

# New Hampshire Pharmacy Laws & Rules



*October 2019*

\* IMPORTANT NOTE \*

This document reflects the NH pharmacy laws and rules in effect as of the above date. If it has been several months from the time this document was created, be sure to check [www.oplc.nh.gov/pharmacy/laws-rules.htm](http://www.oplc.nh.gov/pharmacy/laws-rules.htm) for the most current laws and rules.

# **TITLE XXX**

## **OCCUPATIONS AND PROFESSIONS**

### **CHAPTER 318**

#### **PHARMACISTS AND PHARMACIES**

##### **Section 318:1**

###### **318:1 Definitions. –**

In this chapter:

I. "Administer" means an act whereby a single dose of a drug is instilled into the body of, applied to the body of, or otherwise given to a person or animal for immediate consumption or use.

I-a. "Advanced practice registered nurse" means a person licensed to practice as an advanced practice registered nurse in this state pursuant to RSA 326-B:18.

II. "At retail" means the dispensing of drugs or medicines pursuant to the order of a physician, dentist, veterinarian, or advanced practice registered nurse, whether or not such drugs or medicines are dispensed for a valuable consideration.

III. "Board", when not otherwise limited, means the New Hampshire pharmacy board.

III-a. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order or initiative based on the pharmacist-patient-prescriber relationship in the course of professional practice or, for the purpose of, or as an incident, to research, teaching, or chemical analysis, but not selling or dispensing. "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

"Compounding" shall not include the reconstitution of powdered formulations before dispensing or the addition of flavoring. "Compounding" shall not include the simple addition of flavoring, nor shall it include the preparation of a single dose of a nonhazardous commercially available drug or licensed biologic for administration within 2 hours of preparation to an individual patient when done in accordance with the manufacturer's approved labeling or instructions consistent with that labeling.

IV. "Dentist" means a practitioner of dentistry duly registered under the laws of this or some other state.

V. "Dispense" means to distribute, leave with, give away, dispose of, deliver, or sell one or more doses of a drug that will be administered or taken at a later date, time, or location and shall include the transfer of more than a single dose of a medication from one container to another and the labeling or otherwise identifying a container holding more than a single dose of a drug.

V-a. "Distributor" means a person or persons who supply or facilitate the supply of prescription drugs to persons other than consumers.

VI. "Drugs", when not otherwise limited, means all substances used as medicines or in the practice of medicine.

VI-a. "Fee splitting" means any discount, rebate, dividend, shared income, or economic benefit from the sale of prescription medicine by a pharmacist or pharmacy with an individual licensed to prescribe medicine or such individual's spouse or dependent children.

VI-b. "Emergency medical care provider" means a person licensed to provide emergency medical care under RSA 151-B.

VI-c. "Foreign pharmacy graduate" is a pharmacist whose undergraduate pharmacy degree was conferred outside the United States by a pharmacy school listed in the World Directory of Schools of Pharmacy published by the World Health Organization.

VI-d. "FPGEC" means the Foreign Pharmacy Graduate Equivalency Committee administered by the National Association of Boards of Pharmacy.

VI-e. "FPGEE" means the Foreign Pharmacy Graduate Equivalency Examination administered by the National Association of Boards of Pharmacy and recognized and approved by the board.

VI-f. "Hormonal contraceptives" means pills, patches, and rings which the United States Food and Drug Administration (FDA) classifies as available by prescription for the purpose of contraception or emergency contraception. It does not include similar items classified as "over the counter" by the FDA, intrauterine devices, shots, or intradermal implants.

VI-g. "Law enforcement officer" means any officer of the state or political subdivision of the state who is empowered by law to conduct investigations of or to make arrests for offenses enumerated in this chapter.

VII. "Licensed pharmacist" or "pharmacist", when not otherwise limited, means a person holding a license under RSA 318:18 and who is, therefore, legally authorized to practice the profession of pharmacy in this state.

VII-a. "Limited retail drug distributor" means a distributor of legend devices or medical gases delivered directly to the consumer pursuant to a practitioner's prescription order, or federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored, or dispensed to patients pursuant to the order of an authorized practitioner.

VII-b. "Mail-order pharmacy" means a pharmacy that is located in a state of the United States, other than this state, whose primary business is to dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, a common carrier, or a delivery service. Mail-order pharmacies include, but are not limited to, pharmacies that do business via the Internet or other electronic media.

VIII. "Manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices for resale. Manufacturing shall be governed by Good Manufacturing Practices as adopted and enforced by the federal Food and Drug Administration.

IX. "Medicine", when not otherwise limited, means a drug or preparation of drugs in suitable form for use as a curative or remedial substance.

IX-a. "Nurse" means a person licensed to perform registered nursing as defined in RSA 326-B.

X. "Pharmacist-in-charge" means the pharmacist who shall be responsible for the practice of pharmacy in and by a pharmacy, including, but not limited to, compliance with all local, state, and federal pharmacy and drug laws, and who shall be responsible for the operation of the pharmacy in the best interests of the public.

XI. "Pharmacy", when not otherwise limited, means the place registered by the board where the

profession of pharmacy is practiced and where drugs, chemicals, medicines, prescriptions, or poisons are compounded, dispensed, stored, or retailed.

[Paragraph XI-a effective until January 1, 2020; see also paragraph XI-a set out below.]

XI-a. "Pharmacy benefits manager" means any person or entity as defined in RSA 420-J:3, XXVIII-a.

[Paragraph XI-a effective January 1, 2020; see also paragraph XI-a set out above.]

XI-a. "Pharmacy benefits manager" means "pharmacy benefits manager" as defined in RSA 402-N:1, VIII.

XI-b. "Pharmacy technician" means a person, other than a pharmacist or a pharmacy intern, either registered or certified by the board for the purpose of assisting a pharmacist in the practice of pharmacy.

XI-aa. "Pharmacy intern" means a person who is registered by the board pursuant to RSA 318:15-b and:

(a) Is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the board and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist starting no earlier than 4 months prior to the third year of study; or

(b) Is a graduate of an approved professional degree program of a school or college of pharmacy or is a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate, who is currently licensed by the board of pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

(c) Is a qualified applicant awaiting examination for licensure or meeting board requirements for re-licensure; or

(d) Is participating in a residency or fellowship program.

XII. "Physician" means a practitioner of medicine duly licensed under the laws of this or some other state.

XII-a. "Physician assistant" means a person licensed as a physician assistant under RSA 328-D.

XII-b. "Podiatrist" means a person authorized by law to practice podiatry in this state pursuant to RSA 315.

XIII. "Poisons", when not otherwise limited, means any drug, chemical medicine or preparation liable to be destructive to adult human life in quantities of 60 grains or less.

XIV. "Practice of pharmacy" means the professional acts performed by a pharmacist and shall include the interpretation and evaluation of prescription orders; the administration, compounding, dispensing, labeling and distribution of drugs and devices; the participation in drug selection and drug-related device selection; drug evaluation; utilization or regimen review; the monitoring of drug therapy and use; medication therapy management in accordance with collaborative pharmacy practice agreements; the proper and safe storage and distribution of drugs and devices, and the proper maintenance of proper records; the responsibility of advising, when necessary or when regulated, of therapeutic values, hazards, and use of drugs and devices; and the offering or performing of these acts, services, operations, or transactions necessary in the

conduct, operation, management, and control of pharmacy.

XV. "Practitioner" or "licensed practitioner" means any person who is lawfully entitled to prescribe, administer, dispense or distribute legend drugs to patients.

XV-a. "Practitioner-patient relationship" means a medical connection between a licensed practitioner and a patient that includes an in-person or face-to-face 2-way real-time interactive communication exam, a history, a diagnosis, a treatment plan appropriate for the practitioner's scope of practice, and documentation of all prescription drugs including name and dosage. A practitioner may prescribe for a patient whom the practitioner does not have a practitioner-patient relationship under the following circumstances: for a patient of another practitioner for whom the prescriber is taking call; for a patient examined by another New Hampshire licensed practitioner; or for medication on a short-term basis for a new patient prior to the patient's first appointment. The definition of a practitioner-patient relationship shall not apply to a practitioner licensed in another state who is consulting to a New Hampshire licensed practitioner with whom the patient has a relationship.

XVI. "Prescription" means a verbal, or written, or facsimile or electronically transmitted order for drugs, medicines and devices by a practitioner licensed in the United States, to be compounded and dispensed by licensed pharmacists in a duly registered pharmacy, and to be kept on file for a period of 4 years. A written order shall include an electronic transmission prescription received and retained in a form complying with rules adopted pursuant to RSA 318:5-a, XV. Prescriptions may also apply to the finished products dispensed or administered by the licensed pharmacist in the registered pharmacy, on order of a licensed practitioner as defined in this section.

XVI-a. "Prescription device" or "legend device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is restricted for distribution and use only upon the order of a licensed practitioner.

XVII. "Prescription drug", "legend drug," or "potent drug" means:

(a) A drug which under federal law is required, prior to being dispensed or delivered, to be labelled with any of the following statements:

(1) "Caution federal law prohibits dispensing without prescription", or

(2) "Caution federal law restricts this drug to use by or on the order of the licensed veterinarian", or

(3) "RX only", or

(b) A drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners.

XVIII. "Nonprescription or proprietary medicine" shall mean non-narcotic medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the laws of this state and the federal government, provided that this definition shall not include the following:

(a) A drug, the label of which bears substantially either the statement "Caution-federal law prohibits dispensing without prescription" or "Warning-may be habit forming."

(b) A drug intended for injection.

XIX. "Supervision" means under the direct charge or direction and does not contemplate absence of the person responsible for providing such supervision, except where permitted by rules of the board under RSA 318:5-a, XIV.

XIX-a. "TOEFL" is the Test of English as a Foreign Language, as administered by American

College Testing (ACT), or its successor, and certified by the FPGEC.

XX. "Veterinarian" means a practitioner of veterinary medicine duly registered under the laws of this or some other state.

XXI. "Wholesaler" means a person with facilities in or outside this state who obtains drugs for distribution or delivery to persons other than consumers.

XXII. "Automated pharmacy system" means mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collects, controls, and maintains all transaction information.

XXIII. "Central prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions, such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.

XXIV. "Electronic transmission prescription" means both image transmissions of a prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber, and data transmissions of a prescription order, other than an electronic image transmission prescription, that is electronically transmitted by computer link, modem, or other computer communication device from a licensed prescriber to a pharmacy.

XXIV-a. "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

XXV. "Attending practitioner" means the physician or advanced practice registered nurse who has the primary responsibility for the treatment and care of the patient.

XXVI. "Collaborative pharmacy practice" means the practice of pharmacy whereby one or more pharmacists jointly agree, on a voluntary basis, to work in conjunction with one or more attending practitioners under written protocol whereby the collaborating pharmacist or pharmacists may perform medication therapy management authorized by the attending practitioner or practitioners under certain specified conditions and limitations.

XXVII. "Collaborative pharmacy practice agreement" means a written and signed specific agreement between a pharmacist, an attending practitioner, and the patient or patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of medication therapy management for the patient.

XXVIII. "Medication therapy management" means the review of medication therapy regimens of patients by a pharmacist for the purpose of evaluating and rendering advice to a practitioner, or evaluating and modifying the medication regimen in accordance with the collaborative pharmacy practice agreement. Decisions involving medication therapy management shall be made in the best interest of the patient. Medication therapy management shall be limited to:

- (a) Implementing, modifying, and managing medication therapy according to the terms of the collaborative pharmacy practice agreement;
- (b) Collecting and reviewing patient histories within the context of needs for pharmacy practice;
- (c) Obtaining and checking vital signs, such as pulse, temperature, blood pressure, and respiration;
- (d) Ordering laboratory tests as specifically set out in the collaborative pharmacy practice agreement between the pharmacist and the attending practitioner that are specific to the medication or protocol-driven;
- (e) Formulating a medication treatment plan that will be shared with the patient's attending

practitioner;

(f) Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;

(g) Performing a comprehensive medication review, in conjunction with the attending practitioner, to identify, resolve, and prevent medication-related problems, including adverse drug events;

(h) Documenting the care delivered and, if applicable, communicating essential information to the patient's other health care providers; and

(i) Providing education and training designed to enhance patient understanding and the appropriate use of his or her medications.

XXIX. "Reverse distributor" means a person or persons who facilitate the removal, disposal, or destruction of prescription drugs to persons other than consumers.

XXX. "Outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all of the requirements of section 503B of the Federal Food, Drug, and Cosmetic Act.

XXXI. (a) "Research organization" means an entity, including a biotechnology company or research institute, whose primary goal is to conduct fundamental research, industrial research, or experimental development relating to drug products, disease and drug diagnostics, and/or drug manufacturing technologies.

(b) A "research organization" shall not include:

(1) A "sponsor," "sponsor-investigator," or "contract research organization" as such terms are defined in 21 C.F.R. section 312.3;

(2) An "applicant" as such term is defined in 21 C.F.R. section 314.3; a "manufacturer," "processor," "packer," or "distributor" as such terms are used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 301 et. seq.); or

(3) A "manufacturer" or "applicant" as such terms are used in 21 C.F.R. section 601.2.

XXXII. "Researcher" means a qualified person representing a research organization licensed by the board pursuant to RSA 318:51-f.

XXXIII. "Licensed advanced pharmacy technician" means a person licensed by the board who:

(a) May perform all functions allowed by federal or state law and approved by the board, under the supervision of a licensed pharmacist who is physically on premises and holds an unrestricted license issued by the board.

(b) May conduct product verification, process refills, verify repackaging of drugs, and perform other pharmacist tasks not required to be completed by a licensed pharmacist.

(c) May perform duties allowed by either certified or registered pharmacy technicians.

(d) Shall not interpret or evaluate a prescription or drug order, verify a compounded drug, or counsel or advise individuals related to the clinical use of a medication.

**Source.** 1921, 122:1. 1925, 84:1. PL 210:1. 1941, 140:1. RL 256:1. RSA 318:1. 1957, 72:1, 2. 1967, 82:1. 1973, 453:3. 1979, 155:1-9. 1981, 484:18, 19. 1985, 324:1. 1992, 245:1. 1993, 67:1; 78:1-3. 1994, 333:1-3. 1996, 267:20. 1997, 149:1-3. 1998, 67:2. 2000, 187:1; 188:1; 271:4. 2001, 15:1; 282:1-3. 2002, 281:1-3. 2005, 177:126, 127; 293:6. 2006, 164:1-3. 2007, 202:1-3. 2008, 217:1. 2009, 54:5. 2010, 74:1; 259:9. 2011, 63:3; 111:1. 2013, 105:3; 121:1, 2. 2014, 150:2, eff. Aug. 15, 2014. 2015, 180:2, 203:1, eff. July 1, 2015; 246:1, eff. Sept. 11, 2015. 2018,

205:1, eff. Aug. 7, 2018; 263:1, eff. June 12, 2018. 2019, 58:1, eff. July 1, 2019; 320:3, eff. Jan. 1, 2020.

### **Section 318:1-a**

**318:1-a Exceptions and Exemptions Not Required to be Negated.** – In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of this chapter, it shall not be necessary to negate any exception, excuse, proviso, or exemption contained herein, and the burden of proof of any such exception, excuse, proviso or exemption shall be upon the defendant.

**Source.** 1987, 181:4, eff. May 12, 1987.

## **Pharmacy Board**

### **Section 318:2**

**318:2 Board.** – There shall be a pharmacy board consisting of 7 members; including 6 practicing pharmacists, at least one of whom shall be a full-time hospital pharmacist, and one public member, each to be appointed by the governor, with the approval of the council, to a term of 5 years. No member shall be appointed to more than 2 consecutive terms and no member shall serve for more than 10 consecutive years. Only board members provided for in this section shall have the authority to vote in board determinations.

**Source.** 1921, 122:2. PL 210:2. RL 256:2. RSA 318:2. 1973, 453:13. 1979, 155:10. 1981, 484:3. 2009, 66:1, eff. Aug. 8, 2009.

### **Section 318:2-a**

**318:2-a Repealed by 2015, 276:108, IX, eff. July 1, 2015.** –

### **Section 318:3**

#### **318:3 Eligibility.** –

I. Pharmacist members of the board shall have been licensed pharmacists for at least 10 years, and at the time of their appointment shall have practiced pharmacy in this state for at least 5 years.

II. The public member of the board shall be a person who is not, and never was, a member of the pharmaceutical profession or the spouse of any such person, and who does not have, and never has had, a material financial interest in either the provision of pharmaceutical services or an activity directly related to pharmacy, including the representation of the board or profession for a fee at any time during the 5 years preceding appointment.

**Source.** 1921, 122:2. PL 210:3. RL 256:3. RSA 318:3. 1973, 453:1. 1981, 484:4, eff. July 1, 1981.



## **Section 318:4**

**318:4 Compensation.** – The members of the board shall be paid \$100 a day and their necessary expenses while actually engaged in the performance of their duties.

**Source.** 1921, 122:2. PL 210:4. RL 256:4. RSA 318:4. 1963, 83:1. 1973, 453:2. 1979, 155:11. 1981, 484:18. 2007, 202:4, eff. Jan. 1, 2008.

## **Section 318:5**

### **318:5 Officers and Duties.** –

- I. The board shall have a president, vice-president, and a secretary, who shall be elected from among their number annually in the month of September.
- II. The president shall serve as chief executive officer of the board and shall preside at all meetings and hearings of the board and shall appoint any subcommittees from among the members as deemed necessary. In the absence of the president, the vice-president shall perform the duties of the president.

**Source.** 1921, 122:2. PL 210:5. RL 256:5. RSA 318:5. 1979, 155:12. 1981, 484:18. 1985, 324:2, eff. Jan. 1, 1986. 2019, 264:1, eff. Sept. 17, 2019.

