

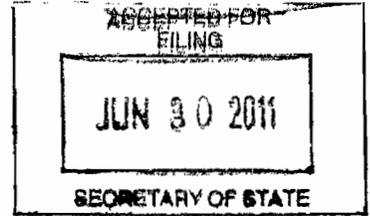
Rule-Making Cover Sheet

MAPA-1

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333.

2011-209

- 1. Agency: Department of Professional and Financial Regulation, Office of Licensing and Registration, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Licensure of Retail Suppliers of Medical Oxygen
4. Chapter number assigned to the rule: 34
5. Date(s)/method(s) of notice: 12/15/10, Secretary of State consolidated rulemaking advertisement; 11/24/10, posting on OLR's web site; 12/8/10, notice to interested parties
6. Date(s)/place(s) of hearing(s): 1/6/11, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, Maine



- 7-A. Type: [X] new rule [] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8615

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

- [] Provisional adoption (prior to Legislative review)
[] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Dana J. Hunter, Jr., hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on June 2, 2011.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Dana J. Hunter, Jr., Board Vice President

11. Approved as to form and legality by the Attorney General on [Handwritten Date]

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Judith M. Peters



EFFECTIVE DATE: JUL - 5 2011

5602 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 34: LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN**

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

1. Definition

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

1. Medical oxygen. "Medical oxygen" means oxygen in liquid or gaseous form intended for therapeutic use.
2. Retail supplier of medical oxygen. "Retail supplier of medical oxygen" means a person who sells or dispenses medical oxygen to a consumer—
 - A. Pursuant to a prescription from a practitioner; or
 - B. In circumstances where a prescription is required by federal law.

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

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

2. Exception for Licensed Pharmacies

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

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

A retail supplier of medical oxygen licensed under this chapter who sells oxygen 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 medical oxygen 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 medical oxygen 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 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 medical oxygen;
- B. All trade or business names used by the retail supplier of medical oxygen;
- C. The names of the owner of the retail supplier of medical oxygen, 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;
 - E. The days and hours of operation of the retail supplier of medical oxygen; 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. 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 must file a separate application for each facility that sells or dispenses medical oxygen.

4. License Term; Renewal

All retail supplier of medical oxygen 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 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 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 medical oxygen must be authorized by a prescription from a practitioner. A retail supplier of medical oxygen 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 medical oxygen 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. Patient Records

A retail supplier of medical oxygen 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

1. Current Good Manufacturing Practices

A retail supplier of medical oxygen that manufactures, processes, packages or holds oxygen 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 Parts 210 and 211 (April 1, 2010 edition).

2. Incorporation by Reference

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

- A. Title 21 CFR Part 210, “Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General” promulgated by the U.S. Food and Drug Administration (April 1, 2010 edition). This document is available from the FDA on line at:

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

This document may also be obtained from the State Law Library, State House, Augusta, Maine, tel. (207) 287-1600.

- B. Title 21 CFR Part 211, “Current Good Manufacturing Practice for Finished Pharmaceuticals” promulgated by the U.S. Food and Drug Administration (April 1, 2010 edition). This document is available from the FDA on line at:

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

This document may also be obtained from the State Law Library, State House, Augusta, Maine, tel. (207) 287-1600.

9. 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), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

**BASIS STATEMENT AND RESPONSE TO COMMENTS;
FINDINGS PURSUANT TO EXECUTIVE ORDER 14 FY 11/12**

**CHAPTER 34
LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN**

ADOPTED JUNE 2, 2011

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 illnesses such as emphysema, other forms of chronic obstructive pulmonary disease, cystic fibrosis, heart disease and migraine headaches.

Although retail pharmacies may sell oxygen to consumers, to the best of the board's knowledge only one or two of them do. Oxygen is typically sold to patients by home medical equipment suppliers who are not otherwise required to be licensed by the board. Licensure is necessary to ensure that prescriptions for oxygen are accurately filled by home medical equipment suppliers, 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.

Title 32 MRSA §13751(3) authorizes the board to issue retail pharmacy licenses of limited scope when the nature of the business so warrants. Nuclear drug outlets and providers of sterile pharmaceuticals exemplify this exercise of the board's authority. Like these specialized pharmacies, as well as full-service pharmacies, retail suppliers of medical oxygen dispense a prescription drug upon the order of a practitioner, and hence must be licensed by the board.

