or unit) of marijuana products included in the delivery;
      iv. The date of transport and time of departure from the production facility;
      v. The make, model, and license plate number of the delivery vehicle;
      vi. The date and time of arrival at the pharmacy; and
      vii. The name and signature of the pharmacy’s agent.
   b. The pharmacy’s agent shall compare the transport manifest to the products transferred to his possession, and when correct, shall return a signed copy of the manifest to the producer before departing from the production facility.
   c. The pharmacy’s agent shall place the products in a locked, safe, and secure storage compartment that is part of the motor vehicle, or in the alternative, in a locked storage container that has a separate key or combination pad, and further, the product shall not visible or recognizable from outside the vehicle, and further, the vehicle shall not bear the name of the pharmacy or any markings to indicate the vehicle contains marijuana
   d. The pharmacy’s agent shall maintain physical control of the vehicle at all times during the transport, and shall not leave the vehicle unattended at any time.
   e. The pharmacy’s agent shall have access to a secure form of communication with the pharmacy as well as the ability to contact law enforcement through the 911 emergency system.
   f. Upon arrival at the pharmacy, the pharmacy’s agent shall deliver the product to a pharmacist for verification of receipt; the pharmacist shall time, date, and sign the delivery manifest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR 45:1473 (October 2019), LR 46:568 (April 2020).

§2445. Marijuana Pharmacy Permit

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

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

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

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

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

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

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

1. *Metropolitan*, composed of the parishes of Jefferson, Orleans, Plaquemines, and St. Bernard;
2. *Capitol*, composed of the parishes of Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton Rouge, and West Feliciana;
3. *Teche*, composed of the parishes of Assumption, Lafourche, St. Charles, St. James, St. John, St. Mary, and Terrebonne;
4. *Acadian*, composed of the parishes of Acadia, Evangeline, Iberia, Lafayette, St. Landry, St. Martin, and Vermilion;
5. *Southwest*, composed of the parishes of Allen, Beauregard, Calcasieu, Cameron, and Jefferson Davis;
6. *Central*, composed of the parishes of Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon, and Winn;
7. *Northwest*, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster;
8. *Northeast*, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, and West Carroll; and
9. *Southeast*, composed of the parishes of Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington.

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

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

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

J. 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.

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

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

§2447. Licensing Procedures

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:
    a. Within the two-year period preceding the date of the application, the person or any member of the person's immediate family served as a member of the board or its staff.
5. The applicant shall provide a complete street address reflecting the location at which the applicant proposes to operate the marijuana pharmacy.
6. The applicant shall provide the following information and records in the application process:
    a. A detailed description of any other services or products to be offered by the marijuana pharmacy;
    b. Details regarding the applicant's plans to maintain adequate control against the diversion, theft, or loss of marijuana;
    c. Documents or information sufficient to establish the applicant is authorized to conduct business in Louisiana and that all applicable state and local building, fire and zoning requirements, and local ordinances will be met;
    d. Text and graphic materials showing the exterior appearance of the proposed marijuana pharmacy and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;
    e. A blueprint of the proposed marijuana pharmacy which shall, at a minimum, show and identify:
        i. The square footage of the area which will constitute the prescription department;
        ii. The square footage of the overall marijuana pharmacy;
        iii. The square footage and location of areas used as storerooms or stockrooms;
        iv. The size of the counter that will be used for the dispensing and sale of marijuana;
        v. The location of the marijuana pharmacy sink and refrigerator, if any;
        vi. The location of all approved safes and vaults that will be used to store marijuana;
        vii. The location of the toilet facilities;
        viii. The location of the break room and location of lockers for personal belongings;
        ix. The location and size of the patient counseling area(s);
        x. The location(s) where any other products or services will be offered; and
        xi. The location of all areas that may contain marijuana showing the location of walls, partitions, counters, and all areas of ingress and egress.
    f. Such other documents and information reasonably required by the board to determine the applicant's suitability for permitting or to protect the public's health and safety.
7. The owner's managing officer and the pharmacist-in-charge shall be fully identified within the application and they both shall sign and date the application form.
8. The applicant shall direct the following persons to submit to the criminal history record check process used by the board, at the applicant's expense:
    a. The owner's managing officer;
    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 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 marijuana pharmacy, including but not limited to, evidence of his

escrow account, letter of credit, or surety bond of at least $100,000 in a financial institution headquartered in Louisiana.

a. The pharmacy's $100,000 escrow account, letter of credit, or surety bond shall be payable to the board in the event the board determines after a due process hearing that the pharmacy has failed to timely and successfully complete the construction of the pharmacy or to operate such pharmacy in compliance with the provisions of this Subchapter.
b. The board shall permit the pharmacy's escrow account, letter of credit, or surety bond to be reduced by $25,000 upon the successful achievement of each of the following milestones"
    i. A determination by the board that the pharmacy is fully operational and able to commence and has begun dispensing of marijuana as provided in this Subchapter;
    ii. A determination by the board that the pharmacy remained operational and without substantial interruption and without any violation of law or regulation for a one year period; and
    iii. A determination by the board that the pharmacy remained operational and without substantial interruption and without any violation of law or regulation for a second one year period.
    iv. The pharmacy shall maintain the escrow account, letter of credit, or surety bond for a minimum of $25,000 for the remainder of its operation.
c. In the event a pharmacy voluntarily chooses not to renew the pharmacy permit and follows proper closure procedures, the board shall extinguish the obligations under the escrow account, letter of credit, or surety bond at the end of the permit's term.

11. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the application processing or permit selection process.
12. The board may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a marijuana pharmacy. The board may verify the information and assess the applicant's character and fitness by, among other actions:
    a. Contacting the applicant by telephone, electronic mail, mail, or such other means as is reasonable under the circumstances;
    b. Conducting one or more on-site visits of the location for the proposed marijuana pharmacy, or other pharmacies associated with the applicant or any of the applicant's owners;
    c. Conducting background checks or contacting references of the applicant, its managing officer, any of the corporate officers, or any shareholder, as well as the pharmacist-in-charge;
    d. Contacting state regulators in any other states where the applicant, the applicant's owners or corporate officers, or its pharmacist-in-charge are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; or
    e. Requiring a personal meeting with the owner's managing officer and the pharmacist-in-charge and the submission of additional information or documents.
13. The application shall be accompanied by payment of the permit fees and administrative hearing fee authorized by R.S. 37:1184 and 40:1013.
14. When the staff has determined an entity's application package is complete, the application shall be referred to the board's Application Review Committee, and further, the applicant shall be properly notified at least 30 days prior to the committee's hearing during which their application will be considered.
15. During the hearing held by the board's Application Review Committee, the members shall consider, but are not limited to, the following criteria when evaluating an application for a marijuana pharmacy permit:
    a. The character and fitness of the owner's managing officer, the pharmacist-in-charge, any of the owners and any other person who may have control or influence over the operation of the proposed marijuana pharmacy;
    b. The location for the proposed marijuana pharmacy including, but not limited to:
        i. Its proximity to previously approved marijuana pharmacies or locations of proposed marijuana pharmacies with pending applications;
        ii. Whether the patient population in the area proposed by the marijuana pharmacy permit applicant justifies the need for a marijuana pharmacy, or an additional marijuana pharmacy, in that area;
        iii. Whether the proximity of the proposed marijuana pharmacy will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment; or
        iv. Whether the number of marijuana pharmacies in the locality is such that the granting of a permit is detrimental to the public interest. In reaching a conclusion in this respect, the board may consider the population of, the number of like permits and number of all permits existent in, the

particular municipality and the immediate neighborhood concerned, the effect that a new permit may have on such town or neighborhood or on like permits existent in such municipality or neighborhood.