## **Section 318:5-a**

### **318:5-a Rulemaking Authority.** –

The board shall adopt rules, pursuant to RSA 541-A, relative to:

- I. The application procedure for any license issued under this chapter;
- II. The qualifications of applicants in addition to those requirements set by statute;
- III. Design and content of all forms required under this chapter;
- IV. How an applicant shall be examined, including:
  - (a) Time and place of examination;
  - (b) The subjects to be tested;
  - (c) Passing grade; and
  - (d) Disposition of examination papers;
- IV-a. The standards for registering pharmacies and licensing pharmacists and the practice of pharmacy;
- IV-b. The standards for licensure of research organizations;
- V. How a license shall be renewed;
- VI. Ethical standards required to be met by each holder of any license issued under this chapter and how such license may be revoked for violation of these standards;
- VII. The establishment of all fees and fines required under this chapter, including application fees for nonresidents. Fees for licensure of research organizations shall not be greater than the fees charged for registering pharmacies;
- VII-a. Continuing education requirements under this chapter;
- VIII. Procedures for the conduct of hearings consistent with the requirements of due process;
- IX. Procedures for the inspection of licensees;
- X. Registration or certification of pharmacy technicians, including:

- (a) Requirements for registration or certification;
- (b) The duties, functions, and standards of conduct of pharmacy technicians;
- (c) Requirements for the supervision of pharmacy technicians by licensed pharmacists;
- (d) Standards for denial and revocation of registration and certification;
- (e) Establishment of the effective period of registration or certification;
- (f) Requirements for renewal of registration or certification; and
- (g) Requirements for reinstatement of registration or certification.

XI. The establishment of fees for registration or certification of pharmacy technicians, including fees for renewal or reinstatement.

XI-a. Registration of pharmacy interns, including:

- (a) Requirements for registration;
- (b) The duties, functions, and standards of conduct of pharmacy interns;
- (c) Requirements for the supervision of pharmacy interns by licensed pharmacists;
- (d) Standards for denial and revocation of registration;
- (e) Establishment of the effective period of registration;
- (f) Requirements for renewal of registration; and
- (g) Requirements for reinstatement of registration.

XI-b. The establishment of fees for registration of pharmacy interns, including fees for renewal or reinstatement.

XI-c. Licensure of advanced pharmacy technicians, including:

- (a) Requirements for licensure, including experience and education requirements.
- (b) The duties, functions, and standards of conduct of licensed advanced pharmacy technicians.
- (c) Standards for the supervision of licensed advanced pharmacy technicians by licensed pharmacists.
- (d) Standards for denial and revocation of licensure.
- (e) Establishment of the effective period of a license.
- (f) Requirements for renewal of a license.
- (g) Requirements for reinstatement of a license.

XII. Procedures for the use, documentation, security, maintenance, and monitoring of automated pharmacy systems, including the placement of automated pharmacy systems in long-term care facilities, hospices, and state or county correctional institutions, for the purposes of storage and dispensing of controlled and non-controlled prescription drugs.

XIII. Standards for contracting, implementation, and operation of central prescription processing.

XIV. The adoption of protocols and procedures for the temporary absence of a pharmacist from a pharmacy while on duty.

XV. The requirements for the use of electronic transmission prescriptions, including the contents of such order and the verification of electronic signatures.

XVI. Procedures and protocols for emergency contraception drug therapy, pursuant to RSA 318:47-e.

XVII. The education and training standards and other requirements for pharmacists who, pursuant to prescriber-approved protocol:

- (a) Administer prescription medications, including influenza immunizations.
- (b) Engage in collaborative pharmacy practices.

XVIII. Disclosure and confidentiality relative to the New Hampshire Rx advantage program, pursuant to RSA 161-L:3.

XIX. Dispensing hormonal contraceptives in accordance with RSA 318:47-*l*.

XX. The standards and procedures for licensure of drug or device distribution agents.

**Source.** 1981, 484:5. 1985, 324:3. 1988, 106:1; 210:3. 2000, 188:2. 2001, 282:5, 6. 2002, 281:4. 2005, 131:2; 177:128, 129. 2006, 164:4. 2007, 202:5, 6; 297:9. 2013, 105:2, eff. Aug. 23, 2013. 2015, 203:2, 3, eff. July 1, 2015. 2018, 205:3, eff. Aug. 7, 2018. 2019, 58:2, eff. July 1, 2019; 264:2, eff. Sept. 17, 2019.

### **Section 318:5-b**

**318:5-b Completion of Survey; Rulemaking.** – The board shall adopt rules, pursuant to RSA 541-A, requiring, as part of the license renewal process, completion by licensees of a survey or opt-out form provided by the office of rural health, department of health and human services, for the purpose of collecting data regarding the New Hampshire primary care workforce, pursuant to the commission established in RSA 126-T. Any rules adopted under this section shall provide the licensee with written notice of his or her opportunity to opt-out from participation in the survey.

**Source.** 2017, 131:4, eff. June 16, 2017. 2019, 254:6, eff. July 1, 2019.

### **Section 318:6**

**318:6 Secretary.** – It shall be the duty of the secretary to keep a record of the meetings of the board and to conduct its correspondence. The secretary shall file a record of the licensure of pharmacists which shall be open to the inspection of any person in the office of the secretary of state.

**Source.** 1921, 122:3. PL 210:6. RL 256:6. 1949, 280:2. RSA 318:6. 1979, 155:13. 1981, 484:18, 20, eff. July 1, 1981.

### **Section 318:6-a**

#### **318:6-a Fees. –**

I. The board shall establish fees for examination of applicants, for licenses and for renewal of licenses to practice pharmacy, for licensed advanced pharmacy technicians, for registration and certification of pharmacy technicians, and for transcribing and transferring records and other services.

II. The fee for restoration of a suspended, revoked, or voluntarily surrendered license, registration, or certification under this chapter shall not include the assessment of charges or renewal fees for the period in which the licensee, registrant, or certificate holder was not permitted to practice in this state.

**Source.** 1981, 484:6. 2000, 188:3. 2007, 202:7, eff. Jan. 1, 2008. 2015, 10:1, eff. July 4, 2015. 2019, 58:4, eff. July 1, 2019.

### **Section 318:7**

**318:7 Repealed by 2002, 254:5, IX, eff. July 1, 2002. –**

### **Section 318:8**

**318:8 Enforcement of Law.** – It shall be the duty of the board, through officials and employees appointed by it or under its supervision for that purpose, and of all peace officers within the state, and of all county attorneys, to enforce all the provisions of this chapter. When so requested, the department of health and human services and its officials and employees shall cooperate with the board in collecting and analyzing samples of drugs and medicines sold, or suspected of being sold, in violation of this chapter. The members of the board, its inspectors and investigators shall have free access during business hours to all places where drugs, medicines, poisons or hypodermic devices are held, stored, or offered for sale and to all records of sale and disposition of drugs.

**Source.** 1921, 122:5. PL 210:8. 1931, 123:1. RL 256:8. RSA 318:8. 1965, 275:2. 1981, 484:18. 1985, 324:4. 1995, 310:181, eff. Nov. 1, 1995.

### **Section 318:8-a**

**318:8-a Inspection and Regulation of Certain Users of Prescription Drugs.** – All physicians, veterinarians, dentists, advanced registered nurse practitioners, physician assistants, and clinics under contract to the department of health and human services and agricultural, technical, or industrial users of prescription drugs shall be subject to inspection and regulation by the board of pharmacy with regard to the storage, labeling, distribution, and disposal of prescription drugs.

**Source.** 1988, 158:1. 1994, 333:4. 1995, 310:181. 1998, 67:3, eff. July 11, 1998.

### **Section 318:9**

**318:9 Repealed by 2015, 276:108, X, eff. July 1, 2015. –**

### **Section 318:9-a**

**318:9-a Inspectional Services.** – The pharmacy board shall provide inspectional services under this chapter and RSA 318-B:25 to the board of medicine, the board of veterinary medicine, the board of podiatry, the board of registration in optometry, the board of dental examiners, the board of nursing, and the naturopathic board of examiners.

**Source.** 1985, 363:2. 1993, 333:1. 1994, 333:5. 1995, 286:26. 2013, 144:106, eff. July 1, 2013. 2018, 80:11, eff. July 24, 2018.

### **Section 318:10**

**318:10 Examinations.** – The board shall hold meetings for the granting of licenses and the transaction of other business at least quarterly, and at such time and place as they may see fit.

They shall evaluate through an examination all persons, in the art and science of pharmacy and its allied branches, who meet the requirements herein provided and who make application for licensure as licensed pharmacists.

**Source.** 1921, 122:6. PL 210:10. RL 256:10. RSA 318:10. 1981, 484:18, 20. 2010, 259:1, eff. July 6, 2010.

### **Section 318:11**

**318:11 Reports.** – The office of professional licensure and certification shall file with the governor and council, on or before December 1 biennially, a report upon the condition of pharmacy in the state and containing a record of their acts and proceedings.