However, retail suppliers of medical oxygen need not be subject to the full range of rules that apply to full-service pharmacies. Pharmaceutical skills are not necessary for the filling of oxygen prescriptions and delivery of cylinders. Section 2(10) of the adopted rule accordingly states that this group of licensees need not have a pharmacist or pharmacist in charge. Due to the specialized nature of their operation, other requirements of the board's rules are also inapplicable to these licensees. This chapter accordingly does not require retail suppliers of medical oxygen to observe minimum hours of operation, maintain a secure prescription filing area, maintain patient profiles, or fill prescriptions for a period of no longer than 15 months.

A less intrusive level of regulation by the board is further justified by the high level of regulation that retail suppliers of medical oxygen must already comply with. The U.S. Department of Transportation has promulgated detailed rules governing the construction, pressurization, operational safety and shipment of oxygen cylinders.¹ The FDA has promulgated good manufacturing guidelines for the filling, testing and labeling of compressed medical gas containers.² Most extensive of all, however, is oversight by the Centers for Medicare and Medicaid Services. ("CMS") No prescription for oxygen is reimbursable unless it is supported by a Certificate of Medical Necessity signed by the prescribing physician.³ To participate in the Medicare and Medicaid programs, a retail supplier of medical oxygen must obtain a supplier number, which requires proof of appropriate liability insurance and other assurances,⁴ post a minimum \$50,000 surety bond,⁵ comply with the DMEPOS supplier standards in order to obtain and retain billing privileges,⁶ meet quality standards prescribed by the Secretary of Health and Human Services,⁷ and engage an independent accrediting agency approved by DHHS to certify that the supplier did in fact meet the quality standards.⁸

Due to the demographic served by retail suppliers of medical oxygen, the CMS laws and rules function as the primary regulatory scheme. In fact, it was suppliers' concerns over an accreditation requirement relating to state licensing that led to this rulemaking proceeding in the first place.⁹ For this reason, this chapter contains relatively few substantive requirements. Many of the provisions in the proposed rule were relaxed or removed in the adopted rule for the reasons discussed in the Response to Comments below.

¹ 49 CFR Parts 173-178

² Compressed Medical Gases Guideline, February 1989 revision

³ See 42 USC §1395m(j)(2)

⁴ See 42 USC §1395m(j)(1)

⁵ See 42 USC §1395m(a)(16)(B)

⁶ See 42 CFR §424.57, entitled "Special Payment Rules for Items Furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges." ("DMEPOS" stands for durable medical equipment, prosthetics, orthotics and supplies and is a supplier type that includes suppliers of oxygen delivery systems.

⁷ See 42 USC §1395m(a)(20). The quality standards, entitled "Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Quality Standards," were finalized in October 2008 outside of the rulemaking process and are available from the CMS DMEPOS web page at http://www.cms.gov/MedicareProviderSupEnroll/07_DMEPOS Accreditation.asp as "DMEPOS Accreditation Standards."

⁸ See 42 USC §1395m(a)(20). The criteria for approval of accrediting agencies are set forth in 42 CFR §424.58. Descriptions of the 10 accrediting agencies approved by CMS may be downloaded from the web site cited in note 7 above.

⁹ See the Emergency Findings dated November 15, 2010 that accompanied the board's initial adoption of this chapter on an emergency basis.

Response to Comments

Bruce Gerrity
Preti Flaherty Belliveau & Pachios
on behalf of Maine Optometric Association

- ◆ The definition of “prescription device” in Section 1(1) of the proposed rule incorrectly cites 21 USC §351(h) as the federal definition of “device.” The federal definition of “device” is found in 21 USC §321(h). The reference to §351(h) in the proposed rule was likely clerical error. The citation should be corrected accordingly.
 - Board response: The commenter is correct. The intended citation was 21 USC §321(h). No correction has been made, as the entire definition of “prescription device” has been removed from the adopted rule for the reasons discussed below.
- ◆ The definition of device in Section 1(1) of the proposed rule is extremely broad. As defined in 21 USC §321(h), “device” means:

...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.

Although the focus of the proposed rule is regulation of oxygen, the breadth of the definition of “device” also includes within its scope contact lenses, glasses and other ophthalmologic aids, such as eye patches. The unintentional regulation of these devices by the board should be eliminated. Regulation of contact lens and other ophthalmologic aids exceeds the purpose of Chapter 34 as expressed in the emergency findings and basis statement that accompanied emergency adoption of this chapter on November 15, 2010. Regulation by the board would likely create inconsistencies with regulation by the Board of Optometry pursuant to the Maine optometric code. In addition, the prescription and dispensing of contact lenses is thoroughly regulated by the Federal Trade Commission.

- Board response: The commenter is correct. The board did not intend to regulate contact lenses, glasses and other ophthalmologic aids. This

comment also focused the board's attention on a larger issue: whether it is necessary for the board to regulate any prescription devices at all.

Home medical equipment suppliers typically deliver oxygen concentrators as well as oxygen in cylinders. Oxygen concentrators are prescription medical devices. But prescription devices also include a wide variety of medical appliances and technology in addition to contact lenses. Examples of prescription devices intended for home use are ventilators and nebulizers, wheelchairs, infusion pumps, blood glucose meters, apnea monitors and other home monitoring devices.¹⁰ The board is aware of no pressing need to regulate this large universe of prescription medical devices.

Contact with the New England Medical Equipment Dealers Association ("NEMED") confirmed that home medical equipment providers that supply liquid or pressurized oxygen (i.e., the prescription drug) to consumers in cylinders are the same businesses that also rent oxygen concentrators (i.e., the prescription device) to consumers. The board finds that licensing of sellers of prescription devices is unnecessary to accomplish the primary purpose of this rulemaking proceeding, as described in the emergency findings: appropriate licensure of medical oxygen suppliers to prevent their loss of MaineCare reimbursement. For this reason, the adopted rule does not require licensure of sellers of prescription medical devices. The adopted rule requires licensure only of retail suppliers of medical oxygen.

Karyn Estrella, Executive Director
New England Medical Equipment Dealers Association

- ◆ Nebulizers should be excluded from the scope of the rule. Nebulizers are a prescription device that are sold by durable medical equipment providers that do not sell medical oxygen, as well as by retail suppliers of medical oxygen.
 - Board response: The board agrees that only retail suppliers of medical oxygen should be subject to licensure under this chapter.

- ◆ The definition of "retail supplier of medical oxygen" should provide that a licensee who does not engage in manufacturing practices should be allowed to sell or dispense oxygen to a professional practice such as a doctor's office or nursing home without having to be licensed as a wholesaler with the board.
 - Board response: The commenter seeks to avoid the need for retail suppliers of medical oxygen who also sell to doctor's offices or nursing

¹⁰ 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>

homes to be dually-licensed with the board as both a retail supplier of medical oxygen under this chapter and a wholesale drug outlet under Chapter 12 of the board's rules.

The retail supplier of medical oxygen license created by this chapter is a type of retail pharmacy authorized by 32 MRSA §13751(2). As noted in the basis statement, 32 MRSA §13751(3) authorizes the board to “issue various types of licenses with varying restrictions to [retail pharmacies] when the board determines it necessary by reason of the type of pharmacy requesting a license.” Although the license category of retail pharmacy is not defined in the pharmacy law, the term is generally understood to mean a pharmacy that sells prescription drugs directly to the person or the representative of the person for whom a drug is prescribed. The overwhelming majority of retail pharmacies licensed by the board are standalone drug stores, supermarkets or mass-market retailers. By authority of §13751(3), the board also licenses specialty retail pharmacies that sell only by prescription but do not operate walk-up pharmacies. Specialty retail pharmacies of this nature consist of nuclear medicine drug outlets (Chapter 17), suppliers of sterile pharmaceuticals (Chapter 18) and now, retail suppliers of medical oxygen.

However, retail suppliers of medical oxygen also sell to physicians, dentists and nursing homes. Unlike sales to individual customers, these sales are not pursuant to prescription for a specific individual. Rather, sales to practitioners and nursing homes are for emergency use. A medical office needs oxygen on hand for patients who come to the office in respiratory distress. Emergency administration of oxygen at a nursing home may be authorized by a standing order from a physician. A nursing home typically has oxygen cylinders on a “crash cart” that is wheeled to the room of a stricken resident.

