CHAPTER Ph 2500 DRUG OR DEVICE DISTRIBUTION AGENT

Statutory Authority: RSA 318:51-g

PART Ph 2501 PURPOSE AND SCOPE

Ph 2501.01 Purpose. The purpose of this chapter is to set forth the requirements, limitations, and prohibitions for Drug or Device Distribution Agents that participate in the business of facilitating the distribution of prescription drugs, medical gases, or prescription medical devices or equipment from a manufacturer to a wholesaler to ensure that, for the protection of the public, all Drug or Device Distribution Agent activities regulated by the Board are performed in compliance with applicable state laws and rules by those who are licensed by the Board.

Ph 2501.02 Scope. The provisions of this chapter shall apply to, and impose duties upon, all Drug or Device Distribution Agents holding licenses issued by the Board.

PART Ph 2502 DEFINITIONS

Ph 2502.01 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) "Authorized distributor of record” means a wholesale distributor or a third-party logistics provider with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug, medical gas, or prescription medical device or equipment. An ongoing relationship is deemed to exist between the third-party logistics provider and the manufacturer or between the wholesale distributor and a manufacturer when the third-party logistics provider or the wholesale distributor, including any affiliated group of the wholesale distributor as defined in section 1504 of the Internal Revenue Code [26 U.S.C. 1504], complies with the following:

i. The wholesale distributor or a third-party logistics provider has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and

ii. The wholesale distributor or a third-party logistics provider is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

(c) “Broker or Jobber” is defined as parties that mediate between a buyer and a seller, or act in any way to bring buyers and sellers together, for the sale or shipment of prescription drugs, medical gases, or prescription medical equipment/devices;

(d) “Drug or Device Distribution Agent” means anyone that participates in the business of facilitating the distribution of prescription drugs, medical gases, or prescription medical devices or equipment from a manufacturer to a wholesale into and within the State of New Hampshire without taking ownership or possession;

(e) “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;

(f) “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;

(g) "Normal distribution channel" means a chain of custody for a prescription drug, medical gas, or prescription medical device or equipment which goes, directly or by drop shipment, from a manufacturer of the prescription drug, medical gas, or prescription medical device or equipment, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor to:

   i. A pharmacy, to a patient or other designated person authorized by law to dispense or administer the prescription drug, medical gas, or prescription medical device or equipment to a patient;

   ii. A wholesale distributor, to a pharmacy, to a patient or other designated person authorized by law to dispense or administer the prescription drug, medical gas, or prescription medical device or equipment to a patient;

   iii. A wholesale distributor, to a chain pharmacy warehouse, to that chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the prescription drug, medical gas, or prescription medical device or equipment to a patient; or

   iv. a chain pharmacy warehouse, to the chain pharmacy warehouse's intracompany pharmacy, to a patient or other designated person authorized by law to dispense or administer the prescription drug, medical gas, or prescription medical device or equipment to a patient.

(h) "Pedigree" is a document or an electronic file containing information that records each distribution of any given prescription drug, medical gas, or prescription medical device or equipment;

(i) “Third-Party Logistics Provider (3PL)” means a person that contracts with a wholesale distributor or a prescription drug, medical gas, or prescription medical device or equipment’s manufacturer to provide or coordinate warehousing, wholesale distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug, medical gas, or prescription medical device or equipment or have general responsibility to direct the prescription drug, medical gas, or prescription medical device or equipment’s sale or disposition. The third-party logistics provider must be licensed independently and to be considered part of the normal distribution channel must also be an authorized distributor of record;
Virtual Manufacturer” means anyone that owns the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for a prescription drug, medical gas, or prescription medical device or equipment that contracts with others for the actual manufacturing of the prescription drug, medical gas, or prescription medical device or equipment;

“Virtual Wholesale Distributor” means anyone engaged in wholesale distribution of prescription drugs, medical gases, or prescription medical devices or equipment in or into the State which:

1. may or may not take title but does not take physical possession of the prescription drug, medical gas, or prescription medical device or equipment;
2. must be licensed by the state Board of Pharmacy or other appropriate state agency as a Wholesale Distributor; and
3. must be registered as a business entity with the appropriate state or local authority(s) and must operate out of a commercial facility and not out of a residence or personal dwelling. Such location is exempt from the Wholesale Distributor licensure requirements specifically related to possession and storage of prescription drugs, medical gases, or prescription medical devices or equipment.

PART Ph 2503 LICENSING OF DRUG OR DEVICE DISTRIBUTION AGENTS

Ph 2503.01 License Required.

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

(b) No license shall be issued, reinstated or renewed for a Drug or Device Distribution Agent unless the same shall be operated in a manner prescribed by RSA 318:51-g and according to Ph 2500;

(c) Separate licenses shall be required for each specialty the Drug or Device Distribution Agent operates as and for each site owned and operated by the Drug or Device Distribution Agent;

(d) The Board shall provide, on a biennial basis, a license renewal notification to all licensed Drug or Device Distribution Agents by electronic mail;

(e) The prescribed fee for a Drug or Device Distribution Agent license shall be $1,000;

(f) Applications for licensure of Drug or Device Distribution Agent may be filed at the Board office as identified in Ph 103.03, or electronically.

