

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 34: LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN AND PRESCRIPTION DEVICES (EMERGENCY RULE)**

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:

EMERGENCY FINDINGS

CHAPTER 34 (EMERGENCY)

LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN AND PRESCRIPTION DEVICES

ADOPTED NOVEMBER 15, 2010

The board finds that:

1. Oxygen used for medical purposes is defined as a drug at both the federal and state levels. Oxygen may only be dispensed to a patient pursuant to a prescription issued by a practitioner such as an allopathic physician, osteopathic physician, physician assistant or advanced nurse practitioner.

2. Medical oxygen is sold at retail to patients suffering from emphysema, other forms of chronic obstructive pulmonary disease, cystic fibrosis or heart disease.

3. Oxygen for home respiratory therapy, as described above, may be delivered to the patient by the seller in metal cylinders, or in smaller containers designed for easier portability. As an alternative to delivery of oxygen, a patient may purchase an oxygen concentrator for home or travel use.

4. An oxygen concentrator is a machine that removes nitrogen from the air so as to generate oxygen for immediate use by the patient. An oxygen concentrator is a “device” for which a prescription from a practitioner is required by federal and state law.

5. Although retail pharmacies are authorized to dispense oxygen and oxygen concentrators, very few do. The board is aware of only two retail pharmacies that sell oxygen at retail.

6. The board licenses wholesale pharmacies pursuant to federal and state law. Title 32 MRSA §13702-A(34) defines wholesaler as “a person who buys prescription drugs for resale and distribution to persons *other than consumers.*” (emphasis added)

7. The board also licenses manufacturers pursuant to federal and state law. Although Maine law does not prohibit manufacturers from selling to consumers, manufacturers typically sell to wholesalers, not consumers.

8. On information and belief, there are about 75 oxygen facilities in the State. As noted above, only two of these facilities are licensed retail pharmacies. The others are licensed as either manufacturers or wholesalers by the board. All licenses issued by the board expire annually on December 31.

9. The board does not require an applicant for a manufacturer or wholesaler license to specify the drugs that the applicant manufactures or sells. This past spring, the board began to learn that oxygen dealers who sell at retail had obtained manufacturer and wholesaler licenses for which they did not qualify. The board does not intend to renew manufacturer or wholesaler licenses for which a current licensee does not qualify. As noted above, these licenses will expire on December 31.

10. On September 10, 2010, the board preliminarily denied manufacturer or wholesaler licenses to an additional five entities that are engaged in the business of selling oxygen at retail.

11. The Maine Department of Human Services has informed the board that sellers of medical oxygen must be licensed as required by law in order to maintain their eligibility for Medicare/MaineCare reimbursement. On information and belief, the reimbursement status of many medical oxygen sellers will be in jeopardy if they are not licensed in compliance with Maine pharmacy law. Such a development would jeopardize the availability of medical oxygen to Maine citizens.

12. Under the board's regulatory scheme, a seller of oxygen at retail is required to obtain a retail pharmacy license. To obtain a retail pharmacy license, the applicant must hire a pharmacist in charge, observe minimum hours of operation and maintain a secured prescription filling area. In the judgment of the board, the hiring of a pharmacist is not strictly necessary for a seller of medical oxygen or prescription devices only, and the access and security measures required of retail pharmacies are inapplicable to these businesses.

13. Licensure of retail suppliers of medical oxygen and prescription devices is necessary to ensure that prescriptions for medical oxygen and 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. A new limited category license is necessary for this purpose.

14. For the reasons described above and in the accompanying Basis Statement, the board has created the new license category of retail supplier of medical oxygen and prescription devices.

15. Ordinarily, a license becomes effective only after an application has been approved by the board. The board's experience is that most applications for business licenses are rarely complete upon initial filing, and require additional information from the applicant and varying amounts of staff review. If all retail suppliers of medical oxygen and prescription devices were to immediately apply for the new license, the

likely result is that many oxygen suppliers would be unlicensed upon the expiration of their manufacturer or wholesaler license come December 31, 2010.

16. To avoid jeopardizing these entities' eligibility for MaineCare/Medicaid reimbursement, the emergency rule provides that an applicant whose application demonstrates the applicant's prima facie eligibility for licensure as a retail supplier of medical oxygen and prescription devices will be issued a 90-day temporary license by the board upon receipt of the application. The applicant will have 60 days from the date of receipt to complete the application; the board will act on timely-completed applications within the 90-day duration of the temporary license.

In the judgment of the board, these findings constitute an emergency. Adoption of the board's rules on an emergency basis is necessary to avoid the immediate threat to public health described in these findings. Pursuant to 5 MRSA §8052(6), these rules shall become effective immediately upon filing with the Secretary of State.

. . .

Modifications of procedures: The following rulemaking procedures were modified in the adoption of this emergency rule:

- The board did not advertise or issue a notice of agency rulemaking for the emergency rule.
- The board did not schedule a rulemaking hearing or provide an opportunity for written comments on the emergency rule.
- The adopted emergency rule will become effective immediately upon filing with the Secretary of State, instead of five days after filing.

BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 34 (EMERGENCY)
LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN
AND PRESCRIPTION DEVICES

ADOPTED NOVEMBER 15, 2010

Basis Statement

Oxygen used for medical purposes is defined as a drug at both the state and federal levels. Oxygen may only be dispensed to a patient pursuant to a prescription issued by a practitioner such as an allopathic physician, osteopathic physician, physician assistant or advanced nurse practitioner. Medical oxygen is sold at retail to patients suffering from emphysema, other forms of chronic obstructive pulmonary disease, cystic fibrosis or heart disease and is typically delivered to the patient's residence by the seller.