Title 32 MRSA §13758 requires manufacturers and wholesalers to be licensed with the board. Title 32 MRSA §13702-A defines “wholesaler” as “a person who buys prescription drugs for resale and distribution to persons other than consumers.” Because practitioners and nursing homes are not consumers, the Maine pharmacy licensing law can be read as requiring retail suppliers of medical oxygen to also obtain a wholesaler license if they wish to sell to these entities.

However, the definition of “wholesaler” in 32 MRSA §13758 is not the entire story. The overall state and federal pharmacy licensing scheme supports NEMED’s position.

The federal Prescription Drug Marketing Act of 1987, in 21 USC §353(e), requires states to license wholesale drug distributors in accordance with a rule promulgated by the Secretary of Health and Human Services. The federal law and rule generally define “wholesale distribution” as the

distribution of prescription drugs to persons other than the consumer or patient. See 21 USC §353(e)(3)(B); 21 CFR §205.3(f). But the federal law and rule also exempt from the definition of “wholesale distribution”—

...a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons.

21 USC §§353(e)(3)(B) and 353(c)(3)(B)(iv).

...[t]he sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, emergency medical reasons includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

21 CFR §205.3(f)(5)

Chapter 12 of the board’s rules requires the registration (i.e., licensure) of manufacturers and wholesalers. Chapter 16 of the board’s rules contains standards for operation of wholesalers and manufacturers. These chapters were adopted to implement the Prescription Drug Marketing Act of 1987.¹¹ To that end, Chapter 1, Section 37 of the board’s rules defines “wholesale distributor” as:

...anyone engaged in *wholesale distribution* of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private label distributors; jobbers; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A wholesale distributor includes a wholesaler as defined in 32 M.R.S.A. §13702(26).

(emphasis added)

Chapter 1, Section 36 of the board’s rules defines “wholesale distribution” as:

...the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, *but does not include:*

...

(5) *The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons; for purposes of this section, “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;*

(emphasis added)

¹¹ See the basis statement dated October 12, 2004 that accompanied the boards’ adoption of Chapter 16. See also the statement of purpose that appeared as Section B of the predecessor to Chapters 12 and 16 of the board’s rules, viz. Chapter 15, Registration of Wholesale Drug Distributors, eff. August 12, 1992.

The board's rules accordingly track the federal law and rule in recognizing drug sales for emergency medical reasons as an exception to the requirement of licensure as a wholesaler.

There is good reason for this. Unlike typical wholesale transactions, sales to physicians and nursing homes are not made for purposes of resale. Physicians and nursing homes stand as proxies for the actual patients, whose identities are of necessity unknown at the time of sale. Equally important, little regulatory purpose would be served by requiring NEMED members (and other like businesses) to obtain two licenses from the board for an activity that doesn't fall within either. The substantive requirements of Chapter 16 have little applicability to home medical equipment suppliers who do not otherwise engage in activities which clearly trigger the need for licensure as manufacturer or wholesaler. In these circumstances, there is no conceivable increase in protection of the public health or safety that is discernible from dual licensure.

The board has accordingly added the following provision as Section 2(3) of this chapter:

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

A retail supplier of medical oxygen licensed under this chapter who sells oxygen 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.

This subsection expresses the board's intent that a retail supplier of medical oxygen who also sells to a licensed practitioner or health care facility need not, by virtue of those sales alone, be licensed as a wholesaler. A retail supplier of medical oxygen who engages in other sales which do fall within the definitions of "wholesale distribution" and "wholesaler distributor" in Chapter 1 of the board's rules will be subject to the wholesaler licensing requirements of Chapters 12 and 16 of the board's rules.¹²

(responses to comments of Karyn Estrella continued)

¹² NEMED, through Ms. Estrella, submitted additional information subsequent to the rulemaking hearing at the request of board staff. The follow-up comment included draft rule language to exempt a licensed retail supplier of medical oxygen who is registered as a manufacturer or repacker with the FDA from having to be licensed as a wholesaler by the board. The board does not have statutory authority to grant this exemption. If a retail supplier of medical oxygen engages in the manufacture or wholesale distribution of drugs as defined in Maine law and rules, licensure as a manufacturer or wholesale drug outlet is mandatory under 32 MRSA §13751(1), §13751(2)(C) or §13758, and Chapter 12 of the board's rules.

