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) means 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" means 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" means

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 disease in humans or other 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" means 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 is 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 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 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;
   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 is 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 care giver:
    a. Instructions for use of the equipment;
    b. Safety precautions;
    c. Cleaning procedures;
    d. Maintenance procedures;
    e. Return demonstrations 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 care giver to comply with the prescription or medical order, and the ability of the patient or care giver to operate and clean the equipment as instructed.

D. Requirements for Providers of Other Durable Medical Equipment
1. Providers who sell, rent or furnish other 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 device; and
    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 health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:504 (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 a 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 destructions.
   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 20 miles (driving distance) of the location of the telepharmacy dispensing site.
   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 new community pharmacy opens at a location within 20 miles (driving distance) of the telepharmacy dispensing site, then the board shall not renew the telepharmacy dispensing site's pharmacy permit. The board shall notify the central pharmacy supervising the telepharmacy dispensing site of the new pharmacy operating within 20 miles (driving distance) of the telepharmacy dispensing site, and of the requirement for the telepharmacy dispensing site to close permanently on or before the expiration date of the telepharmacy dispensing site's current renewal of its pharmacy permit. The closure shall be accomplished in compliance with the provisions of Section 1133 of the board's rules. In lieu of permanent closure, the telepharmacy dispensing site may elect to apply for and complete the conversion of its permit to a community pharmacy permit prior to the expiration date of the telepharmacy 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 inspections of the telepharmacy dispensing site. The policies and procedures 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 41:2149 (October 2015).

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,

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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 Substance 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 any 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 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).