**Source.** 1921, 122:31. PL 210:11. RL 256:11. RSA 318:11. 1973, 140:16. 1981, 484:18, eff. July 1, 1981. 2015, 276:72, eff. July 1, 2015.

## **Licensed Pharmacists**

### **Section 318:12**

**318:12 Repealed by 1988, 158:5, I, eff. June 21, 1988. –**

### **Section 318:13**

**318:13 Repealed by 1988, 158:5, II, eff. June 21, 1988. –**

### **Section 318:14**

**318:14 Pharmacy.** – A licensed pharmacist shall have the right to conduct a pharmacy for the compounding, according to the provisions of RSA 318:14-a, of medicines upon physicians', dentists', optometrists', podiatrists', veterinarians', advanced practice registered nurses', naturopathic doctors', and physician assistants' prescriptions or valid orders for the sale and distribution of drugs, medicines, and poisons.

**Source.** 1921, 122:8. PL 210:14. RL 256:14. RSA 318:14. 1981, 484:19. 1994, 333:6. 2010, 259:2. 2013, 121:3, eff. Jan. 1, 2014.

### **Section 318:14-a**

**318:14-a Compounding.** –

I. Products that are not commercially available may be compounded for hospital or office use but shall not be resold or dispensed. Nonprescription items may be compounded upon order by a practitioner for sale as long as the labeling complies with RSA 318:47-a and the product is not a copy of, or similar to, prescription or nonprescription products. Except as provided in rules adopted under paragraph V for veterinarians, all compounding shall be done in compliance with

the United States Pharmacopeia as defined by board of pharmacy rules.

II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

III. A pharmacist shall offer a compounded drug product to a practitioner for administration to an individual patient, in limited quantities. The compounded drug products are for practitioner administration only and shall not be re-dispensed. The pharmacist shall maintain records to indicate what compounded drug products were provided to the medical office or practice.

Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services, in accordance with state law and rules of the board, as well as applicable federal laws.

IV. Where a commercial drug shortage exists because a manufacturer is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, and the manufacturer cannot supply the drug product to the public or to practitioners for use, a pharmacist may compound a limited quantity using the active pharmaceutical ingredient and sell to a patient with a valid prescription from a valid prescriber.

When the compounded drug product is sold to a medical office or practice it is for the practitioner to administer to patients, and shall not be for resale.

V. The board shall adopt rules under RSA 541-A concerning the regulation of compounding, including exceptions for veterinarians from compliance with the United States Pharmacopeia chapter 797.

VI. Labeling requirements pursuant to paragraph II shall not apply when medication is dispensed to institutionalized patients as provided under RSA 318:47-b.

**Source.** 2013, 121:4, eff. Jan. 1, 2014. 2019, 296:1, 2, eff. Sept. 27, 2019.

## **Section 318:15**

**318:15 Repealed by 1979, 155:31, eff. Aug. 5, 1979. –**

## **Section 318:15-a**

**318:15-a Pharmacy Technician.** – No person shall perform the functions or duties of a pharmacy technician unless such person is either registered by the board to perform certain functions or, upon completion of training, certified to perform certain functions, and does so under standards of supervision established by rules of the board adopted pursuant to RSA 541-A.

**Source.** 2000, 188:4. 2007, 202:8, eff. Jan. 1, 2008.

## **Section 318:15-b**

**318:15-b Pharmacy Interns.** – No person shall perform the functions or duties of a pharmacy intern unless such person is registered by the board to perform certain functions, and does so under standards of supervision established by rules of the board adopted pursuant to RSA 541-A.

**Source.** 2013, 105:1, eff. Aug. 23, 2013.

### **Section 318:15-c**

#### **318:15-c Licensed Advanced Pharmacy Technician. –**

- I. No person employed as a licensed advanced pharmacy technician shall perform the functions or duties of a licensed advanced pharmacy technician as defined in RSA 318:1, XXXIII unless such person is issued a license by the board and does so under standards of supervision established by rules of the board adopted pursuant to RSA 318:5-a, XI-c.
- II. When a pharmacy employs a licensed advanced pharmacy technician, in addition to dispensing prescriptions the pharmacist shall provide clinical services and the pharmacy owner shall provide the resources necessary for the pharmacist to safely provide the clinical services as determined in rules adopted by the board.
- III. Nothing in this section shall require a pharmacy to employ a licensed advanced pharmacy technician.

**Source.** 2019, 58:3, eff. July 1, 2019.

### **Section 318:16**

**318:16 Special Permits. –** In case of death or under extreme conditions, the board may, in its discretion, issue a special permit to operate a pharmacy in a manner and under conditions that will safeguard the interests of the public for a period not to exceed 60 days.

**Source.** 1921, 122:9. PL 210:16. RL 256:16. RSA 318:16. 1981, 484:18, eff. July 1, 1981.

### **Section 318:16-a**

#### **318:16-a Standards for Collaborative Pharmacy Practice. –**

- I. For a pharmacist to participate in a collaborative pharmacy practice agreement, the pharmacist shall:
  - (a) Hold an unrestricted and current license to practice as a pharmacist in New Hampshire.
  - (b) Have at least \$1,000,000 of professional liability insurance coverage.
  - (c) Have the knowledge base necessary for proper monitoring, including, but not limited to, associated disease states, relevant laboratory tests, adverse events, drug and food interactions, safety, and efficacy. Depending upon the complexity of the services being provided, the pharmacist may be required to have additional credentials or training and shall demonstrate the receipt of approval by the board of pharmacy.
- II. Any practitioner with prescriptive authority who holds an active, unrestricted license in the state of New Hampshire may enter into a collaborative pharmacy practice agreement. A service authorized by a practitioner to be performed by a pharmacist under a collaborative pharmacy practice agreement must be within the practitioner's current scope of practice.
- III. Collaborative pharmacy practice agreements may be between single or multiple pharmacists and a single or multiple practitioners.
- IV. Collaborative pharmacy practice agreements shall meet the following general requirements:
  - (a) Each protocol developed pursuant to the collaborative pharmacy practice agreement shall

contain detailed direction concerning the services that the pharmacist may perform for patients. The protocol shall include, but not be limited to:

- (1) The specific drug or drugs to be managed by the pharmacist.
  - (2) The terms and conditions under which drug therapy may be implemented, modified, or discontinued.
  - (3) The conditions and events upon which the pharmacist is required to notify the collaborating practitioner and the manner and time frame in which notification will occur.
  - (4) The laboratory tests that may be ordered in accordance with medication therapy management.
  - (5) Activities which may be performed by the pharmacist in conjunction with the protocol, which shall be documented as specified in the protocol.
  - (6) A statement of the expected amount of time the pharmacist will dedicate to performing duties specified under the protocol.
- (b) Collaborative pharmacy practice agreements shall state the beginning and ending dates of the period of time during which the agreement is in effect, and may be terminated, in writing, by either party at any time. Collaborative pharmacy practice agreements shall be renewed at a minimum every 2 years. When collaborative pharmacy practice agreements are terminated, the patient shall be informed and provided with details to allow for the uninterrupted continuation of their medication therapy management regimen.
- (c) Ongoing metrics for quality assurance and safety monitoring shall be agreed upon by the practitioner and pharmacist and shall be included in the collaborative practice agreement. These metrics shall be consistent with metrics adopted or enforced by regulatory bodies.

V. Supervision of the collaborative pharmacy practice agreement shall include:

- (a) Protocols developed based on evidence-based guidelines for best practices.
- (b) The referring practitioner receiving progress visit notes from each patient encounter in a time specified in the agreement.
- (c) The referring practitioner providing supervision for the treatment management of the referred patient.
- (d) The retention on file of the collaborative pharmacy practice agreement and protocols at the pharmacist's place of practice and at the practitioner's administrative office or place of practice, which shall be available upon request.

VI. Neither the attending practitioner nor the pharmacist in a collaborative practice pharmacy agreement may seek to gain personal financial benefit by participating in any incentive-based program or accept any inducement that influences or encourages therapeutic or product changes or the ordering of tests or services.

**Source.** 2006, 164:6, eff. July 23, 2006. 2016, 214:1, eff. Aug. 6, 2016.

## **Section 318:16-b**

### **318:16-b Pharmacist Administration of Vaccines. –**

A pharmacist or pharmacy intern under the direct supervision of an immunizing pharmacist may administer influenza vaccines to the general public and a pharmacist or pharmacy intern may administer pneumococcal and varicella zoster vaccines to individuals 18 years of age or older, provided all of the criteria in this section have been met. The pharmacist and pharmacy intern shall:

- I. Hold a current license to practice as a pharmacist or be registered as a pharmacy intern under



RSA 318:15-b in New Hampshire.

II. Possess at least \$1,000,000 of professional liability insurance coverage.

III. In order to administer influenza, pneumococcal, and varicella zoster vaccines, have completed training specific to the administering of the respective vaccines that includes programs approved by the Accreditation Council for Pharmacy Education (ACPE) or curriculum-based programs from an ACPE-accredited college of pharmacy or state or local health department programs or programs recognized by the board.

