

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 34-A: LICENSURE OF RETAIL SUPPLIERS OF PRESCRIPTION MEDICAL DEVICES

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

1. Authority

A retail supplier of prescription medical devices is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3).

2. License Required

1. General Requirement

Devices requiring a prescription from a practitioner for use by a specific person may be sold at retail. A retail supplier of prescription medical devices located within or outside Maine who sells or dispenses a prescription medical device to consumers who reside in Maine shall obtain a retail supplier of prescription medical device license from the board. A retail supplier of prescription medical devices need not have a pharmacist in charge or a pharmacist.

2. Exception for Licensed Pharmacies

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

3. Exception of Ophthalmologic Aids

This chapter is not intended to regulate nor does it apply to prescribers or dispensers of ophthalmologic aid prescription devices such as contact lenses, glasses, eye patches or other ophthalmologic aids.

4. Sales for Emergency Medical Use – Dual Licensure Not Required

A retail supplier of prescription medical devices licensed under this chapter who sells devices for emergency medical use to a licensed practitioner or licensed health care facility need not, by virtue of those sales alone, be licensed as a wholesaler pursuant to Chapter 12 of the board's rules.

3. Temporary Licensure

1. Timeline

The board may issue a temporary license as a retail supplier of prescription medical 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 shall 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 prescription medical devices must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, 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 shall 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 prescription medical devices;
- B. All trade or business names used by the retail supplier of prescription medical devices;
- C. The names of the owner of the retail supplier of prescription medical devices, including:
 - (a) 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;
 - (b) 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;

- (c) 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.
- (d) 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 prescription medical devices;
- E. The days and hours of operation of the retail supplier of prescription medical devices;
- F. A scaled drawing of the facility demonstrating sufficient space for the proper carrying on of the business of a retail supplier of prescription medical devices. The drawing must identify the use of all space within the facility;
- G. Such other information as the board may require.

2. **Processing of Application**

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the retail supplier of prescription medical devices will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

3. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

4. Separate License for Each Facility

The owner of a retail supplier of prescription medical devices must file a separate application for each facility that sells or dispenses prescription medical devices.

5. License Term; Renewal

All retail suppliers of prescription medical 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 Professional and Occupational Regulation, entitled "Establishment of License Fees."

6. Change of Ownership, Location or Application Information

Upon a change of ownership, a retail supplier of prescription medical 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 prescription medical devices shall file a new application with the board 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 prescription medical devices must be authorized by a prescription from a practitioner. A retail supplier of prescription medical devices may fill a prescription for the

length of medical need authorized by the prescribing practitioner. If the length of medical need is not specified, the prescription drug order is valid for 15 months.

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 prescription 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 3rd 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. Patient Records

A retail supplier of prescription medical devices shall keep in written or any electronic format prescriptions, invoices and delivery records for each patient served. Records must be retained for 3 years from the date of last delivery to a patient and must be produced to an inspector or representative of the board upon request.

8. Compliance with Current Good Manufacturing Practices; Incorporation by Reference

A retail supplier of prescription medical devices that manufactures, processes, packages or holds devices as defined in the Federal Food, Drug, and Cosmetic Act and its implementing rules shall comply with the current good manufacturing practices promulgated by the Food and Drug Administration in 21 CFR Part 820 “Quality System Regulation” (Revised April 1, 2013), available online. The board hereby incorporates this document by reference into this chapter.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

9. Packaging, Storage and Labeling

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

STATUTORY AUTHORITY: 22 MRSA §2681(6); 32 MRSA §§13720, 13721(1)(E), 13722(1)(A), (B) and (C), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE: