

Rule-Making Cover Sheet

MAPA-1

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

2012-64

1. **Agency:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. **Agency umbrella and unit number:** 02-392
(2 digit umbrella # and 3 digit unit #)
3. **Title of rule:** Licensure of Manufacturers and Wholesalers
4. **Chapter number assigned to the rule:** 12
(must be 3 digits or less)
5. **Date(s)/method(s) of notice:** Newspaper advertisement by Secretary of State, 10-12-11; mailing to interested parties, 09-29-11; posting on OPOR's web site, 09-28-11
6. **Date(s)/place(s) of hearing(s):** 11-03-11, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. **Type:** 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 repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.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) 624-8625

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

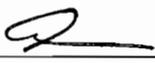
- Provisional adoption (prior to Legislative review) Final adoption
 Emergency adoption of major-substantive rule

10. **Certification Statement:** I, Joseph Bruno, 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 February 2, 2012.

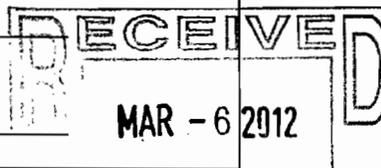
Signature: 
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. **Approved as to form and legality by the Attorney General on** 3/1/12
(date)

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

Printed Name: CHARLES J. MANS



EFFECTIVE DATE: **MAR 11 2012**

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 12: REGISTRATION LICENSURE OF MANUFACTURERS AND WHOLESALE DRUG-OUTLETS WHOLESALE PHARMACIES WHOLESALE DRUG DISTRIBUTORS AND MANUFACTURERS**

Summary: This chapter sets forth ~~registration~~ license requirements for ~~wholesale drug outlets~~ wholesalers, also known as ~~wholesalers~~ wholesale pharmacies or wholesale drug distributors, and manufacturers.

1. Scope

This chapter applies to manufacturers and ~~wholesale drug outlets~~ wholesalers.

2. Application for Registration Licensure

The manufacturer or ~~wholesale drug outlet~~ wholesaler shall provide the following information on forms supplied by the board, along with such other information as the board may require. Applications will not be considered for approval until they are complete. Incomplete applications will be returned to the applicant.

1. The name, physical address, contact address, telephone number, email address and world wide web address of the ~~wholesale drug outlet~~ wholesaler or manufacturer;
2. All trade or business names used by the ~~wholesale drug outlet~~ wholesaler or manufacturer;
3. The name, address, 24-hour telephone number and email address of a contact person for the facility used by the ~~wholesale drug outlet~~ wholesaler or manufacturer for storing, handling and distributing prescription drugs.
4. Type of ownership or operation (i.e., partnership, corporation, limited liability company or sole proprietorship); and
5. The name(s) of the owner and/or operator of the ~~wholesale drug outlet~~ wholesaler or manufacturer, 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 stock 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 if such certificate is required by 13-C M.R.S.A. §1501;

C. If 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;

6. The DEA number;

6-A. If the applicant is accredited by VAWD, proof of current accreditation.

7. ~~Verification of licensure for~~ A list of all jurisdictions in which the manufacturer or wholesale drug outlet/wholesaler has at any time been licensed as of the date of application to the board, along with the license number and license expiration date for each such jurisdiction;

7-A. Disclosure of, and the final disposition document pertaining to, any disciplinary action taken against the manufacturer or wholesaler by a licensing or regulatory authority in any jurisdiction. If the applicant is accredited by VAWD, such disclosure and documentation need only pertain to the period of time subsequent to the wholesaler's initial accreditation or most recent annual renewal of accreditation.

8. A copy of the most recent inspection report from the state in which the manufacturer or ~~wholesale drug outlet~~wholesaler is located. If a wholesaler is accredited by VAWD, this information need not be provided; and

9. The 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."

3. **Separate Applications for Separate Facilities**

The owner must file a separate application for each facility that manufactures or distributes wholesale prescription drugs. Applications need not be filed for business locations at which no manufacturing or distribution occurs.

4. Minimum Qualifications

The board will consider the following factors in determining the eligibility for ~~registration~~ licensure of persons who engage in the manufacture or wholesale distribution of drugs:

1. Subject to 5 M.R.S.A. §5301 *et seq.*, any findings by the board that the applicant has violated any federal, state or local laws relating to drug manufacturing or distribution;
2. Subject to 5 M.R.S.A. §5301 *et seq.*, any felony convictions of the applicant under federal, state or local laws;
3. The applicant's past experience in the manufacture or distribution of drugs;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. ~~Suspension or revocation~~ Disciplinary action taken by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of drugs;
6. Compliance with previously granted licenses of any kind; ~~and~~
7. Compliance with the requirements to maintain and/or make available to the board or to federal, state or local law enforcement officials those records required to be maintained by manufacturers or wholesale drug distributors; and
8. Accreditation by VAWD.

5. Change of Owner or Location; Change in Other Registration Information

Upon a change of ownership, a manufacturer or ~~wholesale drug outlet~~ wholesaler shall file a new application with the board ~~by registered mail~~ no less than 7 days prior to the change. Upon a change of location, a manufacturer or ~~wholesale drug outlet~~ wholesaler shall file a new application with the board ~~by first class mail~~ 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. ~~In the event of any other change in the information provided by the manufacturer or wholesale drug outlet in its most recent application, the manufacturer or wholesale drug outlet shall notify the board via letter, fax or email within 7 days after the change.~~

6. Operation of Manufacturer or ~~Wholesale Drug Outlet~~ Wholesaler

A manufacturer or ~~wholesale drug outlet~~wholesaler shall comply with the rules of operation contained in Chapter ~~1716~~, "Operation of ~~Wholesale Drug Outlets~~Wholesalers and Manufacturers" of the board's rules.

STATUTORY AUTHORITY: 32 M.R.S.A. §§13720, 13721(1)(E), 13723, 13751, 13758

EFFECTIVE DATE:

November 8, 2004 - filing 2004-514