CHAPTER Ph 1000 MANUFACTURERS

Statutory Authority: RSA 318:51-a

PART Ph 1001 PURPOSE AND SCOPE

Ph 1001.01 Purpose. The purpose of this chapter is to set forth the requirements, limitations, and prohibitions for Manufacturers that are engaged in the manufacture of a drug, is responsible or otherwise accountable to the Food and Drug Administration (FDA) for the manufacture of the drug, or is the private label manufacturer of products bearing its NDC number that is intended for sale, distribution, dispensing or administration, and who holds one or more registrations or licenses with the FDA, all Manufacturer activities regulated by the Board are performed in compliance with applicable state laws and rules by those who are licensed by the Board.

Ph 1001.02 Scope. The provisions of this chapter shall apply to, and impose duties upon, all Manufacturers holding licenses issued by the Board.

PART Ph 1002 DEFINITIONS

Ph 1002.01 Definitions. Except where the context makes another meaning manifest, the following definitions shall apply:

(a) “Abbreviated New Drug Application (ANDA)” contains data which is submitted to FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references;

(b) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug;

(c) “Manufacturer” means any person, including a manufacturer's co-manufacturing partner, that is engaged in the manufacture of a drug, is responsible or otherwise accountable to the Food and Drug Administration (FDA) for the manufacture of the drug, or is the private label manufacturer or distributor of products bearing its NDC number that is intended for sale, distribution, dispensing or administration, and who holds one or more of the following registration numbers or licenses with the FDA:

(1) A New Drug Application number (NDA);
(2) An Abbreviated New Drug application number (ANDA);
(3) A Labeler Code number (LC) or National Drug Code Number (NDC);
(4) An FDA Central File Number (CFN);
(5) An FDA Establishment Identifier number (FEI);
(6) A Biologic License Application (BLA);
(7) An Outsourcing Facility.

(d) “National Drug Code (NDC)” The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360)). Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the
information submitted as part of the listing information in the NDC Directory which is updated daily. The information submitted as part of the listing process, the NDC number, and the NDC Directory are used in the implementation and enforcement of the Act;

(e) “New Drug Application (NDA)” is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA. Documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged;

(f) "Pedigree" is a document or an electronic file containing information that records each distribution of any given prescription drug;

(g) “US FDA CGMP” or “U.S. Food & Drug Administration’s Current Good Manufacturing Practices” ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have;

PART Ph 1003 LICENSING OF MANUFACTURERS

Ph 1003.01 License Required.

(a) No person or facility shall act as a Manufacturer, as defined in RSA 318:51-a, without first obtaining a license to do so from the Board;

(b) No license shall be issued, reinstated or renewed for a Manufacturer unless the same shall be operated in a manner prescribed by RSA 318:51-a and according to Ph 100; 

(c) Separate licenses shall be required for each facility site owned and operated by the Manufacturer;

(d) No license shall be issued to an in-state facility until such time as the applicant has satisfactorily passed 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.

(e) The Board shall provide, on a biennial basis, a license renewal notification to all licensed Manufacturers by electronic mail;
The prescribed fee for a Manufacturer license shall be $1,000;

Applications for licensure of Manufacturer may be filed at the Board office as identified in Ph 103.03, or electronically.

Ph 1003.02 Application Content.

(a) Manufacturer applicants shall complete and submit an initial application for a Manufacturer (form Ph-MFR1), or electronic equivalent, for licensure to the Board which shall contain all of the following:

1. Legal name and DBA (Doing Business As) name;
2. Physical, mailing, and website address;
3. Owner’s name, ownership type, and parent company name;
4. State of Incorporation and Federal Tax ID number;
5. NABP e-Profile ID number;
6. Site contact person’s information to include name, title, phone number and e-mail address (cannot be an employee from a third party company);
7. Licensing contact person’s information to include name, title, phone number and e-mail address (cannot be an employee from a third party company);
8. An indication of the ownership type:
   i. Individual
   ii. Limited Liability Company
   iii. Sole Proprietorship
   iv. Partnership
   v. Corporation
   vi. Other (must specify)
9. An indication of the types of products to be sold/shipped to New Hampshire:
   i. Controlled Substances
   ii. Medical Gases (at wholesale)
   iii. Veterinarian Prescription Drugs
   iv. Human Prescription Drugs
   v. Prescription Devices (at wholesale)
   vi. Other (must specify)
10. An indication of which entities product will be sold/shipped to:
   i. Pharmacies
   ii. Dentists
   iii. Nursing Homes
   iv. Hospitals
(11) An indication as to whether the applicant:

i. supplies pedigrees for all legend products;
ii. conforms to US FDA CGMP regulations as required
iii. has a written Drug Diversion Detection and Prevention Policy available;
iv. has adequate security for the facility;
v. maintains sufficient liability insurance coverage;

(12) An indication as to whether the applicant:

i. holds the title, NDA, or ANDA for all product(s)
ii. physically manufactures the product(s)
iii. possesses any drugs on location
iv. provides their name and location on the labels of the products

If none of the immediately preceding apply to the applicant, then their facility will need to apply for a Drug or Device Distribution Agent permit instead of a Manufacturer.

