Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
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December 28, 2012

Office of the Governor
PO Box 94004
Baton Rouge LA 70804-9004

Certified Mail – Return Receipt Requested

Re: Notice of Emergency Rule

Dear Governor Jindal:

In compliance with the provisions of La. R.S. 49:953(B), this will serve notice of the Board's adoption of an Emergency Rule effective today. Copies of the Declaration of Emergency and the Rule are enclosed. In the event you desire any further information about this topic, please contact my office directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

Encls.

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DECLARATION OF EMERGENCY

Department of Health and Hospitals
Board of Pharmacy

Durable Medical Equipment (DME) Permit
(LAC 46:LIII.2401)

The Louisiana Board of Pharmacy is exercising the emergency provisions of the Administrative Procedure Act, specifically at R.S. 49:953.B, to promulgate a new Rule relative to the creation of a new type of pharmacy permit specifically for providers of durable medical equipment (DME) that do not provide prescription drugs. The Emergency Rule is necessary to allow the Board of Pharmacy to issue DME permits to qualifying providers as quickly as possible.

The board has had a long-standing requirement for a pharmacy permit for any entity that wished to provide prescription drugs or devices to Louisiana citizens. The rules for the pharmacy permit contain minimum specifications for the physical plant that reflect concern for any place that stores controlled dangerous substances and other prescription drugs. Moreover, those minimum specifications require the presence of a pharmacist in the prescription department whenever the pharmacy is open for business. There are a growing number of entities that supply prescription devices or equipment but no prescription drugs. The board has determined that public safety does not require the same level of minimum specifications in business settings that do not contain prescription drugs. The board seeks to establish a separate set of rules for DME providers that do not stock or supply prescription drugs to facilitate the creation and issuance of a DME permit in lieu of the presently-required pharmacy permit.

The federal Centers for Medicare and Medicaid Services (CMS) has recently changed their eligibility criteria for DME providers intending to submit claims for services to Medicare to require evidence of compliance with state credentialing requirements.

A delay in promulgating this proposed Rule will result in some DME suppliers that do not stock prescription drugs being disqualified from participation in Medicare, which has the potential of adversely affecting their financial position. Since these suppliers provide vital services to Medicare beneficiaries across the state, the board has determined that this emergency rule is necessary to prevent imminent peril to the public health, safety, and welfare. This Declaration of Emergency was originally effective May 2, 2012 and re-published on August 31, 2012. Although the Board has initiated the formal rulemaking process, the emergency rule will expire before the Board can complete the process. Therefore, the Board is re-publishing this declaration and emergency rule. It is effective December 28, 2012, and shall remain in effect for the maximum time period allowed under the Administrative Procedure Act or until adoption of the final Rule, whichever shall first occur.

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.

Medical Gas—those gases 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 38:

§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 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 38:

§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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:

§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 38.

Malcolm Broussard
Executive Director

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