

Notice of Agency Rule-making Proposal

AGENCY: Department of Professional and Financial Regulation, Office of Licensing and Regulation, Maine Board of Pharmacy

CHAPTER NUMBER AND TITLE: Chapter 34, Licensure of Retail Suppliers of Medical Oxygen and Prescription Devices

PROPOSED RULE NUMBER (*leave blank; assigned by Secretary of State*):

CONTACT PERSON FOR THIS FILING: Geraldine Betts, Board Administrator, Office of Licensing and Registration, 35 State House Station, Augusta, ME, (207) 624-8615, geraldine.l.betts@maine.gov

CONTACT PERSON FOR SMALL BUSINESS INFORMATION (if different): Same

PUBLIC HEARING (if any): January 6, 2011, 9:00 a.m., Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, Maine

COMMENT DEADLINE: January 18, 2011

BRIEF *SUMMARY: This chapter requires retail suppliers of medical oxygen and prescription devices to apply for and obtain a new type of limited retail pharmacy license from the board. The board adopted this rule on an emergency basis on November 15, 2010; the board now proposes to adopt the rule on a permanent basis. The proposed rule may be downloaded from OLR's web site at www.maine.gov/professionallicensing or obtained from the agency contact person. The statement of economic impact on small business required by 5 MRSA §8052(5-A) may be obtained from the agency contact person.

The rule describes the purchase, dispensing and delivery records to be created by licensees, provides a 3 year period for retention of records, and requires compliance with current good manufacturing practices prescribed by federal rule. The rule does not require licensees to hire a pharmacist. The retail supplier of medical oxygen and prescription devices license is necessary to ensure that prescriptions for oxygen and prescription medical devices are accurately filled, that records of sale are available to the board in case of an adverse medical event, and that federal and state laws and rules relating to labeling and purity are complied with.

IMPACT ON MUNICIPALITIES OR COUNTIES (if any): None

STATUTORY AUTHORITY FOR THIS RULE: 32 MRSA §§13720, 13721(1)(E), 13722, 13723, 13751(3), 13752, 13752 A, 13743

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different): 21 USC §§ 321(h) and 353(b) (federal Food, Drug and Cosmetics Act); 21 CFR §§10.90, 801.109 & 801.110; 21 CFR Part 820 (implementing rules for Food, Drug and Cosmetic Act)

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: jeffrey.m.frankel@maine.gov

* Check one of the following two boxes.

The above summary is for use in both the newspaper and website notices.

The above summary is for the newspaper notice only. A more detailed summary / basis statement is attached.

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT _____ DATE: _____
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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 34: LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN AND PRESCRIPTION DEVICES**

Summary: This chapter provides for the licensure of retail suppliers of medical oxygen and prescription devices.

1. Definition

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings:

1. Prescription Device. "Prescription device" means a device, as defined in 21 USC §351(h), for which a prescription is required by 21 CFR §801.109 and which bears the legend required by 21 CFR §801.109(b)(1).
2. Retail supplier of medical oxygen or prescription devices. "Retail supplier of medical oxygen and prescription devices" means:
 - A. A person who sells or dispenses oxygen to a consumer—
 - (1) Pursuant to a prescription from a practitioner; or
 - (2) In circumstances where a prescription is required by federal law; or
 - B. A person who sells or dispenses a prescription device to a consumer.

2. License Required**1. General Requirement**

Medical oxygen for use by a specific person, or prescription devices, may be sold at retail only pursuant to a prescription from a practitioner. A retail supplier of medical oxygen or prescription devices located within or outside Maine who sells or dispenses medical oxygen or prescription devices to consumers who reside in Maine shall obtain a retail supplier of medical oxygen and prescription devices license from the board.

[NOTE: A retail supplier of medical oxygen and prescription devices need not have a pharmacist in charge or a pharmacist.

2. Exception

A pharmacy licensed by the board may sell medical oxygen and prescription devices at retail without need of a license under this chapter.

3. Temporary Licensure

1. Timeline

The board may issue a temporary license as a retail supplier of medical oxygen and prescription devices upon receipt of an application for licensure submitted pursuant to Section 4 of this chapter. The application must demonstrate the applicant's prima facie eligibility for licensure. The temporary license expires 90 days from the date of issuance. Within the first 60 days of temporary licensure, a temporary licensee must complete the application to the satisfaction of the board. The board will act on timely-completed applications for licensure within the 90-day period of the temporary license.

2. Limitation

A temporary license may not be extended or renewed. A person may not receive a temporary license more than once.

4. Licensure

1. Application; Fees

An application for licensure as a retail supplier of medical oxygen and prescription devices must be filed on forms provided by the board along with such other information as the board may require. The application must be accompanied by the application and license fees required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Licensing and Registration, entitled "Establishment of License Fees." Except as described in Section 3 of this chapter, incomplete applications will not be accepted and will be returned to the applicant. The applicant must provide the following information:

- A. The name, physical address, contact address, telephone number, email address and world wide web address of the retail supplier of medical oxygen and prescription devices;
- B. All trade or business names used by the retail supplier of medical oxygen and prescription devices;
- C. The names of the owner of the retail supplier of medical oxygen and prescription devices, including:

- (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If the applicant is a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
 - (4) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- D. The job title, name, address, telephone number, email address and emergency contact information of the person responsible for operation of the retail supplier of medical oxygen and prescription devices;
 - E. The days and hours of operation of the retail supplier of medical oxygen and prescription devices; and
 - F. A scaled drawing of the facility demonstrating sufficient space for the proper carrying on of the business of a retail supplier of medical oxygen and prescription devices. The drawing must identify the use of all space within the facility.
3. Separate License for Each Facility

The owner of a retail supplier of medical oxygen or prescription devices must file a separate application for each facility that sells or dispenses medical oxygen and prescription devices.
 4. License Term; Renewal

All retail supplier of medical oxygen and prescription devices licenses other than the temporary license expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Licensing and Registration, entitled "Establishment of License Fees."