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

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

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

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

16. Following their evaluation of the applications for a marijuana pharmacy permit, the committee shall develop a recommendation for presentation to the board at the board's next meeting. The board may accept the committee's recommendation, select an alternative applicant, reject all of the applicants, or return all the applicants to the committee for their reconsideration.
17. The board may disqualify any applicant who:
    a. Submits an incomplete, false, inaccurate, or misleading application;
    b. Fails to submit an application by the published deadline; or
    c. Fails to pay all applicable fees.
18. The decision of the board to award or not to award a marijuana pharmacy permit to an applicant shall be final.
19. Upon the approval of an application, the board shall award the marijuana pharmacy permit and state controlled dangerous substance license to the applicant. Upon completion of a satisfactory inspection of the premises, the board shall issue the marijuana pharmacy permit and state controlled dangerous substance license to the applicant awarded the permit.
20. If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such pharmacy within 310 days of being notified of the marijuana pharmacy permit award, the board may, in the board's discretion, rescind such marijuana pharmacy permit, unless such delay was caused by force majeure. A marijuana pharmacy shall be deemed to have commenced operation if the pharmacy is capable of operating in accordance with the applicant's approved application. In the event a marijuana pharmacy permit is rescinded pursuant to this Subsection, the board shall award a marijuana pharmacy permit by selecting among the qualified applicants who applied for the marijuana pharmacy permit that was rescinded. If no other qualified applicant applied for such marijuana pharmacy permit or satisfied the criteria for awarding a permit, the board shall publish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.

B. Application for Renewal of Permit

1. All marijuana pharmacy permits expire at midnight on December 31 of every year, regardless of the date of its initial issuance.
2. The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall complete, sign and date a permit renewal application form supplied by the board, and further, shall include all information requested on the form and attach the pharmacy permit renewal fee and state controlled dangerous substance license renewal fee authorized in R.S. 37:1184 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.
3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
4. In the event the pharmacy does not submit a properly completed renewal application form and fee to the board prior to the expiration of the permit, the permit shall be rendered null and void. A marijuana pharmacy shall not operate with an expired permit. Evidence it has done so will provide sufficient basis for the board to discipline the permit for violation of R.S. 37:1241(A)(12).
5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the board office no later 30 thirty 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 is included with the application.
6. A marijuana pharmacy permit not renewed by 30 days after the expiration date shall be automatically terminated by the board.
7. An application for the reinstatement of a terminated marijuana pharmacy permit shall be referred to the board's Reinstatement Committee for its consideration.

C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits
   1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee, the delinquent fee, the administrative hearing fee, and the reinstatement fees authorized in R.S. 37:1184 and the program fee authorized in R.S. 40:1013.
   2. An application for the reinstatement of a marijuana pharmacy permit previously terminated, suspended or revoked by the board may only be approved following a preliminary hearing to determine whether the reinstatement of the permit is in the public's best interest.

D. Maintenance of Marijuana Pharmacy Permit
   1. A marijuana pharmacy permit is valid only for the entity or person to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the business location recorded thereon.
   2. A duplicate or replacement permit shall be issued upon the written request of the licensee and payment of the fee authorized in R.S. 37:1184. A duplicate or replacement license shall not serve or be used as an additional or second license.
   3. Prior to any person affiliating with a marijuana pharmacy, including any change in the ownership of the permit, such person shall comply with the credentialing requirements of the board. No person shall commence their affiliation with a marijuana pharmacy until approved by the board.
   4. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the permit shall notify the board and request approval of the contemplated name or trade name. The board shall reasonably accommodate such requests, unless there is cause not to do so, e.g., duplicative or misleading names. The marijuana pharmacy shall not change its name or trade name until approved by the board.
   5. Prior to any modification, remodeling, expansion, reduction, other physical, non-cosmetic alteration of the marijuana pharmacy, the owner of the permit shall notify the board and request approval of the contemplated change(s). The board shall reasonably accommodate such request, unless there is cause not to do so, e.g., inconsistent with operating requirements. The marijuana pharmacy shall not make such changes until approved by the board.
   6. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit an application form for that purpose supplied by the board and pay the appropriate fee authorized in R.S. 37:1184. The board may require an inspection of the new location prior to the issuance of the permit for the new location. No marijuana pharmacy shall commence operation in a new location until approved by the board.
   7. The owner of the pharmacy permit shall notify the board no later than 10 days following a change in the pharmacist-in-charge for the marijuana pharmacy permit.
   8. The owner of the pharmacy permit shall notify the board no later than 10 days following a change in the owner's managing officer for the marijuana pharmacy permit.
   9. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall notify the board in accordance with the rules governing the permanent closure of a pharmacy as described in Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1544 (August 2017), amended LR 46:577 (April 2020).