- ◆ Section 5 of the proposed rule states that a retail supplier of medical oxygen may fill a prescription for a period no greater than 15 months from the date written. “Depending on the diagnosis and prescribing physician’s order, an end user may require home oxygen therapy for the remainder of their life. CMS accepts ‘lifetime’ length of need prescriptions in those cases that meet medical qualification criteria and does not require the home medical provider to obtain renewal prescriptions.” The last sentence of Section 5 should be rewritten to read:

A retail supplier of medical oxygen and prescription devices may fill a prescription for oxygen or a device for the length of medical need authorized by the prescribing practitioner. If the duration of use is not specified, the order is valid for 15 months.

- ◆ Section 5 of the proposed rule requires that prescriptions for medical oxygen conform to the requirements for prescriptions in Chapter 19, Section 1 of the board’s rules. Section 1(E) and (F), relating to strength, dosage, quantity and refill authorization, are inapplicable to prescriptions for medical oxygen.
 - Board response to two preceding comments: Comments accepted for the reasons given. Proposed Section 1(5) is replaced by the following:

5. Prescription Drug Order

Each retail sale of medical oxygen must be authorized by a prescription from a practitioner. A retail supplier of medical oxygen 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.

- ◆ The requirements for dispensing records in Section 7 of the proposed rule, “Dispensing Records,” are in many respects inapplicable to prescriptions for medical oxygen. For example, a medical oxygen supplier does not dispense a set amount of oxygen, and in any event cannot vary the flow rate and hours of use per day from what the physician has prescribed. There are no refill counts per se. What the proposed rule refers to as dispensing records does not match the business records of retail suppliers of medical oxygen:

The delivery information is maintained in the patient’s file. As a practical matter dispensing and delivery is the same action for oxygen and medical devices since almost all the patients are at home when they receive the items. A “delivery record / invoice” documents the item(s) that were dispensed to the patient. In addition, the date, the shippers name and address, patient’s name and address, and the name of the delivery person is documented. Oxygen and medical device retailers do not maintain pharmacy type “dispensing logs” or pharmacy type “delivery logs.” In the home oxygen industry applicable FDA and DOT regulations require the

tracking documentation for oxygen containers from receipt from the manufacturer to the final delivery to the patient. The format of the documentation is not a "log" but when all the elements are put together, the documentation accomplishes the same basic goal of pharmacy dispensing and delivery records. Existing delivery tracking documentation processes are acceptable in all other states with a few minor variations.

In addition, Section 7 is unclear as to whether scanned copies of prescriptions may be maintained in lieu of original paper prescriptions.

- ◆ The record retention requirements in Section 8 of the proposed rule, "Retention of Records," are in many respects inapplicable to prescriptions for medical oxygen. Medical oxygen cylinders are not "purchased" by end users. A retail supplier of medical oxygen would have difficulty complying with the draft rule requirement to produce records of all prescriptions filled during the last 12 months or 3 years because prescription records are not sorted by year but are kept by patient name. (However, "[i]ndividual patient records are available immediately and would at a minimum contain all records created over the last 12 months.") It is unclear from the proposed rule if records requested by a board inspector could be produced in hard copy, on a CD, or electronically.
 - Board response to preceding two comments: The board concurs that much of Sections 7 and 8 of the proposed rule did not adapt well from the board's existing rules. To address these concerns, Sections 7 and 8 of the proposed rule are replaced by the following Section 7 in the adopted rule:

7. Patient Records

A retail supplier of medical oxygen 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.

The phrase "or any electronic format" is meant to encompass scanned records, document retention systems, documents on CD or any other means of non-paper recordkeeping.

- ◆ Section 9 of the proposed rule, "Compliance With Current Good Manufacturing Practices," is overly broad in that the current good manufacturing practices promulgated by the FDA only apply to those suppliers of medical oxygen who are manufacturers or repackers under the Federal Food, Drug and Cosmetic Act. Section 9 should be limited accordingly. In point of fact, Section 9 is not necessary at all, as the FDA independently inspects facilities and enforces all applicable FDA rules. In addition, the reference to the 1989 guidelines document should be removed as the guidelines are in the process of revision. (The commenter submitted proposed substitute language for Section 9(1).)