IV. Provide to the board evidence of compliance with paragraphs I-III.

V. Provide notice to the primary care provider, when designated by the patient, of the administration of the pneumococcal and varicella zoster vaccines.

VI. Maintain a record of administration of pneumococcal and varicella zoster vaccinations for each individual as required by state and federal law.

**Source.** 2008, 283:1. 2011, 213:1, eff. Aug. 26, 2011. 2017, 51:1, eff. July 11, 2017.

### **Section 318:16-c**

**318:16-c Repealed by 2015, 190:3, eff. Nov. 2, 2015. –**

### **Section 318:16-d**

#### **318:16-d Pharmacist Administration of Additional Vaccines. –**

In addition to the authority under RSA 318:16-b, a pharmacist or pharmacy intern under the direct supervision of an immunizing pharmacist may administer hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines to individuals 18 years of age or older, provided all of the criteria in this section have been met. The pharmacist and pharmacy intern shall:

I. Hold a current license to practice as a pharmacist in New Hampshire or be registered as a pharmacy intern under RSA 318:15-b in New Hampshire.

II. Possess at least \$1,000,000 of professional liability insurance coverage.

III. In order to administer hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines, have completed training specific to the administering of the respective vaccines that includes programs approved by the Accreditation Council for Pharmacy Education (ACPE) or curriculum-based programs from an ACPE-accredited college of pharmacy or state or local health department programs or programs recognized by the board.

IV. Provide to the board evidence of compliance with paragraphs I-III.

V. Provide notice to the primary care provider, when designated by the patient, of the administration of the hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines.

VI. Maintain a record of administration of hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccinations for each individual as required by state and federal law.

**Source.** 2017, 221:2, eff. Jan. 1, 2018. 2018, 104:1, eff. July 24, 2018.

## **Examinations and Licenses**

### **Section 318:17**

**318:17 Repealed by 1981, 484:22, I, eff. July 1, 1981. –**

## **Section 318:18**

### **318:18 Pharmacists. –**

I. (a) An applicant for examination and licensure as a pharmacist shall have graduated with the basic, professional pharmacy baccalaureate degree or pharmacy doctor degree from a school of pharmacy, college of pharmacy, or pharmacy department of a university approved by the board including programs accredited by the American Council on Pharmaceutical Education or the Canadian Council for Accreditation of Pharmacy Programs or, if a graduate of a foreign school or college of pharmacy other than Canadian, the applicant shall be fully certified by the Foreign Pharmacy Graduate Equivalency Committee (FPGEC) which shall include passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) and Test of English as a Foreign Language (TOEFL), with scores approved by the board of pharmacy as set forth in the rules.

(b) In addition to the above, all applicants for examination and licensure as a pharmacist shall:

(1) Not be less than 18 years of age;

(2) Be of good professional character and temperate habits; and

(3) File proof satisfactory to the board, substantiated by proper affidavits, of a minimum of one year (1,500 hours) internship activity in a community or institutional pharmacy in the United States or Canada or an equivalent program which has been approved by the board of pharmacy; and shall pass the national examination administered by the National Association of Boards of Pharmacy (NABP) to establish his or her fitness to practice the profession of pharmacy. The internship required in this section shall be service and experience in a community or institutional pharmacy under the supervision of a licensed pharmacist and shall be predominantly related to the selling of drugs and medical supplies; interpreting, compounding, preparing and dispensing of prescriptions; preparing of pharmaceutical products; keeping records and making reports required under federal and state statutes; and otherwise practicing pharmacy under the immediate supervision and direction of a licensed pharmacist.

II. The board may deny licensure as a pharmacist for grounds which include, but which shall not be limited to, prior conviction of a felony; or of a misdemeanor resulting from a violation of a federal, state or local drug or pharmacy-related law, rule, or regulation.

**Source.** 1921, 122:11. 1925, 84:2. PL 210:18. RL 256:18. 1949, 280:3. RSA 318:18. 1969, 276:1. 1973, 72:68. 1979, 155:16. 1981, 484:7, 20. 1985, 324:5. 1988, 106:2. 1997, 149:4. 2001, 282:4. 2010, 259:3, eff. July 6, 2010.

## **Section 318:18-a**

**318:18-a Prior Registration. –** Any person registered as a pharmacist in this state on January 1, 1977, shall have all the rights granted to pharmacists under this chapter, as long as such person complies with the licensing requirements of this chapter.

**Source.** 1988, 158:2, eff. June 21, 1988.

## **Section 318:19**

**318:19 Examinations.** – Applicants for licensure as pharmacists shall, to prove their respective requisite knowledge, be examined to a properly varying degree in pharmacy-related subject areas which may include chemistry, math, pharmacology, pharmacy theory, the practice of pharmacy and pharmacy law, and any other areas as the board may prescribe.

**Source.** 1921, 122:13. PL 210:20. RL 256:20. 1949, 280:1, 2. 1981, 484:18, 20. 1985, 324:6, eff. Jan. 1, 1986.

## **Section 318:20**

### **318:20 Impersonating Applicant. –**

I. No one shall impersonate an applicant before the board of pharmacy applying for licensure under the provisions of this chapter.

II. No third party shall sign an application, complete an application, call to check on the status of an application, or submit an application and documentation on behalf of an applicant.

III. No third party shall complete an online renewal, paper renewal, or make any changes or updates to an original application on behalf of an applicant.

IV. Authorization and release forms shall not be accepted as a form of release.

**Source.** 1921, 122:14. PL 210:21. RL 256:21. RSA 318:20. 1981, 484:18, 20, eff. July 1, 1981. 2019, 264:3, eff. Sept. 17, 2019.

## **Section 318:21**

**318:21 Applicants From Other States.** – The board may license any applicant who is licensed in any other state, provided the other state's licensing requirements are substantially equivalent to or greater than those of this state, and further provided that the applicant successfully completes an examination, developed by the board, for the testing of his knowledge of New Hampshire and federal law relative to the practice of pharmacy.

**Source.** 1921, 122:15. PL 210:22. RL 256:22. 1949, 280:1, 2. RSA 318:21. 1979, 155:17. 1981, 484:8. 1985, 324:7, eff. Jan. 1, 1986.

## **Section 318:22**

**318:22 Repealed by 2010, 259:11, eff. July 6, 2010. –**

## **Section 318:23**

**318:23 Application Fee for Pharmacist License.** – Each person applying for a license to practice the profession of pharmacy in this state by way of examination shall pay a reasonable application fee to be established by the pharmacy board. This fee shall include the cost of investigating the applicant's qualifications to become a pharmacist in this state.

**Source.** 1921, 122:15. PL 210:24. RL 256:24. RSA 318:23. 1979, 155:18. 1981, 484:9. 2010, 259:4, eff. July 6, 2010. 2019, 264:4, eff. Sept. 17, 2019.

## **Section 318:24**

**318:24 Repealed by 1979, 155:32, eff. Aug. 5, 1979. –**

## **Section 318:25**

### **318:25 Renewal of License. –**

Pharmacist licenses shall expire biennially in even-numbered years at midnight on December 31. Every licensed pharmacist who wishes to continue to practice the profession of pharmacy shall:

- I. Biennially, in even-numbered years, apply for license renewal no later than midnight on December 31;
- II. Pay a reasonable fee established by the board;
- III. Satisfy any continuing education requirements established by the board; and
- IV. Provide such data relating to his practice, residence, and status as deemed necessary by the board.

**Source.** 1921, 122:17. PL 210:26. RL 256:26. 1949, 280:2. 1953, 155:1. RSA 318:25. 1955, 241:3. 1963, 83:5. 1971, 458:2. 1973, 453:4. 1977, 563:43. 1979, 155:19. 1981, 484:10, eff. July 1, 1981. 2019, 264:5, eff. Sept. 17, 2019.

## **Section 318:26**

**318:26 Neglect to Renew. –** Any failure, neglect or refusal on the part of any person licensed by the board to renew his license as provided in RSA 318:25 shall cause the license to lapse. Licenses lapsed under this section shall not be restored except upon payment of a restoration fee as established by the board, and a showing of evidence, as the board may require, demonstrating professional competence.

**Source.** 1921, 122:17. PL 210:27. RL 256:27. RSA 318:26. 1971, 458:3. 1979, 155:20. 1981, 484:11. 1988, 106:3. 1992, 97:1, eff. July 1, 1992.

## **Section 318:26-a**

**318:26-a Change in Name, Employment, or Residence. –** Any pharmacist, licensed advanced pharmacy technician, or pharmacy technician who changes his or her name, place or status of employment, or residence shall notify the board in writing within 15 days. For failure to report such a change within 15 days, the board may suspend the pharmacist's license, the advanced pharmacy technician's license, or the pharmacy technician's registration. Reinstatement shall be made only upon payment of a reasonable fee as established by the board.