Ph 2503.02 Application Content.

(a) Drug or Device Distribution Agent applicants shall complete and submit an “Initial Application for Drug or Device Distribution Agent” form (Ph-DDA1), or electronic equivalent, for licensure to the Board that 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 as to:
   i. nature of business to be conducted in New Hampshire;
   ii. type of prescription drugs/products that will be shipped into New Hampshire;
   iii. type of facility that the applicant will be providing services for.

(9) An indication as to whether the applicant:
   i. supplies pedigrees for all legend products;
   ii. has a written Drug Diversion Detection and Prevention Policy on file;
   iii. has adequate security for the facility;
   iv. maintains sufficient liability insurance coverage;
   v. possesses any drugs on location.

(10) An indication as to whether or not the applicant or any 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;
xii. been found liable in any lawsuit or arbitration proceeding involving allegations of fraud, illegal or dishonest activities;
xiii. had a business relationship terminated for any fraudulent, illegal or dishonest activities;
xiv. been denied issuance of, or pursuant to disciplinary proceedings, refused renewal of a license, registration or permit by any Board or agency in any State;
xv. convicted of any crime under the laws of the United States, or any State pertaining to the manufacturing, distribution, sale or dispensing of drugs or narcotics.

(11) 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) Drug or Device Distribution Agent applicants shall submit all of the following as attachments to the application as described above in Ph 2503.02 (a):

i. copy of home state license(s) or a letter of explanation, signed and dated, stating that licensure is not required by home state with evidence of Law/Rule;
ii. copy of all current DEA registration(s);
iii. copy of all controlled substances registration(s);
iv. copy of most recent inspection report that was conducted within the last 5 years 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 by home state with evidence of Law/Rule;
v. 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;
vi. brief written description of services offered or the nature of business to be conducted in New Hampshire;
vii. copy of an organizational chart;
viii. list of owners & corporate officers or partners, including title, address, phone number and email address;
ix. copy of sample condensed pedigree;
x. copy of Verified-Accredited Wholesale Distributors (VAWD) Certificate of Accreditation or a notarized letter attesting that the facility is in compliance with
criteria set out for accreditation by the National Association of Boards of Pharmacy (NABP);

xi. list of all manufacturers, wholesale distributors and dispensers for whom the applicant provides services for;

xii. list of facilities/customers in New Hampshire to which prescription drugs, medical gases, or prescription medical devices or equipment will be shipped to;

xiii. list of all State and Federal licenses, registrations or permits held by facility to include license number, license type, status and expiration;

In addition to (b) i. – xiii. above, all Virtual Manufacturers shall also submit the following:

xiv. copy of Verified-Accredited Wholesale Distributors (VAWD) Certificates of Accreditation for all associated Third Party Logistic Providers (3PLs) that ship or will ship products for the Virtual Manufacturer;

xv. full name and address of contract manufacturers and wholesale distributors;

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

xvii. 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;

In addition to (b) i. – xviii. above, all Third-Party Logistic Providers (3PLs) shall also submit the following:

xviii. list of all trading partners services are provided for

PART Ph 2504 CHANGES IN SUPPORTING DATA

Ph 2504.01 Reporting Changes.

(a) The Drug or Device Distribution Agent 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 Drug or Device Distribution Agent;

(2) Legal and Doing Business As (DBA) Name, previous and current;

(3) Physical and mailing address, previous and current;

(4) Effective date of the change;

(5) Updated home state license(s), DEA registration(s) and controlled substances registration(s) must be provided for any name or address change.
(c) Any licensed Drug or Device Distribution Agent 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 2504.02 Notice of Disciplinary Action. A Drug or Device Distribution Agent 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 2504.03 Ownership Change. An initial application and subsequently a new license shall be required for a change of ownership of an established Drug or Device Distribution Agent to a successor business entity which results in a change in the controlling interest in the company. An indirect ownership change or change from the grandparent level and up shall only require a company letter from the person who is responsible for the actions of the license.

PART Ph 2505 REVOCATION AND DENIAL

Ph 2505.01 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 Drug or Device Distribution Agent, 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-g, the provisions of Ph 2500, 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:

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

   b. 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; or
(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 Drug or Device Distribution Agent 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 2506 RENEWALS

Ph 2506.01 Renewal of a Drug or Device Distribution Agent.

(a) All Drug or Device Distribution Agent licenses shall expire biennially on June 30 of even numbered years;

(b) A Drug or Device Distribution Agent 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 Drug or Device Distribution Agent must provide information and documentation as described above in Ph 2503.02;

(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 2506.02 Failure to Comply.