(13) An indication as to whether the applicant physically distributes any drugs that they do not manufacture or for which they do not hold title, NDA or ANDA, or which do not have their name on the label(s)?

If yes, then the applicant will need to apply for a Wholesale Distributor and/or a Drug or Device Distribution Agent permit in addition to this application.

(14) An indication as to whether or not the applicant or any of their owner(s), officer(s), designated representative(s), partner(s) and/or stockholder(s) have within the past five (5) years:

i. been charged, disciplined, fined or punished for violating any Federal or State laws regulating prescription drugs, medical gases, or prescription medical devices or equipment;
ii. had a license, registration or permit disciplined, denied, refused, or revoked for violations of any pharmacy laws/drug laws in any State;
iii. been charged, convicted, fined, or entered in a plea of guilty or nolo contendere in any criminal prosecution, felony or misdemeanor, in any State, or in a United States court;
   a. for any offense relating to drugs, narcotics, controlled substances, or alcohol, whether or not a sentence was imposed;
   b. for any offense involving the practice of pharmacy, or relating to acts committed within a pharmacy or drug distributor setting or incident to pharmacy practice, whether or not a sentence was imposed;
   c. for any offense involving fraud, dishonesty, or moral turpitude (i.e. Medicaid fraud, theft of money or drugs, or robbery), whether or not a sentence was imposed;
iv. had an application for a drug distributor license, registration or permit or pharmacy license, registration or permit denied, refused or revoked in any State or Country;
v. had disciplinary action taken against them, or a pharmacy or drug distributor facility they owned, or a pharmacy or drug distributor facility where they were employed, by the Board of Pharmacy (or its equivalent) in any State or Country;
vi. violated the drug laws, rules, statutes and/or regulations of any State or Country or the United States;
vii. been convicted of any felony for conduct relating to prescription drugs, any felony for violation of 21 U.S.C. § 331 (i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering;
viii. pled guilty or nolo contendere to or been found guilty of violating Federal or State requirements for licensure that present a threat of serious adverse health consequences or death to humans;
ix. had a license, registration or permit issued by a controlled substance authority revoked, suspended, surrendered, limited or restricted;
x. had any disciplinary action ever taken, or is any such action currently pending by any State or Federal Authority in connection with a violation of any Federal or State drug law or regulation;
xi. had a drug license, registration or permit for the facility under any local, State or Federal law ever been suspended or revoked;

If (i. – xv.) immediately preceding produces a ‘yes’ answer, then the applicant will be required to provide a detailed explanation along with applicable documentation when submitting an application as described above in Ph 1003.02 (a).

(15) A signed attestation from the designated representative stating that they are authorized by the applicant to sign the application and affirm that the application, including any accompanying documents, have been examined and to the best of their knowledge and belief it is a true, correct and complete application, and that if the license applied for is granted, they will agree to and submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the Laws and Rules herein;

(b) Manufacturer applicants shall submit all the following as attachments to the application as described above in Ph 1003.02 (a):

(1) copy of home state licenses(s) or letter of explanation, signed and dated, stating licensure is not required by home state with evidence of Law/Rule;
(2) copy of all current DEA registration(s) (even if you do not wish to ship controls into New Hampshire);
(3) copy of home state controlled substances registration (even if you do not wish to ship controls into New Hampshire);
(4) copy of FDA drug establishment or device establishment registration(s);
(5) copy of most recent inspection report (conducted within the last 5 years and provided by home state or National Association of Boards of Pharmacy (NABP) or a letter of explanation, signed and dated, stating that inspection is not required/available by home state with evidence of Law/Rule or attached proof;

(6) copy of full unredacted FDA Establishment Inspection Report (conducted within the last 5 years), any 483(s) issued as a result of that inspection, and the company’s response(s) to the 483(s);

(7) copy of Certificate of Authority or Certificate of Good Standing received from the New Hampshire Secretary of State’s Office and a New Hampshire Trade Name Certificate for any Doing Business As (DBA) name;

(8) brief description of services offered or nature of business to be conducted in New Hampshire;