5. Change of Ownership, Location or Application Information

Upon a change of ownership, a retail supplier of medical oxygen and prescription devices shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a retail supplier of medical oxygen and prescription devices shall file a new application with the board by no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

5. Prescription Drug Order

Each retail sale of medical oxygen and prescription devices must be authorized by a prescription from a practitioner. The prescription must contain, at a minimum, the information required by Chapter 19, Section 1 of the board's rules, entitled "Receipt and Handling of Prescription Drug Orders." A retail supplier of medical oxygen and prescription devices may fill a prescription for oxygen or a device for a period no greater than 15 months from the date written.

6. Maine Rx Plus Prescriptions

With each prescription dispensed to a participant in the Maine Rx Plus Program, 22 MRSA §2681 et seq., the retail supplier of medical oxygen and medical devices shall disclose to the purchaser in writing the usual and customary price of the prescription to a purchaser not covered by or enrolled in any type of health insurance, prescription drug benefit or 3d party payor plan, public or private, and the amount of savings provided to the purchaser as a result of the Maine Rx Plus Program. No proprietary information need be disclosed pursuant to this subsection.

7. Dispensing Records

A retail supplier of medical oxygen and prescription devices shall create a dispensing record for each original, refill and transferred prescription that it fills. The dispensing record must include, at a minimum, the following information:

1. The original or faxed prescription, or record of a telephone or computer prescription;
2. If for oxygen: the amount of oxygen dispensed, if different than the amount specified in the prescription;

3. If for a device: the device dispensed, if different than the device specified in the prescription;
4. Date of dispensing;
5. Prescription number or its equivalent;
6. Records of refills to date;
7. The name of the person who dispensed each sale of oxygen or a device pursuant to the prescription; and
8. If for oxygen, the name of the person who delivered each sale of oxygen to the patient and the place of delivery.

8. Retention of Records

1. Purchase Records

A retail supplier of medical oxygen and prescription devices shall retain records of wholesale oxygen or device purchases for 3 years.

2. Prescription Drug Orders

A. Except as set forth in Section 9(2)(B) of this chapter, a retail supplier of medical oxygen and prescription devices shall retain each written or faxed prescription for 3 years from the date of last fill. The supplier may retain a scanned or microfiched unadulterated copy of the prescription in place of the original. The scan or microfiche must include any information appearing on the reverse side of the prescription.

B. A retail supplier of medical oxygen and prescription devices that uses an automatic data processing system that meets the requirements of Chapter 19, Section 7 of the board's rules need not retain prescriptions.

3. Dispensing and Delivery Records

A retail supplier of medical oxygen and prescription devices shall retain dispensing and delivery records for 3 years from the date of last fill.

4. Production at Time of Inspection

A retail supplier of medical oxygen and prescription devices shall produce to an inspector or representative of the board, upon request of the inspector or representative, any and all records which the licensee is required to retain. Production of records for the most recent 12-month period must be made immediately at the time of inspection or investigation. The balance of the records requested must be produced within 3 business days of the request.

9. Compliance With Current Good Manufacturing Practices

1. Retail Suppliers of Medical Oxygen

A retail supplier of medical oxygen shall comply with the current good manufacturing practices promulgated by the Food and Drug Administration in 21 CFR Parts 210 and 211 (April 1, 2010 edition). The board will recognize compliance with the Compressed Medical Gases Guideline (February 1989 Revision) promulgated by the FDA pursuant to 21 CFR Section 10.90 as also constituting compliance with the current good manufacturing practices.

2. Retail Suppliers of Prescription Devices

A retail supplier of prescription devices shall comply with the current good manufacturing practices promulgated by the Food and Drug Administration in 21 CFR Part 820 (April 1, 2010 edition). The board will recognize compliance with the Medical Device Quality Systems Manual: A Small Entities Compliance Guide, HHS Publication FDA 97-4179 (1st ed. December 1996) promulgated by the FDA as also constituting compliance with the current good manufacturing practices.

3. Incorporation by Reference

The board hereby incorporates the following documents by reference into this chapter:

- A. Compressed Medical Gases Guideline, U.S. Food and Drug Administration, (February 1989 Revision). This document is available from the FDA on line at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm124716.htm>

This document may also be obtained from: U.S. Food and Drug Administration, Office of Training and Communications, Division of Drug Information, 10903 New Hampshire Avenue, Silver Spring, MD 20993, tel. 301-796-3400.

- B. Medical Device Quality Systems Manual: A Small Entities Compliance Guide, U.S. Food and Drug Administration, HHS Publication FDA 97-4179 (1st ed. December 1996). The document is available from FDA on line at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/default.htm>

This document may also be obtained from: Superintendent of Documents,
U.S. Government Printing Office, Washington D.C. 20402, tel. 202-512-
1800

10. Packaging, Storage and Labeling

A retail supplier of medical oxygen shall store, package and label oxygen in accordance with the requirements of the U.S. Pharmacopoeia.

STATUTORY AUTHORITY: 32 MRSa §§13720, 13721(1)(E), 13722, 13723, 13751(3),
13752, 13752-A, 13743

EFFECTIVE DATE: