

Readopt with amendment Ph 1001.01, effective 10-15-20 (Document #13117), to read as follows:

CHAPTER Ph 1000 STANDARDS OF PRACTICE FOR MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS

PART Ph 1001 LICENSING

Ph 1001.01 License Required.

(a) No person shall manufacture or act as a wholesale distributor of prescription drugs or prescription devices without first obtaining a license to do so from the ***office of professional licensure and certification (OPLC)*** ~~board~~ pursuant to ***Ph 305.07 and Ph 305.08*** ~~this chapter~~. No license shall be issued or renewed for a manufacturer or wholesale drug distributor unless the same shall be operated in a manner prescribed by law and according to ***this chapter*** ~~the rules adopted by the board with respect thereto~~.

(b) Separate licenses shall be required for each manufacturing and distribution site owned or operated by a manufacturer or wholesale distributor. Provided however, that an agent or employee of any licensed manufacturer or wholesale distributor shall not be required to be licensed under this section and may lawfully possess prescription drugs and devices if the agency or employee is acting in the usual course of ~~his or her~~ ***their*** business or employment.

~~(c) All licenses for manufacturers and wholesale distributors of prescription drugs and medical devices containing a prescription drug shall expire biennially on June 30th of every even-numbered year. The renewal application may be obtained from the board office. Alternatively, applicants may file the renewal application online at <https://nhlicenses.nh.gov/eGov/Login.aspx>.~~

~~— (d) The prescribed fee for original and biennial renewal licenses for manufacturers and wholesale distributors of prescription drugs and devices shall be \$500.~~

~~— (e) No in-state license shall be issued until such time as the applicant has satisfactorily completed a site inspection performed by the board confirming the facility:~~

- ~~(1) Is of suitable size, construction, and location to allow proper storage, handling and security of drugs;~~
- ~~(2) Is located in a commercially zoned area;~~
- ~~(3) Has adequate outside lighting to allow for proper security;~~
- ~~(4) Has notified the local police department that legend drugs are being stored at the facility;~~
- ~~and~~
- ~~(5) Has a functioning alarm system in place.~~

Repeal Ph 1001.02 and Ph 1001.03, effective 10-22-16 (Document #12007), as follows:

~~— Ph 1001.02 Obtaining and Filing a License Application. Applications for licensure of manufacturers, wholesalers and distributors may be obtained from, and shall be filed at, the board office, identified in Ph 1003.03.~~

~~— Ph 1001.03 Application Contents.~~

~~— (a) The applicant for licensure shall complete and submit the board provided form Ph A-5, revised 09/16.~~

~~— (b) Applicants shall also submit 2 photographs of the existing exterior of the facility in which the applicant is located. These photographs shall include any outside signage. Artist sketches or architect plans or drawings shall not be acceptable.~~

~~— (c) Applicants shall also submit at least 4 photographs of the interior of the facility showing legend drug storage areas, refrigeration units and any specially constructed areas for storage of controlled substances.~~

~~— (d) In state applicants shall also submit a sealed floor plan of the proposed facility.~~

~~— (e) Applicants shall supply a list of all states where licensed and include license number.~~

Readopt Ph 1002.01, effective 10-22-16 (Document #12007), to read as follows:

Ph 1002.01 Storage Conditions.

(a) All facilities at which prescription drugs are repackaged, wholesaled, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall provide storage areas that have:

- (1) Adequate lighting;
- (2) Adequate ventilation;
- (3) Proper sanitation;
- (4) All drugs or chemicals shall be stored at appropriate temperatures and humidity per label requirements;
- (5) Refrigerator temperatures are monitored on a daily basis; and
- (6) Room temperature is maintained and monitored on a daily basis.

(b) A separate storage section shall be provided for prescription drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.

Readopt Ph 1002.02, effective 10-22-16 (Document #12007), to read as follows:

Ph 1002.02 Facilities.

(a) All buildings in which prescription drugs are wholesaled, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to meet the requirements set forth in this chapter.

(b) Buildings shall meet all applicable federal, state, and local standards. A facility shall not be located in a residence. All facilities shall be located in an area that is commercially zoned.

(c) A wholesale drug distribution facility shall notify the local police department or other appropriate law enforcement agency that it is a distributor of prescription drug products and controlled substances.

Readopt Ph 1002.03, effective 10-22-16 (Document #12007), to read as follows:

Ph 1002.03 Security.

(a) Each wholesale drug distribution center shall be equipped with an internal alarm system to detect entry after hours. The alarm system shall be of the type that transmits a signal directly to a central station protection company, to a local or state police agency that has a legal duty to respond, or a 24 hour control station operated by the wholesale drug distributor.

(b) Manufacturers and wholesale drug distributors shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide protection against theft by personnel.

Readopt Ph 1002.04, effective 10-22-16 (Document #12007), to read as follows:

Ph 1002.04 Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of prescription drugs shall be maintained and made available for inspection by the board's inspectors for a period of 2 years.

(b) Records may be kept at a central location rather than at each distribution center, but records shall be made available for inspection within 72 hours of request by the board's inspectors.

Repeal Ph 1002.05, effective 10-22-16 (Document #12007), as follows:

~~Ph 1002.05 Inspections.~~

~~(a) Inspections shall be performed by the board's inspectors and be conducted at the request of the board.~~

~~(b) Inspections shall be conducted during normal business hours.~~

~~(c) Information that is considered to contain trade secrets or which might be proprietary in nature shall be protected from public disclosure.~~

Readopt and renumber Ph 1002.06, effective 10-22-16 (Document #12007), as Ph 1002.05 to read as follows:

Ph 1002.056 Written Policies and Procedures.

(a) Written policies and procedures shall be developed by management personnel to assure that the manufacturer and wholesale drug distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises shall include fires, floods, or other natural disasters, and situations of local, state or national emergency.

(b) Written policies and procedures described in (a) above shall also provide for:

(1) The management and correction of all errors or inaccuracies in inventories;

(2) The assurance that any outdated stock, or any stock with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, shall be prepared for return to the manufacturer or otherwise destroyed;

(3) The control over the shipping and receiving of all stock within the operation; and

(4) A process for storage and disposal of hazardous drugs.

(c) Policies and procedures will be reviewed on a regular basis.

(d) A copy of the policies and procedures, or sections thereof, shall be made available to the board upon request.

(e) All manufacturers, wholesalers and distributors shall notify the board when it initiates a class I recall based on an FDA inspection.

Readopt and renumber Ph 1002.07, effective 10-22-16 (Document #12007), as Ph 1002.06 to read as follows:

Ph 1002.067 Returned Goods. A wholesale operation shall maintain a procedure for the proper handling and disposal of returned goods.

Readopt and renumber Ph 1002.08, effective 10-22-16 (Document #12007), as Ph 1002.07 to read as follows:

Ph 1002.078 Handling Recalls.

(a) A wholesale operation shall maintain a written policy for handling recalls and withdrawals for products.

(b) Policies required by (a) above shall cover all recalls and withdrawals of prescription drug products due to:

(1) Any voluntary action on the part of the manufacturer;

(2) The direction of the Food and Drug Administration, or any other federal, state or local governmental agency; and

(3) Replacement of existing merchandise with an improved product or new package design.

Readopt and renumber Ph 1002.09, effective 10-22-16 (Document #12007), as Ph 1002.08 to read as follows:

Ph 1002.089 Responsibility for Operation. A wholesale drug distribution operation shall maintain a list of principals and persons in charge including officers, directors, or primary stockholders and their qualifications.

Readopt and renumber Ph 1002.10, effective 10-22-16 (Document #12007), as Ph 1002.09 to read as follows:

Ph 1002.409 Compliance with State and Federal Law.

(a) All manufacturers, wholesalers and distributors shall comply with all applicable state and federal laws, regulations and rules.

(b) All manufacturers, wholesalers and distributors, doing business in New Hampshire, shall, before shipping or distributing any prescription drug, verify that the recipient is properly licensed to receive and possess such drugs.

(c) All manufacturers, wholesalers and distributors, licensed and doing business in the state of New Hampshire, shall not provide unsolicited controlled drug samples to licensed practitioners.

(d) A manufacturer's license shall allow for the direct wholesaling or distribution of such drugs to other licensed or authorized recipients.

(e) A duly authorized agent of a manufacturer, wholesaler or distributor licensed in this state, may possess and distribute potent or prescription drugs to individuals who may lawfully possess such drugs as may be necessary to further the licensed activity of the manufacturer, wholesaler or distributor.