**Source.** 1979, 155:21. 1981, 484:18, 21. 1985, 324:8. 2010, 259:5, eff. July 6, 2010. 2019, 58:5, eff. July 1, 2019.

## **Section 318:27**

**318:27 Repealed by 1979, 155:33, eff. Aug. 5, 1979. –**

## **Section 318:28**

**318:28 Display of Licenses.** – All licenses as pharmacists shall at all times be conspicuously displayed in the pharmacy where the licensee is engaged as such.

**Source.** 1921, 122:18. PL 210:29. RL 256:29. 1949, 280:1, 2. RSA 318:28. 1973, 453:5. 1981, 484:21, eff. July 1, 1981.

## **Section 318:29**

### **318:29 Disciplinary Action.** –

I. The board may undertake disciplinary action against any licensee, permittee, registrant, or certificate holder:

- (a) Upon its own initiative; or
- (b) Upon written complaint of any person which alleges that a licensee, permittee, registrant, or certificate holder has committed misconduct under paragraph II or V of this section or any other applicable provision of this chapter or RSA 318-B, and which specifies the grounds therefor.

II. Misconduct sufficient to support disciplinary proceedings under this section shall include:

- (a) The practice of fraud or deceit in procuring or attempting to procure a license, permit, registration, or certificate to practice under this chapter;
- (b) Conviction of a felony or any offense involving moral turpitude;
- (c) Any dishonest or unprofessional conduct, or gross or repeated negligent conduct in the practice of pharmacy or in performing activities ancillary to the practice of pharmacy or any particular aspect or specialty thereof;
- (d) Behavior which demonstrates a clear conflict with the basic knowledge and competence expected of licensed pharmacists or any particular aspect or specialty of the practice of pharmacy, or any intentional act which demonstrates a clear inconsistency with the health and safety of persons making use of the professional services of any person licensed under this chapter;
- (e) Addiction to the use of alcohol or other habit-forming drugs to a degree which renders him or her unfit to practice under this chapter;
- (f) Mental or physical incompetency to practice under this chapter; or
- (g) Willful or repeated violation of any provision of this chapter, any substantive rule of the board, or any other federal, state, or local drug or pharmacy-related law, rule, or regulation.

(h) [Repealed.]

III. [Repealed.]

IV. The board may take disciplinary action in any one or more of the following ways:

- (a) By reprimand;
- (b) By suspension, limitation or restriction of a license or probation for any period of time deemed reasonable by the board;
- (c) By revocation of license;
- (d) By assessing administrative fines in amounts established by the board;
- (e) By requiring the person to participate in a program of continuing education in the area or areas in which he or she has been found deficient; or
- (f) By requiring the licensee to submit to the care, observation or treatment of a physician, counseling service, health care facility, professional assistance program, or any comparable

person or facility approved by the board.

V. The board may, after notice and hearing, suspend or revoke a pharmacy permit, license, or registration for grounds which include, but are not limited to:

- (a) The suspension, revocation, or expiration of the pharmacist license of the pharmacist-in-charge.
- (b) Termination of the employment of the pharmacist-in-charge with the pharmacy.
- (c) Operation of the pharmacy in a manner that is in violation of federal, state, or local drug or pharmacy-related law, rule, or regulation.
- (d) Conviction of the pharmacist-in-charge, an owner, a corporate officer, the corporation, or the pharmacy of a felony, a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule or regulation, or an act involving moral turpitude or gross immorality.
- (e) Unsanitary conditions.
- (f) Fraud, intentional misrepresentation or perjury in securing the permit, license, or registration or in any hearing before the board.
- (g) Unprofessional conduct which includes, but is not limited to, violations of federal, state, or local drug or pharmacy-related laws, rules, or regulations, or other acts or omissions which, in the opinion of the board, pose a threat to the well-being or the safety of the public.
- (h) Fee splitting for professional services. This does not prohibit rent payments under a rental or lease agreement for the operation of a pharmacy by a pharmacist or pharmacy to an individual licensed to prescribe medicine.
- (i) Any ownership or control of an ownership interest of a pharmacy within the state by an individual licensed to prescribe medicine, or a corporation, professional association or partnership consisting of such prescriber or prescriber's immediate family members, except such corporations as are expressly exempt from income taxation under section 501(c)(3) of the United States Internal Revenue Code. This shall not include ownership of investment securities purchased by the practitioner on terms available to the general public and which are publicly traded. This subparagraph shall not apply to the ownership or control of an ownership interest of an institutional pharmacy operated within the state by or for hospitals, as defined in RSA 151:2, I(a), licensed by the state pursuant to RSA 151.
- (j) The sale, rental, trade, transfer, or release of patient identifiable medical information for the purpose of sales or marketing of services or products without written authorization.

**Source.** 1921, 122:19. PL 210:30. RL 256:30. 1949, 280:2. RSA 318:29. 1957, 72:3. 1979, 155:22. 1981, 484:12. 1985, 324:9, 10. 1988, 210:2. 1989, 258:1. 1992, 97:2-8, 13, I, II. 1993, 67:2. 1995, 56:1. 1998, 236:3. 2005, 177:130. 2010, 259:6. 2012, 282:15, eff. June 30, 2015.

## **Section 318:29-a**

### **318:29-a Impaired Pharmacist Program. –**

I. Any pharmaceutical peer review committee may report relevant facts to the board relating to the acts of any pharmacist in this state if they have knowledge relating to the pharmacist which, in the opinion of the peer review committee, might provide grounds for disciplinary action as specified in RSA 318:29, II.

II. Any committee of a professional society comprised primarily of pharmacists, its staff, or any district or local intervenor participating in a program established to aid pharmacists impaired by

substance abuse or mental or physical illness may report in writing to the board the name of the impaired pharmacist together with the pertinent information relating to his impairment. The board may report to any committee of such professional society or the society's designated staff information which it may receive with regard to any pharmacist who may be impaired by substance abuse or mental or physical illness.

III. Upon a determination by the board that a report submitted by a peer review committee or professional society committee is without merit, the report shall be expunged from the pharmacist's individual record in the board's office. A pharmacist or his authorized representative shall be entitled on request to examine the pharmacist's peer review or the pharmaceutical organization committee report submitted to the board and to place into the record a statement of reasonable length of the pharmacist's view with respect to any information existing in the report.

IV. Notwithstanding the provisions of RSA 91-A, the records and proceedings of the board, compiled in conjunction with an impaired pharmacist peer review committee, shall be confidential and are not to be considered open records unless the affected pharmacist so requests; provided, however, the board may disclose this confidential information only:

(a) In a disciplinary hearing before the board or in a subsequent trial or appeal of a board action or order;

(b) To the pharmacist licensing or disciplinary authorities of other jurisdictions; or

(c) Pursuant to an order of a court of competent jurisdiction.

V. (a) No employee or member of the board, peer review committee member, pharmaceutical organization committee member, pharmaceutical organization district or local intervenor furnishing in good faith information, data, reports, or records for the purpose of aiding the impaired pharmacist shall by reason of furnishing such information be liable for damages to any person.

(b) No employee or member of the board or such committee, staff, or intervenor program shall be liable for damages to any person for any action taken or recommendations made by such board, committee, or staff unless he is found to have acted recklessly or wantonly.

VI. (a) The board may contract with other organizations to operate the impaired pharmacist program for pharmacists who are impaired by drug or alcohol abuse or mental or physical illness. This program shall include, but is not limited to, education, intervention and post-treatment monitoring.

(b) The board may allocate an amount determined by the board from each pharmacist biennial license renewal fee it collects to provide funding for the impaired pharmacist program as set forth in subparagraph VI(a).

**Source.** 1985, 324:11. 1992, 20:1. 2014, 311:1, eff. Jan. 1, 2015. 2019, 264:6, eff. Sept. 17, 2019.

## **Section 318:29-b**

### **318:29-b Denial or Revocation of License. –**

I. Upon receipt of an administratively final order from the licensing authority of another jurisdiction which imposes disciplinary sanctions against a licensee, permittee, registrant, or certificate holder of the board, or a person applying for a license, permit, registration, or certificate, the board may issue an order directing the licensee, permittee, registrant, or applicant to appear and show cause why similar disciplinary sanctions or, in the case of an applicant, why

the license, permit, or registration denial or restriction, should not be imposed in this state. In any such proceeding, the decision of the foreign licensing authority may not be collaterally attacked, but the licensee, permittee, registrant, or applicant shall be given the opportunity to demonstrate why a lesser sanction should be imposed.

II. The board may issue any disciplinary sanction or take any action with regard to any pending application pursuant to this section otherwise permitted by this chapter, including sanctions or actions which are more stringent than those imposed by the foreign jurisdiction.

III. The board may adopt summary procedures for handling proceedings brought under this chapter, but shall furnish the respondent at least 10 days' written notice and a reasonable opportunity to be heard. The board may require a licensee, permittee, registrant, or certificate holder to suspend practice in this state as a condition of postponing a hearing date established for allegations brought under this section.