§2449. Marijuana Pharmacy Personnel; Therapeutic Marijuana Designation

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

B. The owner's managing officer and all persons holding a professional credential from the board shall first obtain a Therapeutic Marijuana (TM) designation from the board before affiliating with a marijuana pharmacy.

C. The board may issue a TM designation to a person who has filed the application for that designation supplied by the board and has completed a criminal background check for the board within the two- year period prior to the date of the application for the TM designation, and that person:
   1. Has been listed as an owner's managing officer on an application for a marijuana pharmacy permit, or on a request to become a replacement owner's managing officer for an existing marijuana pharmacy permit; or
   2. Holds one of the following professional credentials issued by the board (pharmacist, pharmacy intern, or certified pharmacy technician) and further, that professional credential was issued by the board at least two years prior to the date of the application for the TM designation, is in active status and has not been disciplined by the board within the two-year period prior to the date of the application for the TM designation.

D. The board may restrict, suspend, or revoke a TM designation for cause, but only pursuant to the Administrative Procedure Act.

E. No pharmacist, pharmacy intern, or certified pharmacy technician may practice within a marijuana pharmacy in the absence of an active professional credential, an active TM designation, as well as access privileges to the state prescription monitoring program. A pharmacist may elect to not allow a pharmacy intern or pharmacy technician to function as his delegate with respect to access privileges to the state prescription monitoring program, but the pharmacist shall have such access. A pharmacy technician candidate shall not practice in a marijuana pharmacy.

F. A pharmacist shall first acquire a Pharmacist-in-Charge (PIC) privilege, as described in §1105 of this Part, and the TM designation, as described in this Section, before accepting an appointment as the PIC of a marijuana pharmacy.
   1. The PIC of the marijuana pharmacy shall comply with the requirements of §1105 of this Part.
   2. The PIC shall be responsible for notice to the board of all pharmacists, pharmacy interns, and pharmacy technicians practicing at the marijuana pharmacy. The PIC shall cause such notice to be received in the board office in written form (mail, fax, or electronic mail) no later than 10 days after the arrival or departure of the pharmacist, pharmacy intern, or pharmacy technician.

G. The PIC shall insure and document the initial and continuing competency of the entire professional staff to provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the PIC shall provide access to education and training in the following domains:
   1. Policies and procedures of the pharmacy, especially those relating to the tasks and functions that employee is expected to perform;
   2. Professional conduct, ethics, and patient confidentiality; and
   3. Developments in the therapeutic use of marijuana.

   Further, the PIC shall document such education and training, provide such records to the board when requested, and retain such records for at least two years after the employee disassociates with the pharmacy.

H. The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy interns) and Chapter 9 (pharmacy technicians) of this Part.

I. In addition to the scope of practice limitations found in Chapter 9 of this Part, pharmacy technicians practicing in a marijuana pharmacy shall not:
   1. Consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient medication record;
   2. Consult with the physician who issued the recommendation/prescription/order for marijuana to the patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;
   3. Interpret the patient's clinical data or provide medical advice;
   4. Perform professional consultations with physicians, nurses, or other health care professionals or their authorized agents; or
   5. Determine whether a different brand or formulation of marijuana should be dispensed for the marijuana product or formulation recommended/prescribed/ordered by the physician or requested by the patient or his caregiver.

AUHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1546 (August 2017).

§2451. Operation of Marijuana Pharmacy

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

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

C. A marijuana pharmacy shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:
   1. It may acquire marijuana from an authorized producer pursuant to the provisions of R.S. 40:1046; and
   2. It may dispense and sell marijuana to a patient with a recommendation/prescription/order for such marijuana or the patient's caregiver.