A medical "device" is defined as follows:

By federal law—

...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals,
and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 USC §321(h)

By state law—

...an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component part or accessory, that is required under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

32 MRSA §13702-A(8)

In plain English, a device is “any product or equipment used to diagnose a disease or other conditions, to cure, to treat or to prevent disease.”¹ Examples of devices in the home setting are ventilators and nebulizers, wheelchairs, infusion pumps, blood glucose meters apnea monitors.² Oxygen concentrators, a substitute for the delivery of oxygen cylinders, are also classified as devices.

Title 21 USC §353(b) requires a prescription for any drug which is unsafe to use except under supervision of a licensed practitioner. Title 21 CFR §801.109 recognizes a like category of prescription devices:

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device...³

Prescription devices must carry the legend, “Caution: Federal law restricts this device to sale by or on the order of a -----.”⁴

Oxygen for home respiratory therapy is typically delivered in metal cylinders or smaller containers designed for easier portability. As an alternative to delivery of oxygen, a patient may purchase an oxygen concentrator for home use. Oxygen concentrators are prescription devices as described above.

Retail pharmacies may sell oxygen to consumers within the scope of their license. To the best of the board’s knowledge, only one or two of them do. Retail pharmacies may also sell prescription medical devices within the scope of their license. Yet only a small portion of the vast number of prescription devices are typically available at a retail pharmacy.

There may be approximately 75 retail suppliers of medical oxygen in the State. As discussed in the accompanying Emergency Findings, some of these businesses were improperly licensed as wholesalers or manufacturers by the board. Others have not been licensed at all.

OLR believes that many of the retail oxygen sellers also sell prescription devices such as oxygen concentrators. OLR cannot reliably estimate how many sellers of prescription devices are active in the State, or sell in Maine from out of state. Title 32 MRSA

¹ Home Health Care Medical Devices: A Checklist, U.S. Department of Health and Human Services / Food and Drug Administration / Center for Devices and Radiological Health (2003), available at: <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/UCM070218.pdf>

² Id.

³ See also 21 CFR §801.110, which recognizes that prescription devices will be delivered by the ultimate purchaser or user “by a licensed practitioner in the course of his professional practice *or upon a prescription or other order lawfully issued in the course of his professional practice.*” (emphasis added)

⁴ The blank is to be filled with the word “physician”, “dentist”, “veterinarian”, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device. 21 CFR §21.109(b)(1).

§13722(1) authorizes the board to promulgate rules concerning the sale of devices as well as drugs.

Licensure is necessary to ensure that prescriptions for oxygen and prescription 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.

The board currently licenses the following types of retail pharmacies:

- Retail Drug Outlet (Chapters 8, 13)
- Rural Health Center (Chapters 9, 14)
- Free Clinic (Chapters 10, 15)
- Nuclear Drug Outlet (Chapter 17)
- Sterile Pharmaceuticals (Chapter 18)

Many of the retail pharmacy requirements in Chapter 13, such as minimum hours of operation and a secured prescription filling area, have little applicability to a retail supplier of medical oxygen and prescription devices. In particular, retail suppliers of medical oxygen maintain that there is no need for them to have a pharmacist in charge, one of the core requirements for a retail pharmacy. Upon consideration, the board agrees that day-to-day pharmaceutical skills are not necessary for the filling and setup of medical oxygen and prescription devices. The note following Section 1(2) of the new chapter accordingly states, “A retail supplier of medical oxygen and prescription devices need not have a pharmacist in charge or a pharmacist.”

Title 32 MRSA §13751(3) authorizes the board to issue retail pharmacy licenses of limited scope when the nature of the business so warrants. The four specialized retail pharmacy licenses noted above – rural health centers, free clinics, nuclear drug outlets and sterile pharmaceuticals – exemplify the board’s exercise of this authority. What they all have in common, though, is the dispensing of prescription drugs upon the order of a practitioner. The selling of medical oxygen for home respiratory care and the selling of prescription devices share this characteristic and similarly warrant an appropriate level of regulation by the board.

With the exception of the 90-day temporary license discussed in the emergency findings, the application and renewal provisions are similar to those already in place for retail drug outlets. The requirement of separate licensure for each facility under common ownership is borrowed from Chapter 12 of the board’s rules involving registration of manufacturers and wholesale drug outlets.

The substantive provisions of this chapter are found in Sections 5 through 10. The core requirement, found in Section 5, is that medical oxygen and prescription devices may only be dispensed upon receipt of a prescription drug order from a practitioner. (“Prescription drug order” and “practitioner” are both defined in 32 MRSA §13702-A.)

The board is aware that devices which are not prescription devices are frequently prescribed by practitioners as medically necessary in order that the patient may be reimbursed by a third-party payor. Wheelchairs are a frequent example. Only devices which bear the prescription legend quoted above fall within the scope of the new rule.

Sections 7 and 8 relate to recordkeeping and records retention, and are vital to the board's ability to investigate an adverse medical event. Sections 9 and 10 reference quality and purity controls required by federal law and rule.

Response to Comments

Due to the emergency nature of this rulemaking proceeding, no opportunity for comments was provided.