Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
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November 13, 2012

Senator John A Alario, Jr, President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804-9183

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Re: Report No. 1 of 3 for Regulatory Project 2012-11 ~ Durable Medical Equipment Permit

Dear Senator Alario:

The Board has initiated the rulemaking process to establish regulations for suppliers of durable medical equipment. In connection with this regulatory project, you should find the following documents in this packet:

- Notice of Intent
- Proposed Rule
- Family Impact Statement
- Solicitation of Comments & Testimony
- Fiscal & Economic Impact Statement
- Regulatory Flexibility Analysis

As indicated in the solicitation, we will convene a public hearing on December 27, 2012 to receive public comments and testimony on this proposal. We will summarize those comments and our responses thereto in our next report to you. In the event you have any questions or need additional information, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

cc: Chair, Senate Health & Welfare Committee
Speaker, House of Representatives
Chair, House Health & Welfare Committee
Director, Community Outreach Services, La. Economic Development
Editor, *Louisiana Register*
Reference File

Notice of Intent

Department of Health and Hospitals
Board of Pharmacy

Durable Medical Equipment Permit

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to create a new chapter of rules for limited service pharmacies, and further, to provide for the first classification of permit for such pharmacies to be issued to those suppliers of durable medical equipment that do not stock or supply prescription drugs. The proposed rule identifies the durable medical equipment, medical devices and medical gases authorized by the permit, provides for the credentialing process, defines the standards of practice for durable medical equipment providers, and provides for certain exemptions to the credentialing requirement.

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:
(1) Oxygen and oxygen delivery system;
(2) Ventilators;
(3) Respiratory disease management devices;
(4) Continuous positive airway pressure (CPAP) devices;
(5) Electronic and computerized wheelchairs and seating systems;
(6) Apnea monitors;
(7) Transcutaneous electrical nerve stimulator (TENS) units;
(8) Low air loss cutaneous pressure management devices;
(9) Sequential compression devices;
(10) Feeding pumps;
(11) Home phototherapy devices;
(12) Infusion delivery devices;
(13) Distribution of medical gases to end users for human consumption;
(14) Hospital beds;
(15) Nebulizers; and
(16) 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 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 38:1178 (May 2012).

§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 or legend drugs.
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 38:1178 (May 2012)

§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 alternation, 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 seventy-two (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 38:1179 (May 2012)

§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, 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 38:1180 (May 2012).

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment.

I. The effect on the stability of the family.

We can discern no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

We can discern no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

We can discern no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

We can discern no effect on family earnings or family budget.

V. The effect on the behavior and personal responsibility of children.

We can discern no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

We can discern no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Thursday, December 27, 2012 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS

The Board proposes to establish a special classification of pharmacy permit intended for use by durable medical equipment (DME) providers that do not stock prescription or legend drugs. The requirements for a DME permit will be less stringent in terms of minimum physical specifications compared to the requirements warranted for prescription drugs or controlled substances. It is estimated that implementation of the proposed rule will cost the agency $500 in FY 13 for printing costs.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS

The proposed rule will require this subset of DME providers to obtain and maintain a DME permit, which costs $150, instead of a pharmacy permit. Previously, the requirement that DME providers that do not sell prescription drugs obtain a pharmacy permit was not enforced since the Board anticipated creating the specialized DME permit. As a result of rule change, the Board estimates 500 suppliers will apply for the new DME permit in FY 13, resulting in approximately $75,000 in increased revenue for the Board in the first year (500 x $150). The Board estimates an additional $75,000 in annual revenue in subsequent years from renewal fees ($125 each) and any additional new permit applications [($125 x 450 renewals) + ($150 x 125 new permits) = $75,000].

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

In addition to the $150 initial permit fee and $125 annual renewal fee, DME providers are required to use an electronic recordkeeping system. However, the rule permits the provider to use the information system of their choice to maintain transaction information as well as repair logs for the equipment and devices it stocks and supplies. As such, costs will vary according to the system each provider chooses to purchase and utilize.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT

No effect on competition and employment is anticipated as a result of this proposed rule.

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

The recordkeeping and reporting requirements are focused on outcomes; providers are free to select their own methods for achieving compliance.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The seventy-two hour requirement for the production of records is facilitated by the requirement for the use of electronic recordkeeping systems.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

Providers are free to simplify their recordkeeping systems as long as they can achieve the outcomes specified in the proposed rule.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

The practice standards focus on outcomes, and providers are free to select their operational standards.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions for small businesses in the proposed rule.