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

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

F. Only a pharmacist may dispense marijuana, and only a pharmacist, pharmacy intern, or pharmacy technician may sell marijuana to patients and caregivers. A pharmacy intern or pharmacy technician may assist, under the direct supervision of a pharmacist, in the dispensing of marijuana.

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

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

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

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

1. A marijuana pharmacy that closes during its normal hours of operation shall implement procedures to notify patients and caregivers of when the marijuana pharmacy will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs.
2. In the event the pharmacist on duty leaves the prescription department, the prescription department shall comply with the provisions of §1109 (temporary absence) or §1111 (closure) of this Part.

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

1. Limitations on the right to possess and use marijuana pursuant to R.S. 40:1046;
2. Safe techniques for proper use of marijuana and paraphernalia;
3. Alternative methods and forms of consumption by which one can use marijuana;
4. Signs and symptoms of substance abuse; and
5. Opportunities to participate in substance abuse programs.

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

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

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

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

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

Q. No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a marijuana pharmacy, except that a caregiver may deliver marijuana to the caregiver's patient.

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

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

T. Right of inspection. The board, or its agent, representative, or designee, is authorized:

1. To enter a marijuana pharmacy at any time during its hours of operation, or any other place, including a vehicle, wherein marijuana is held, dispensed, sold, or otherwise disposed of;
2. To inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein, including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities; and
3. To inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished material.

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1547 (August 2017).

§2453. Security Requirements for Marijuana Pharmacies

A. A marijuana pharmacy shall:
   1. Store all marijuana in an approved safe or vault, as defined in this Subchapter, and in such a manner as to prevent diversion, theft, or loss;
   2. Maintain all marijuana in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;
   3. Not permit any person less than 18 years of age to enter the prescription department, with the exception of patients being counseled by the pharmacist;
   4. Keep all approved safes and vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana;
   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. 24-hour recordings from all video cameras, which the pharmacy shall make available for immediate viewing by the board or its authorized representative upon request and shall retain for at least 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;
10. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);
11. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and
12. The ability to remain operational during a power outage.

C. A pharmacy shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.
1. A pharmacy shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.
2. A pharmacy shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, and the board's authorized representative.
3. A pharmacy shall make available to the board upon request a current list of authorized employees and service employees that have access to the surveillance room.

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

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

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

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

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017).

§2455. Reportable Security Events

A. Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana, or of any loss or unauthorized alternation of records related to marijuana or patients, a pharmacy shall immediately notify:
1. Appropriate law enforcement authorities; and
2. The board.

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

C. A pharmacy shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:
1. An alarm activation or other event that requires response by public safety personnel;
2. A breach of security;
3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and
4. Corrective measures taken, if any.

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017).

§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 this Part except when this Subchapter grants exceptions or imposes more stringent requirements.
2. In the event the marijuana pharmacy intends to close permanently, the pharmacist-in-charge (PIC) shall comply with the pharmacy closure procedures described in Chapter 11 of this Part, and further, the owner of the pharmacy permit shall not prevent or interfere with the PIC's performance of those tasks.
    a. In addition to the other closure requirements, the closing pharmacy shall include in its notice to the board and to the public the identification of the destination pharmacy where the closing pharmacy's prescription records will be transferred. That destination pharmacy shall be the marijuana pharmacy nearest the closing pharmacy, unless otherwise approved by the board.

D. Recordkeeping Requirements

1. Prescription/recommendation/order (hereinafter, "request") for Marijuana
    a. A request generated, signed, and transmitted in electronic format which is compliant with the standards for electronic prescribing of controlled substances identified in 21 CFR 1311 (or its successor) shall be construed as a validly formatted request.
    b. The request shall identify the physician issuing the request as well as the person's debilitating medical condition for which the marijuana product is intended.
2. When the pharmacy receives a request for marijuana from a recommending physician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with §1123 of this Part.
3. Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at least two years after the date of dispensing, and further, shall be readily retrievable upon request by the board.
4. Inventory of Marijuana Product
    a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana products acquired, held, dispensed, and disposed by the pharmacy.
    b. The pharmacy shall access the LMMTS and enter all inventory-related transactions in that system.
    c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product

inventory from the production facility, the pharmacist shall verify the agent is at least 21 years of age and is eligible to drive on public roadways.

d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the possession of the pharmacy on any date which is within one year of the previous annual inventory, and further, shall conduct additional inventory counts on the following occasions:
   i. arrival of a new pharmacist-in-charge;
   ii. discovery of any significant loss, disappearance, or theft of marijuana product;
   iii. departure of a pharmacist-in-charge; and
   iv. permanent closure of the pharmacy.