- Board response: Good manufacturing practice standards contained in 21 CFR Parts 210 and 211 apply to manufacturing, processing, packing or holding of a drug. 21 CFR §210.1(a). This includes packaging and labeling operations, testing, and quality control of drug products. 21 CFR §210.3(13). Parts 210 and 211 implement 21 USC §351(a)(2)(B), which defines as adulterated any drug as to which:

...the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;

The board agrees that Section 9 of the proposed rule (Section 8 in the adopted rule) should be rewritten to identify only those retail suppliers of medical oxygen who are subject to 21 CFR Parts 210 and 211, i.e., those who manufacture, process, pack or hold oxygen.

The board declines to delete reference to Chapters 210 and 211 entirely, as the framework of the board's rules is that a licensee's violation of federal drug laws or rules also constitutes a violation of the board's rules. See Chapter 29 of the board's rules, entitled "Violations of Federal Law or Rule." For this reason, Section 8(2) has been rewritten to expressly incorporate Chapters 210 and 211 by reference into the adopted rules.

Board staff's research is consistent with the commenter's statement that the guidelines are in the process of revision and that reference to the guidelines in the board's rule may in the foreseeable future be obsolete. For this reason, mention of the guidelines has been deleted from the adopted rules.

For the reasons discussed herein, the board has re-written Section 8 of the adopted rules to read:

8. Compliance With Current Good Manufacturing Practice;
Incorporation by Reference

1. Current Good Manufacturing Practices

A retail supplier of medical oxygen that manufactures, processes, packages or holds oxygen 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 Parts 210 and 211 (April 1, 2010 edition).

2. Incorporation by Reference

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

- A. Title 21 CFR Part 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General" promulgated by the U.S. Food and Drug Administration (April 1, 2010 edition). This document is available from the FDA on line at:

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

This document may also be obtained from the State Law Library, State House, Augusta, Maine 04333, tel. (207) 287-1600.

- B. Title 21 CFR Part 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals" promulgated by the U.S. Food and Drug Administration (April 1, 2010 edition). This document is available from the FDA on line at:

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

This document may also be obtained from the State Law Library, State House, Augusta, Maine 04333, tel. (207) 287-1600.

- ◆ The commenter submitted draft rule language defining "accrediting body;" requiring an applicant for licensure as a retail supplier of medical oxygen to include documentation of accreditation with its license application; and exempting licensees, who will have demonstrated accreditation in order to obtain licensure, from site inspections except for cause. The draft language would also allow the 24 retail suppliers of medical oxygen already licensed under the emergency adoption of this chapter to demonstrate accreditation in order to qualify for the exemption.
 - Board response: Retail suppliers of medical oxygen have all achieved accreditation from an accrediting body recognized by CMS in order to participate in the Medicare-Medicaid program. However, initial site inspection is a one-time statutory requirement that the board has applied to all retail pharmacies, even limited retail pharmacies such as nuclear pharmacies and providers of sterile pharmaceuticals. See 32 MRSA §13752-A(1)(B). Initial site visits are scheduled for a time convenient to the licensee. The board does not consider the initial site visit to be an onerous requirement, and the site visit does not delay licensure. Although the board has authority to waive this requirement (see 32 MRSA §13752-A(1)(A)), it declines to do so on a blanket basis.

- ◆ The medical oxygen industry has existed in this state for nearly 35 years. Over those years the amount of regulation has evolved. NEMED members are now very heavily regulated. The first agency that interacted with our industry was the Department of Transportation. Oxygen containers in transit are hazardous materials. They are also regarded as medical devices containing a drug that must be delivered to a patient as a service. A patient cannot effectively deal with this at home unless all components are involved.

A second agency interacting with our industry is the FDA, when the current good manufacturing practices came out in the 1970s. The current good manufacturing practices had to have a guidance document written, as the manufacturing process for oxygen and other medical gases do not fit the traditional drug manufacturing model. Medical oxygen suppliers primarily move oxygen between containers, which is deemed manufacturing or repackaging. This has led to a tremendous amount of paperwork. The DOT has ratcheted things up to another level because you are required to track that hazardous material when it is on trucks and being moved around. Much of this tracking information might meet the intent of the Maine pharmacy law; it just doesn't look like traditional pharmacy documentation.