**Source.** 1992, 97:9. 2005, 177:131, eff. July 1, 2005.

### **Section 318:29-c**

**318:29-c Immunity From Civil Action.** – No civil action shall be maintained against the board or any member thereof or its agents or employees with regard to any action or activity taken in the performance of any duty or authority established by this chapter. No civil action shall be maintained against any organization or its members or against any other person for or by reason of any good faith statement, report, communication, or testimony to the board or determination by the board in relation to proceedings under this chapter.

**Source.** 1992, 97:9, eff. July 1, 1992.

### **Section 318:29-d**

**318:29-d Pharmacists Not Liable.** – A pharmacist who dispenses drugs to a midwife certified under RSA 326-D shall not be liable for any adverse reactions caused by any method of use by the midwife.

**Source.** 1999, 213:3, eff. July 6, 1999.

### **Section 318:30**

#### **318:30 Investigatory Powers of the Board; Complaints.** –

I. The board may investigate possible misconduct by licensees, permittees, registrants, certificate holders, applicants, and any other matters governed by the provisions of this chapter and RSA 318-B. Investigations may be conducted with or without the issuance of a board order setting forth the general scope of the investigation. Board investigations and any information obtained by the board pursuant to such investigations shall be exempt from the public disclosure provisions of RSA 91-A, unless such information subsequently becomes the subject of a public disciplinary hearing. However, the board may disclose information obtained in an investigation to law enforcement or health licensing agencies in this state or any other jurisdiction, or in accordance with specific statutory requirements or court orders.



II. The board may appoint legal counsel, technical advisors or other investigators retained through the office of professional licensure and certification to assist with any investigation and with adjudicatory hearings.

III. The board may commence a formal or informal investigation, or an adjudicative hearing, concerning allegations of misconduct and other matters within the scope of this chapter on its own motion whenever it has a reasonable basis for doing so, and the type of procedure chosen shall be a matter reserved to the discretion of the board. Investigations may be conducted on an ex parte basis.

IV. (a) The board may administer oaths or affirmations, preserve testimony, and issue subpoenas for witnesses and for documents during any formal investigation or adjudicatory hearing. The board may also subpoena patient records, as provided in paragraph V, during informal investigations.

(b) Subpoenas not covered by paragraph V shall be served in accordance with the procedures and fee schedules established by the superior court, except that:

(1) Persons licensed or registered by the board shall not be entitled to a witness fee or mileage expenses for travel within the state.

(2) Witness fees and mileage expenses need not be tendered in advance if the subpoena is annotated "Fees Guaranteed by the New Hampshire Board of Pharmacy."

(3) The respondent shall be allowed at least 48 hours to comply.

V. The board may at any time subpoena medical and pharmacy records from its licensees, registrants, and permittees and from physicians, dentists, veterinarians, advanced registered nurses, hospitals, and other health care providers or facilities licensed by or certified in this state. Such subpoenas shall be served by certified mail or by personal delivery to the address shown on the licensee's, registrant's, or permittee's current license, certificate or permit, and no witness or other fee shall be required. A minimum of 15 days' advance notice shall be allowed for complying with a subpoena duces tecum issued under this chapter.

VI. Persons holding or applying for licenses or other privileges granted by the board shall keep the board informed of their current business and residence addresses. A licensee, permittee, or registrant shall receive adequate notice of any hearing or other action taken under this chapter if notice is mailed in a timely fashion to the most recent home or business address furnished to the board by the licensee, permittee, or registrant.

VII. Complaints of licensee misconduct shall be in writing and shall be treated as petitions for the commencement of a disciplinary hearing. The board shall fairly investigate all complaints to the extent and in the manner warranted by the allegations. A complaint which fails to state a cause of action may be summarily denied in whole or in part. Some or all of the allegations in a complaint may be consolidated with another complaint or with issues which the board wishes to investigate or hear on its own motion. If investigation of a complaint results in an offer of settlement by the licensee, permittee, or registrant, the board may settle the allegations against the licensee, permittee, or registrant without the consent of the complainant, provided that material facts are not in dispute and the complainant is given an opportunity to comment upon the terms of the proposed settlement.

VIII. At the commencement of an adjudicatory proceeding, or at any time during a formal or informal investigation, and without issuing a subpoena, the board may mail a statement of the issues being investigated or heard to a licensee or other person who is a proper subject of inquiry and require that licensee or other person to provide a detailed and good faith written response to such statement. The board may also require the licensee or other person to furnish complete

copies of appropriate office records concerning any patient whose treatment is relevant to the matters at issue. The licensee or other person shall respond to such request within a reasonable time period of not less than 15 days, as the board may specify in its written request.

**Source.** 1921, 122:19. PL 210:31. RL 256:31. 1947, 258:1. RSA 318:30. 1979, 155:23. 1981, 484:13. 1985, 324:12. 1988, 106:4. 1989, 258:2. 1992, 97:10. 1994, 333:7. 2005, 177:132. 2010, 259:7, eff. July 6, 2010. 2015, 276:73, eff. July 1, 2015.

### **Section 318:30-a**

**318:30-a Temporary Suspension Where Imminent Threat.** – In cases involving imminent danger to life or health, the board may order suspension of a license, permit, registration, certification, or privilege granted under this chapter pending hearing for a period of no more than 60 days. In such cases, the basis for the board's finding of imminent danger to life or health shall be reduced to writing and combined with a hearing notice which complies with RSA 318:31, II and RSA 541-A:31, III. Notwithstanding the requirements of RSA 541-A:30, III, the board's hearing may commence as much as 30 days after the date of the order suspending the license, permit, registration, or certification. If the board does not commence the hearing within 30 days the suspension order shall be automatically vacated, but a licensee, permittee, registrant, or certificate holder shall be allowed additional time to prepare for or to complete a hearing under this section only by agreeing to a further suspension commensurate with the additional time extended.

**Source.** 1992, 97:11. 1994, 412:36. 2005, 177:133, eff. July 1, 2005.

### **Section 318:31**

#### **318:31 Hearings, Decisions and Appeals. –**

I. Adjudicatory hearings shall be open public proceedings. Any member of the board may preside at such a hearing and issue oaths or affirmations to witnesses.

II. The board shall furnish the licensee or any other respondent with at least 15 days' written notice of the date, time and place of a hearing, except as otherwise provided in this chapter. Such notice shall include an itemization of the issues to be heard, and, in the case of a disciplinary hearing, a statement as to whether the action has been initiated by a written complaint or upon the board's own motion, or both. If a written complaint is involved, the complainant shall also receive a copy of the hearing notice and shall be provided with a reasonable opportunity to intervene as a party.

III. Any person appearing at a board hearing or investigation may be represented by legal counsel, but the board shall have no obligation or authority to appoint or provide an attorney to any such person.

IV. The board may at any time dispose of issues or allegations in an adjudicatory hearing, or an investigation, by default, by settlement agreement or consent order, by issuing an order of dismissal for failing to state a proper basis for disciplinary action or by summary judgment order based upon undisputed material facts. In disciplinary hearings, the board may hold prehearing conferences which shall be exempt from the provisions of RSA 91-A, but all final disciplinary actions, including those which occur without holding a public hearing, shall be available to the

public.

V. Adjudicatory decisions and final disciplinary actions of the board shall be made by a majority of the board members participating in the decision. Such decisions shall not be made public until they have been reduced to writing, signed by a representative of the board, and served upon the parties.

VI. Decisions of the board may be appealed to the supreme court pursuant to RSA 541. No disciplinary sanction imposed by the board shall be stayed during appeal if the board determines that the public well-being so requires.

**Source.** 1921, 122:19. PL 210:32. RL 256:32. 1947, 258:2. RSA 318:31. 1979, 155:24. 1981, 484:14. 1988, 106:5. 1992, 97:12, eff. July 1, 1992.

### **Section 318:32**

**318:32 Repealed by 1981, 484:22, II, eff. July 1, 1981. –**

## **Conferences of Boards, Etc.**

### **Section 318:33**

**318:33 Attendance.** – The board, in order to be informed and to determine the status of boards of pharmacy of other states desiring reciprocal licensure, and in order to be advised regarding the progress of pharmacy throughout the country, may select at least one of its members to meet, at the expense of the state, with like representatives from other state boards of pharmacy. At such meetings, when arranged, there shall be discussed the degree of fitness for licensure which is required by the several state boards of pharmacy.

**Source.** 1921, 122:20. PL 210:34. RL 256:34. RSA 318:33. 1979, 155:25. 1981, 484:18, 20, eff. July 1, 1981.

### **Section 318:34**

**318:34 Repealed by 1981, 484:22, III, eff. July 1, 1981. –**

### **Section 318:35**

**318:35 Association.** – The board, through its representatives, may, with like representatives from other state boards of pharmacy, join in creating and maintaining an association of representatives of the several state boards of pharmacy to be engaged in the general advancement of pharmacy and the keeping of records pertaining to reciprocal licensure of pharmacists, and, at its discretion the board may give to such association information which it possesses relating to such aims and objects.