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

5. The pharmacy shall develop and maintain sufficient records to fully reveal the business transactions related to marijuana products, including their procurement and sale, for the current tax year as well as the two immediately preceding tax years, all of which shall be made available to the board upon request.
6. The board may require any pharmacy or its owners to furnish such information as the board considers necessary for the proper administration of R.S. 40:1046, and may require a financial audit of the business of any marijuana pharmacy, and the expense thereof shall be paid by the marijuana pharmacy.

E. Professional Practice Standards
1. Prior to dispensing any marijuana product to a patient, the pharmacist shall review that patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending physician.
2. Labeling of Marijuana Product Dispensed
   a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by the LDAF, and further, the pharmacy dispensing label shall not overlay or obscure the producer label in any way.
   b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:
      i. Name and address of the pharmacy dispensing the product;
      ii. Telephone number or other contact information of the pharmacy dispensing the product;
      iii. Name of the recommending physician;
      iv. Name of the patient;
      v. Date the product was dispensed;
      vi. Prescription number, which shall be a unique identifier for that specific transaction;
      vii. Name of the marijuana product, including any concentration, strength, or other identifiers of the marijuana product;
      viii. Quantity of marijuana dispensed;
      ix. Directions for use of the product;
      x. Expiration date of the product, which shall not exceed the expiration date determined by the producer of the product; and
      xi. Other information selected by the dispensing pharmacist to inform the patient as to the best use of the product for the intended purpose.
3. The pharmacist shall perform prospective drug utilization review and shall counsel every patient receiving marijuana product every time it is dispensed, in compliance with the rules on drug utilization review and patient counseling in Chapter 5 of this Part.
4. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with the reporting requirements as found in Chapter 29 of this Part.
5. Disposal of Marijuana Product.
   a. A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is determined to be misbranded, adulterated, expired, deteriorated, undesired, excess, unauthorized, or unfit for dispensing; however, once accepted by the pharmacy, no marijuana product may be returned to any producer.
   b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the product shall be removed from active dispensing stock and quarantined in the pharmacy pending its disposal, and further, the removal from active dispensing stock shall be recorded in the LMMTS.
   c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the waste with other ground materials so the resulting mixture is at least 50 percent non-marijuana waste by volume. Material used to grand with the waste may include:
      i. Yard waste;
      ii. Paper waste;
      iii. Cardboard waste;

iv. Plastic waste; or
v. Soil or sand.

d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable shall be disposed of by delivery to an approved solid waste facility for final disposition.
   i. Examples of acceptable permitted solid waste facilities include:
      (a) Compost; anaerobic digester;
      (b) Landfill, incinerator; or
      (c) Waste-to-energy facility.

e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain, at a minimum, the following information:
   i. Brand name and other specific identifiers of the marijuana product disposed;
   ii. Quantity of product disposed;
   iii. Manner of disposal; and
   iv. Signatures of the pharmacist-in-charge disposing the product plus at least one witness who is either a credentialed staff member of that pharmacy or an agent of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017), amended LR 45:1473 (October 2019).

§2459. Advertising

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

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

C. Any advertisement permitted in Paragraph B of this Section shall not:
   1. Make any deceptive, false, or misleading assertions or statements regarding any product; or
   2. Assert that its products are safe because they are regulated by LDAF or the board. The pharmacy may advertise that its products have been tested by an approve laboratory, but shall not assert that its products are safe because they are tested by an approved laboratory.

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

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.
HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1552 (August 2017).