(9) list of all state and federal licenses, registrations or permits held by facility with license #, license type, status and expiration;

(10) List all FDA registration numbers:
   i. New Drug Application number (NDA)
   ii. Abbreviated New Drug Application number (ANDA)
   iii. Labeler Code number (LC) or National Drug Code Number (NDC)
   iv. FDA Central File Number (CFN)
   v. FDA Establishment Identifier number (FEI)
   vi. A Biologic License Application (BLA);
   vii. Outsourcing Facility (503B)

(11) list of all FDA approved drugs, including National Drug Code (NDC) numbers;

(12) copy of the manufacturer invoice that will be used when shipping products into New Hampshire, this must contain the name and address of the applicant;

(13) List of products manufactured or name(s) and address(es) of contract manufacturer(s);

(14) List of primary distributors used, including exclusive distributors, 3PLs and wholesalers to include name(s) and address(es);

(15) List/Description of ownership information and/or organizational chart;

(16) list of owners & corporate officers or partners, including title, address, phone number and email address;

(17) copy of sample condensed pedigree;

(18) list of all manufacturers, wholesale distributors and dispensers for whom the applicant provides services for;

(19) list of facilities/customers in New Hampshire to which prescription drugs, medical gases, or prescription medical devices or equipment will be sold/shipped to;

(20) At least two (2) photographs of the existing exterior of the facility in which the applicant is located. These photographs must include any outside signage (artist sketches or architect plans or drawings are not acceptable);

(21) At least four (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;

(22) Copy of policy and procedure for monitoring temperature and humidity;

(23) Copy of policy and procedure for shipping refrigerated products;

(24) In-state applicants shall also submit a scaled floor plan of the proposed facility;
PART Ph 1004 CHANGES IN SUPPORTING DATA

Ph 1004.01 Reporting Changes.

(a) The Manufacturer to which a license has been issued shall notify the Board within 30 days after a change of any of the applications contents, including but not limited to the following:

1. Legal and/or Doing Business As (DBA) name;
2. Physical and/or mailing address;
3. Site and/or licensing contact person’s information to include name, title, phone number and e-mail address (cannot be an employee from a third party company).

(b) The notice required pursuant to (a) above shall contain:

1. Current New Hampshire license number for the Manufacturer;
2. Legal and Doing Business As (DBA) Name, previous and current;
3. Physical and mailing address, previous and current;
4. Email address, previous and current;
5. Effective date of the change;
6. Updated home state license(s), DEA registration(s) and home state controlled substances registration(s) must be provided for any name or address change.

(c) Any licensed Manufacturer who alters, forges, or intentionally falsifies, or causes to be altered, forged or falsified, any information, documents, or records required to be kept or submitted by this rule shall be subject to disciplinary action under RSA 318:29, II.

(d) Failure to report any of the above changes shall result in the imposition of a $250 administrative fine for the first offense and shall then follow the provisions of Ph 710.02 for any subsequent offenses thereto. A license shall not be issued, reinstated or renewed until all fees and fines are paid in full.

Ph 1004.02 Notice of Disciplinary Action.

A Manufacturer licensed under these rules shall, within 30 days of any written warnings or disciplinary action from any state or federal licensing or enforcement agency, notify the Board in writing and provide a copy of the action to the Board office, identified in Ph 103.03.

Ph 1004.03 Ownership Change.

An initial application and subsequently a new license shall be required for a change of ownership of an established Manufacturer to a successor business entity which results in a change of 50% or more of the controlling interest in the company. An indirect ownership change or change from the grandparent level and up shall only require a letter on company letterhead signed by the person who is responsible for the actions of the permit.
Ph 1004.04 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 1004.05 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 or manufacturer as a package along with:

(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 New Hampshire manufacturer license shall be relinquished to the Board.

PART Ph 1005 REVOCATION AND DENIAL

Ph 1005.01 Effect of Revocation and Denial.

(a) The Board shall refuse to issue a license or shall revoke a license whenever the Board determines that a Manufacturer, its owner(s) or corporate officer(s) has, after notice and opportunity for a hearing, except pursuant to (c) below, committed an act such as but not limited to:

(1) Made a materially false representation or withheld material information in connection with obtaining its license;

(2) Been found guilty of any felony in connection with the practice of pharmacy or distribution of drugs within the past 5 years;

(3) Made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;
(4) Failed to comply with RSA 318:51-a, the provisions of Ph 1000, or both;

(5) Based on an investigation of a complaint resulting from the dispensing of prescription drugs, medical gases, or prescription medical devices or equipment to a resident of New Hampshire been found to be negligent:

   i. By the Board of Pharmacy of the State in which the pharmacy is located; or

   ii. By the New Hampshire Board of Pharmacy if the Board of Pharmacy of the State where the pharmacy is located failed to initiate an investigation of such complaint within 45 days after referral of the complaint from the New Hampshire Board of Pharmacy.