Repeal Ph 1002.11, effective 10-22-16 (Document #12007), as follows:

~~Ph 1002.11 Violations.~~

~~— (a) No manufacturer or wholesaler shall distribute prescription drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.~~

~~— (b) Any person who manufactures, wholesales, or otherwise distributes prescription drugs, according to RSA 318:51-a and the provisions of Ph 1000, shall be subject to disciplinary action as provided in RSA 318:29.~~

Repeal Ph 1002.12, effective 10-15-20 (Document #13117), as follows:

~~Ph 1002.12 Reporting Changes.~~

~~— (a) It shall be the responsibility of the manufacturer or wholesaler to immediately notify the board of any changes of information submitted in the application for licensure.~~

~~— (b) Failure to provide the board with notification of changes in the application contents, within 30 days of such changes, shall subject the licensee, after notice and opportunity to be heard pursuant to Ph 200, to a fine of \$150.00.~~

~~— (c) The deadline for renewal applications shall be midnight June 30th of every even-numbered year. Any application received after that date shall be subject to a \$25.00 reinstatement fee. Licenses shall not be issued until the late fee is satisfied. Licensees shipping to or doing business in New Hampshire with an expired license shall be subject to discipline by the board pursuant to RSA 318:55.~~

~~— (d) If the ownership at the customer service level has changed, the name of the business has changed or more than 50% of the stock ownership has changed hands then a new application shall be required.~~

~~— (e) If a manufacturer, wholesaler, or distributor has any license or permit revoked, suspended, or voluntarily surrendered, the facility shall notify the board within 7 days and include a copy of the corresponding documentation.~~

Repeal Ph 1002.13 through Ph 1002.15, effective 10-22-16 (Document #12007), as follows:

~~Ph 1002.13 Discontinuance of Business.~~

~~— (a) Any licensee that intends to cease business activity shall inform the board, in writing, no less than 30 days prior to the anticipated closing.~~

~~— (b) If the records of receipt and disposition are maintained electronically, a complete record of transactions, for the current 2-year period, shall be reduced to printed form prior to the actual close of business.~~

~~Ph 1002.14 Disposition of Drugs and Records.~~

~~— (a) The balance of any inventory of non-controlled drugs may be sold to another wholesaler or manufacturer with invoices available to each party and a copy for the board's files.~~

~~— (b) The remaining balance of any controlled drugs may be transferred or sold to another wholesaler / manufacturer as a package along with:~~

Text deleted from existing rule shown in ~~struck through~~

- ~~(1) A hard copy record of the receipt and distribution of controlled substances for the past 2 years;~~
 - ~~(2) All CII drugs shall be transferred by DEA Form 222;~~
 - ~~(3) All CIII – V drugs shall be transferred by invoice with copies to the applicable parties and to the board;~~
 - ~~(4) The last 2 completed Biennial Inventory forms;~~
 - ~~(5) All unused DEA 222 forms shall be returned to the DEA, along with the current DEA registration, marked VOID; and~~
 - ~~(6) The current NH manufacturer – wholesaler license shall be relinquished to the board.~~
- ~~Ph 1002.15 Distributing Adulterated or Misbranded Drugs.~~
- ~~— (a) A wholesaler or distributor shall not distribute any drug which is adulterated or misbranded. After notice and opportunity for a hearing, a wholesaler, distributor who is found by the board to have knowingly distributed or otherwise sold for consumption an adulterated or misbranded drug, shall be subject to disciplinary action according to RSA 318:29.~~

APPENDIX A

Rule	Specific State Statute the Rule Implements
Ph 1001.01	RSA 318:51-a, I
Ph 1001.02 (repealed)	
Ph 1001.03 (repealed)	
Ph 1002.01	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.02	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.03	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.04	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.05 (repealed)	
Ph 1002.05 (formerly Ph 1002.06)	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.06 (formerly Ph 1002.07)	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.07 (formerly Ph 1002.08)	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.08 (formerly Ph 1002.09)	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.09 (formerly Ph 1002.10)	RSA 318:5-a, IV-a, VI, and IX; RSA 318:8-a; RSA 318:51-a
Ph 1002.11 (repealed)	
Ph 1002.12 (repealed)	
Ph 1002.13 (repealed)	
Ph 1002.14 (repealed)	
Ph 1002.15 (repealed)	