

# Notice of Agency Rule-making Proposal

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

CHAPTER NUMBER AND TITLE: Chapter 12, Licensure of Manufacturers and Wholesalers

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

BRIEF SUMMARY: 2017 Public Law, Chapter 267, 32 M.R.S. §13759, “An Act to Prohibit Certain Gifts to Health Care Practitioners” directs the Maine Board of Pharmacy to establish definitions by rule for modest meals and refreshments, and reasonable honoraria. This rule sets standards on exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

Date, time and location of PUBLIC HEARING (*if any*): May 8, 2019, 8:00 a.m., 76 Northern Avenue, Gardiner, Maine 04333, Central Conference Room.

COMMENT DEADLINE: May 19, 2019 by 5:00 p.m., 76 Northern Avenue, Gardiner, Maine 04333, Central Conference Room.

CONTACT PERSON FOR THIS FILING (*include name, mailing address, telephone, fax, TTY, e-mail*):  
Geraldine Betts, Program Administrator, 35 State House Station, Augusta, ME 04333,  
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CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT (*if different*): none

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES (*if any*): none

STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S. §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (*if different*): 2017 Public Law, Chapter 267, 32 M.R.S. §13759, “An Act to Prohibit Certain Gifts to Health Care Practitioners”

AGENCY WEBSITE: <http://www.maine.gov/pfr>

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: same as above

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**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**

**392 MAINE BOARD OF PHARMACY**

**Chapter 12: LICENSURE OF MANUFACTURERS AND WHOLESALERS**

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

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**1. Scope**

This chapter applies to manufacturers and wholesalers.

**2. Application for Licensure**

The manufacturer or 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 wholesaler or manufacturer;
2. All trade or business names used by the wholesaler or manufacturer;
3. The name, address, 24-hour telephone number and email address of a contact person for the facility used by the 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 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. A list of all jurisdictions in which the manufacturer or wholesaler 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 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 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. 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;
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 wholesaler shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a manufacturer or wholesaler 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.

**6. Operation of Manufacturer or Wholesaler**

A manufacturer or wholesaler shall comply with the rules of operation contained in Chapter 16, "Operation of Wholesalers and Manufacturers" of the board's rules.

**7. Exception to Prohibition Against Gifts to Practitioners**

The following definitions apply to terms contained in 32 M.R.S. § 13759, which constitute exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

1. For purposes of 32 M.R.S. § 13759(2)(A)(3), "modest meals and refreshments" means food and beverage of minimal value provided to a practitioner in connection with a meeting or presentation about the benefits, risks, and appropriate uses of prescription drugs or medical devices, disease states, or other scientific information as long as the meeting or presentation occurs in a venue and manner conducive to informational communication. Such food and beverage must be of the type and quantity typically provided for conference attendees at the venue where the meeting or presentation occurs.

Board-Accepted Proposed Rulemaking 04042019 (Major Substantive Rulemaking)

2. For purposes of 32 M.R.S. § 13759(2)(C), “reasonable honoraria” means cash and/or a gift given to a practitioner in return for the practitioner speaking at a professional or educational conference sponsored by a manufacturer or wholesaler. The aggregate value of all cash and gifts received by a practitioner for a particular speaking engagement may not exceed an annual limit of \$250 in retail value.
3. For purposes of 32 M.R.S. § 13759(2)(C), “reasonable expenses” means the reasonable and actual expenses for travel, lodging, and meals incurred by a practitioner and that are necessary in order for the practitioner to speak at a professional or educational conference sponsored by a manufacturer or wholesaler.

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STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

EFFECTIVE DATE:

November 8, 2004 - filing 2004-514

AMENDED:

March 11, 2012 – filing 2012-64