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).

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