(6) Been found guilty of any violation of Federal, State or local drug law or have entered into any agreement to resolve violations of such.

(b) A Manufacturer shall notify the Board within 30 days of any order or decision by a Board of Pharmacy, or any other State or Federal Agency, imposing disciplinary action on the pharmacy. Notwithstanding the provisions of paragraph (a) above, if the license, permit or registration in the State where the pharmacy is located, is suspended or revoked, then the pharmacy’s license in New Hampshire shall, after notice and opportunity for hearing, be suspended or revoked for the same period of time.

(c) Notwithstanding the above the Board shall issue a license or not revoke if:

   (1) No harm resulted from the actions of the applicant or registrant;

   (2) There was no intent to violate any provisions of RSA 318;

   (3) Corrective action has been taken by the registrant;

   (4) Remunerations have been made to the affected party(s); and

   (5) The Board determines the action is unlikely to occur again.

PART Ph 1006 RENEWALS

Ph 1006.01 Renewal of a Manufacturer.

   (a) All Manufacturer licenses shall expire biennially on June 30 of even numbered years;

   (b) A Manufacturer applying for renewal shall do so online at https://nhlicenses.nh.gov/eGov/Login.aspx subsequent to receiving renewal instructions provided by the Board through electronic mail;

   (c) As part of the renewal a Manufacturer must provide information and documentation as described above in Ph 1003.02;

   (d) The renewal and prescribed fee of $1,000 shall be filed with the Board as described above no later than June 15 of even numbered years.

Ph 1006.02 Failure to Comply.
(a) Failure to comply with any of the provisions of Ph 1006 shall result in the non-renewal of the Manufacturer license;

(b) If non-renewal occurs, the Manufacturer license will expire, a reinstatement shall be required as described in Ph 1007, and the facility cannot ship into New Hampshire until the license is made active.

PART Ph 1007 REINSTATEMENT

Ph 1007.01 Reinstatement of a Manufacturer.

(a) A Manufacturer who either voluntarily or mistakenly allows their license to lapse as of June 30 of the renewal year shall complete the following procedures in order to apply for a reinstatement of their license:

(1) Complete an initial application found on the Board’s website at https://www.oplc.nh.gov/pharmacy/licensing.htm, or the electronic equivalent;

(2) Submit the completed application and the prescribed fee to the Board;

(3) Submit all required documentation, as indicated on the application; and

(4) Submit a dated statement, signed by the person who is responsible for the actions of the license, to provide why the applicant did not renew their license prior to the expiration date and whether or not the applicant has shipped into New Hampshire since the lapse of the license. If shipments were made, then the applicant must also include:

   i. Who the items were shipped to;
   ii. Quantity of items shipped;
   iii. Title/type of products shipped; and
   iv. Dates of shipments.

PART Ph 1008 STANDARDS OF PRACTICE

Ph 1008.01 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.

Ph 1008.02 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.

Ph 1008.03 Security.

(a) Manufacturers 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.

(b) Internal security policies shall be developed to provide protection against theft.

Ph 1008.04 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.

Ph 1008.05 Inspections for In-State Facilities.

(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.

Ph 1008.06 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;

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

(5) the means to safely distribute NIOSH Hazardous drugs to the receiving entity so that the outer packaging or shipping container alerts the entity to the presence of said hazard and properly safeguards against a hazardous spill during the shipping process.

(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.

Ph 1008.07 Returned Goods.

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

Ph 1008.08 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.

Ph 1008.09 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.

Ph 1008.10 Compliance with State and Federal Law.

(a) All manufacturers shall comply with all applicable state and federal laws, regulations and rules.
(b) All manufacturers doing business in the State of New Hampshire shall, before shipping or distributing any prescription drug, devices or equipment, verify that the recipient is properly licensed to receive and possess such drugs, devices or equipment.

(c) All manufacturers 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 licensed in the State of New Hampshire 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.

Ph 1008.11 Distributing Adulterated or Misbranded Drugs.

A manufacturer shall not distribute any drug which is adulterated or misbranded. After notice and opportunity for a hearing a manufacturer 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.

Ph 1008.12 Violations.

(a) No manufacturer 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 prescription drugs, medical devices or equipment according to RSA 318:51-a and the provisions of Ph 1000, shall be subject to disciplinary action as provided in RSA 318:29.