(a) Failure to comply with any of the provisions of Ph 2506 shall result in the non-renewal of the Drug or Device Distribution Agent license;

(b) If non-renewal occurs, the Drug or Device Distribution Agent will expire, a reinstatement shall be required as described in Ph 2507, and the facility cannot ship into New Hampshire until the license is fully reinstated.
PART Ph 2507 REINSTATEMENT

Ph 2507. 01 Reinstatement of a Drug or Device Distribution Agent.

A Drug or Device Distribution Agent who either voluntarily or accidentally allows their license to lapse as of June 30 of the renewal year shall complete the following procedures in order to reinstate their license:

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

(b) Submit the completed application and the prescribed fee to the board’s office;

(c) Submit any required documentation, as indicated on the application; and

(d) Submit a dated statement that is ink signed by the person who is responsible for the actions of the license. Within this statement 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 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 2508 STANDARDS OF PRACTICE

Ph 2508.01 Record Keeping.

(a) A Drug and Device Distribution Agent must establish and maintain records regarding the distribution or other disposition of a prescription drug, medical gas, or prescription medical device or equipment.

(1) If a Drug and Device Distribution Agent distributes prescription drugs, medical gases, or prescription medical devices or equipment the record must contain, but is not limited to, the following:

i. The source of the prescription drug, medical gas, or prescription medical device or equipment, including the name and physical address of the seller or transferor and any broker or other person involved in the transaction, the address of the location from which the drug was shipped and the address of the location to which the prescription drug, medical gas, or prescription medical device or equipment was shipped;

ii. The name, dose and quantity of the prescription drug, medical gas, or prescription medical device or equipment distributed;

iii. The date of distribution or other disposition of the prescription drug, medical gas, or prescription medical device or equipment.
(2) If a Drug and Device Distribution Agent distributes product to another Drug and Device Distribution Agent, the pedigree must be maintained and provided to the recipient of the distribution.

(b) Records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, authorized law enforcement agencies, and this Board.

(c) Records required under these rules must be maintained for three years.

(d) Records required under these rules that are less than 13 months old must be kept at the address of record or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by these rules must be made available for inspection within three business days of a request.

Ph 2508.02 Prohibited Practices.

(a) The following practices are expressly prohibited:

(1) A Drug and Device Distribution Agent may not participate in the purchase of a prescription drug, medical gas, or prescription medical device or equipment from a closed door pharmacy;

(2) A Drug and Device Distribution Agent may not participate in any way in the sale, distribution or transfer of a prescription drug, medical gas, or prescription medical device or equipment to a person who is required by the laws and rules of New Hampshire to be registered with the Board and who is not appropriately registered. Before authorizing or facilitating the distribution of a prescription drug, medical gas, or prescription medical device or equipment, a Drug and Device Distribution Agent must verify that the person supplying or receiving the prescription drug, medical gas, or prescription medical device or equipment is appropriately registered with the Board.

(b) A Drug and Device Distribution Agent may not perform, cause the performance of, or aid the performance of any of the following:

(1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a prescription drug, medical gas, or prescription medical device or equipment that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution;

(2) The adulteration, misbranding, or counterfeiting of a prescription drug, medical gas, or prescription medical device or equipment;

(3) The receipt of a prescription drug, medical gas, or prescription medical device or equipment that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the prescription drug, medical gas, or prescription medical device or equipment for pay or otherwise;

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a prescription drug, medical gas, or prescription medical device or equipment or the commission of another act with respect to a prescription drug, medical
gas, or prescription medical device or equipment that results in the prescription drug, medical gas, or prescription medical device or equipment being misbranded;

(5) The forging, counterfeiting, simulating, or falsely representing a prescription drug, medical gas, or prescription medical device or equipment using a mark, stamp, tag, label, or other identification device;

(6) The purchase or receipt of a prescription drug, medical gas, or prescription medical device or equipment from a person that is not registered to distribute prescription drugs, medical gases, or prescription medical devices or equipment to the purchaser or recipient;

(7) The sale or transfer of a prescription drug, medical gas, or prescription medical device or equipment to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug, medical gas, or prescription medical device or equipment, to purchase or receive prescription drugs, medical gases, or prescription medical devices or equipment from the person selling or transferring the prescription drug, medical gas, or prescription medical device or equipment;

(8) The failure to maintain or provide records as required under these rules;

(9) Providing the Board, a representative of the Board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to these rules;

(10) Participating in the wholesale distribution of a prescription drug, medical gas, or prescription medical device or equipment that was:

   i. Purchased by a public or private hospital or other health care entity under the terms of an "own-use" contract; or

   ii. Donated or supplied at a reduced price to a charitable organization; or

   iii. Stolen or obtained by fraud or deceit; or

   iv. Illegally imported into the USA.

(11) Facilitating the distribution or attempting to facilitate the distribution of a prescription drug, medical gas, or prescription medical device or equipment by fraud, deceit, or misrepresentation;

(12) Facilitating the distribution of a prescription drug, medical gas, or prescription medical device or equipment that was previously dispensed by a retail pharmacy or a practitioner;

(13) Failing to report an act prohibited by any of the rules in OAR Chapter 855 to the appropriate state or federal authorities.