In 1988, the Joint Commission on the Accreditation of Health Care Organizations, now known as the Joint Commission, started to accredit our type of organization. Beginning in 2008, accreditation was mandated by the Centers for Medicare and Medicaid Services ("CMS"). CMS' quality standards are now incorporated into the accreditation standards of the accrediting bodies, which must themselves now be approved by CMS. The CMS quality standards also recognize respiratory therapists, which are heavily involved with our industry.

"What we're trying to...say is that we have a lot of existing regulation, a lot of existing documentation we currently already keep and we believe that if there are some adjustments to the rules to kind of accept the types of documentation we use we will meet the intent of prescriptions...We've got the types of prescription documentation you guys are asking for. We've got a tremendous amount of traceability because we've got to be prepared to do recalls."

- Board response: The board agrees with the commenter that retail medical oxygen suppliers are heavily regulated by DOT, FDA, CMS and the CMS-mandated accreditation process. For the reasons given by the commenter, the board in this chapter has revised and relaxed many of the safety, security and accountability provisions of its rules that apply to traditional full-service retail pharmacies. See also the related discussion in the basis statement at page 2 above.

- ◆ The board should look carefully at Section 9 of the proposed rules. Only those who do manufacturing as defined by the FDA should be subject to this section. The majority of NEMED members do not do anything with manufactured devices. We use all off-the-shelf devices. “The only thing that we do in manufacturing is if we so happen to transfer gas between containers, which clearly then comes under FDA regulations.”
 - Board response: The board agrees with the commenter. Section 8 of the adopted rule (Section 9 of the proposed rule) has been simplified by: removing provisions that related to the manufacture of prescription devices. The scope of Section 8 has also been narrowed. As discussed at page 10 above, the adopted rule encompasses only those licensees who engage in activity identified in federal law as subject to current good manufacturing practices.

Joe McVety, General Manager
Kennebec Pharmacy and Home Care

- ◆ “I would like to comment about the difference in the standards of practice for which we are held and for which the new licensee’s will be held.

“Kennebec Pharmacy and Home Care is a licensed pharmacy which provides HME and Home Oxygen. Under our current licensure as a pharmacy all of the legend products must be stored behind the counter of the pharmacy.

“As you have heard from the other testimony this is not practical. In order to supply oxygen we are required to store gas cylinders and large tanks of liquid oxygen. As you also heard we are under a lot of scrutiny about the proper storage of the tanks. I would like us to be able to store our oxygen under the same standards as the new licensees.

“Other HME providers under this new license will be able to have foley catheters and other HME supplies which carry the ‘RX only’ stamp out in their front store. These items are petrolatum dressing and other supplies which are intended to be given to the patient upon the order of a physician. You yourselves have stated that a pharmacist is not needed in this process. Once again we are required to store these behind the counter and dispense as a prescription item by a pharmacist. We would like to be able to handle these items like the new licensees are able to handle them.

“I am hoping that we can be held to the same standard as these other providers. As it was noted there are only a couple of us who are pharmacies and providers of oxygen and HME. We certainly did not get represented by NEMED during these hearing, the focus has been on the non-pharmacy providers. I hope you will think of our interest and allow us to participate on an even playing field.”

- Board response: The second and fourth paragraphs of this comment pertain to portions of the proposed rule that would have required retail sellers of prescription devices to be licensed under this chapter. As discussed at pages 3-4 above, the adopted rule does not require retail sellers of prescription devices to be licensed under this chapter (unless they are also happen to be retail suppliers of medical oxygen). No response is necessary to these portions of the comment.

The adopted rule does not impose any particular requirements relating to the storage of oxygen containers by retail suppliers of medical oxygen. The board is unaware of the disparity in storage requirements for retail suppliers of medical oxygen vs. retail pharmacies that the commenter alludes to.

Findings Pursuant to Executive Order 14 FY 11/12

The proposed rules will not have an impact on job growth or creation in the State of Maine. There will be no cost to the public in terms of time and money to comply with the rules. The selling of medical oxygen is regulated by the Maine Pharmacy Act and the board rules discussed in this document as well as the MaineCare program. The selling of medical oxygen is extensively regulated by the federal laws and rules discussed in this document. This chapter is consistent with the federal standards.