**Source.** 1921, 122:20. PL 210:36. RL 256:36. RSA 318:35. 1981, 484:18, 20, eff. July 1, 1981.

## **Section 318:36**

**318:36 Information.** – The board may subscribe for and secure the service of an association engaged in the compilation of pharmaceutical information, knowledge and progress specially adapted to secure efficiency in the work of the board.

**Source.** 1921, 122:20. PL 210:37. RL 256:37. RSA 318:36. 1971, 458:5. 1979, 155:26. 1981, 484:18, eff. July 1, 1981.

# **Licensure of Pharmacies**

## **Section 318:37**

### **318:37 Required; Compliance.** –

I. No person shall conduct or operate a pharmacy for the sale at retail of drugs and medicines unless such pharmacy is registered with and a permit therefor has been issued by the pharmacy board, except as provided in this chapter.

II. (a) No person shall conduct or operate a mail-order pharmacy located outside of this state by shipping, mailing, or delivering prescription drugs into this state unless such pharmacy is registered in New Hampshire and a permit has been issued by the New Hampshire pharmacy board.

(b) To obtain a permit, a mail-order pharmacy shall comply with each of the following:

(1) Maintain a license in good standing from the state in which the mail-order pharmacy is located;

(2) Submit to the New Hampshire pharmacy board an application for registration as provided by the New Hampshire pharmacy board;

(3) Pay all appropriate registration fees;

(4) Submit to the New Hampshire pharmacy board a copy of the state pharmacy license from the state in which the mail-order pharmacy is located;

(5) Submit to the New Hampshire pharmacy board a copy of the state and federal controlled substance registrations from the state in which it is located, if controlled substances are to be shipped into this state.

(c) When requested to do so by the New Hampshire pharmacy board, each mail-order pharmacy shall supply the New Hampshire pharmacy board with any inspection reports, warning notices, disciplinary actions, notice of deficiency reports, or any other related reports from the state in which it is located concerning the operation of a mail-order pharmacy for review of compliance with state and federal drug laws.

(d) Except in emergencies that constitute an immediate threat to the public health and require expedited action by the board, the New Hampshire pharmacy board shall file a complaint with the licensing board of the state in which the mail-order pharmacy is located when known or suspected violations of the laws of the state in which the pharmacy is located are uncovered. If the licensing board in the state in which the mail-order pharmacy is located initiates disciplinary action, the New Hampshire pharmacy board may request the appropriate documents involved in the action for consideration of discipline against the pharmacy registration of the mail-order pharmacy. If no action is taken against the mail-order pharmacy by the licensing board of the state in which it is located, the New Hampshire pharmacy board may request copies of any

investigation reports available from that state.

(e) The New Hampshire pharmacy board shall extend reciprocal cooperation to any state that licenses and regulates mail-order pharmacies for the purpose of investigating complaints against pharmacies located in New Hampshire or the sharing of information and investigative reports, as long as the other state shall extend the same reciprocal cooperation to the New Hampshire pharmacy board.

**Source.** 1921, 122:24. PL 210:38. RL 256:38. RSA 318:37. 1973, 453:6. 1979, 155:27. 1981, 484:18. 2000, 187:2, eff. Oct. 1, 2000.

## **Section 318:38**

### **318:38 Permit; Fees. –**

I. The board shall, upon application and hearing, issue a permit to maintain and operate a pharmacy to such persons, firms, or corporations as they deem qualified to conduct a pharmacy. The permit shall be issued to the pharmacy in the name of the corporation or the owner of the pharmacy. This permit, to be known as a pharmacy permit, shall certify that the designated pharmacist-in-charge has accepted the responsibility for the safe, effective operation of a pharmacy and compliance with all pharmacy and drug laws or regulations; that the premises named in the permit are a fit place to practice pharmacy including, but not limited to, the compounding and dispensing of medicines upon prescriptions and for the manufacture, sale, and distribution of drugs, medicines, and poisons; and that such premises and acts shall be under the direct supervision of a licensed pharmacist. The holder of a pharmacy permit may keep this pharmacy open at all hours for the compounding, dispensing, and sale of drugs and medicines provided that a pharmacist is present and on duty; except that in an institutional setting, in the absence of a pharmacist, a registered nurse, designated by the institution for this purpose, may enter and obtain from an institutional pharmacy such drugs as are needed in an emergency situation or as may otherwise be provided for in this chapter. The applicant for a pharmacy permit or a renewal thereof shall provide the board with all information it deems necessary for determining the applicant's qualifications to own and operate a pharmacy in the public interest.

II. All pharmacy permits shall expire when there is a change of ownership of the pharmacy or at midnight on December 31 biennially in each odd-numbered year. Every pharmacy that wishes to continue to operate as such shall renew its permit no later than December 15 biennially in odd-numbered years or immediately when the permit expires for any other reason. It shall be deemed a violation of the provisions of this chapter for any pharmacy to be open or operated beyond the expiration date of its permit.

III. All applicants for a pharmacy permit shall pay a reasonable fee as established by the board for each original pharmacy permit and for each renewal thereof.

**Source.** 1921, 122:25, 26. PL 210:39. 1931, 123:2. RL 256:39. RSA 318:38. 1955, 241:4. 1963, 83:6. 1967, 191:1. 1971, 458:6. 1973, 453:7. 1977, 563:44. 1979, 155:28. 1981, 484:18, 19, 21. 2001, 282:7, eff. July 1, 2001. 2019, 264:7, eff. Sept. 17, 2019.

## **Section 318:39**

**318:39 Application; Display.** – Application for a permit shall be made in such manner and in such form as the board may determine. The permit shall at all times be exposed in a conspicuous place in the pharmacy for which it is issued.

**Source.** 1921, 122:26. PL 210:40. 1931, 123:3. RL 256:40. RSA 318:39. 1973, 453:8, eff. Aug. 29, 1973.

## **Regulation of Pharmacies**

### **Section 318:40**

**318:40 Unauthorized Practice of Pharmacy.** – Except as provided by RSA 318:42, no person shall engage in the practice of pharmacy without first being licensed by the board. No person shall impersonate a pharmacist or falsely claim to be a pharmacist. No person owning, managing, or conducting any store, not being a licensed pharmacist or having one in his employ, shall exhibit within or outside of such store, or include in any advertisement, the words "drug store", "pharmacy", "apothecary", "drug", "drugs", "medicine", or "medicine shop", or any combination of these terms or other words indicating that such store is a place where medicines are compounded or sold, or exhibit within or without his place of business or in connection with his business any show bottle or globe of colored glass or globe filled with colored liquid which creates the impression that prescription drugs are being offered for sale.

**Source.** 1921, 122:23. 1925, 84:5. PL 210:41. 1931, 123:4. 1933, 61:1. RL 256:41. RSA 318:40. 1973, 528:202. 1988, 158:3, eff. June 21, 1988.

### **Section 318:41**

**318:41 Books and Equipment.** – Each pharmacy shall be equipped with those pharmaceutical utensils, technical equipment and professional references which the board deems necessary for the safe, effective practice of pharmacy. The prescribed equipment and references shall be open to the inspection of the board and its representatives. No pharmacy permit shall be issued or renewed until the pharmacy complies with the provisions of this section, and the board may suspend or revoke a pharmacy permit whenever the pharmaceutical utensils or equipment or the professional references fail to conform with the prescribed list.

**Source.** 1921, 122:21. PL 210:42. 1939, 43:1. RL 256:42. RSA 318:41. 1973, 453:9. 1979, 155:29. 1981, 484:18, eff. July 1, 1981.

### **Section 318:42**

#### **318:42 Dealing in or Possessing Prescription Drugs.** –

It shall be unlawful for any person who is not a licensed pharmacist in a pharmacy registered in accordance with the provisions of this chapter to manufacture, compound, dispense, sell, offer for sale or have in possession any prescription drug as defined in RSA 318:1, XVII, provided that this section shall not prevent the following:

I. Persons from possessing prescription drugs dispensed to them pursuant to a lawful prescription or who are acting as an authorized agent for a person holding a lawful prescription. For purposes of this section, an authorized agent shall mean any person, including but not limited to a family member or caregiver, who has the intent to deliver the prescription drug to the person to whom the prescription drugs are lawfully prescribed.

II. Physicians, dentists, optometrists, podiatrists, veterinarians, advanced practice registered nurses, naturopathic doctors, and physician assistants from possessing, compounding in accordance with RSA 318:14-a, personally administering, or distributing prescription drugs to meet the immediate medical needs of their patients. For advanced practice registered nurses and physician assistants, compounding shall be limited according to RSA 318:42, VIII.

(a) Nothing in this section shall prohibit the dispensing of noncontrolled prescription drugs by an authorized agent of a veterinarian for an animal under the agent's care, provided that the drugs were compounded by or under the supervision of the licensed veterinarian.

(b) Nothing in this section shall prohibit the dispensing or sale by an ophthalmologist of therapeutic contact lenses or the dispensing or sale by an optometrist of therapeutic contact lenses pursuant to RSA 327:6-a.

(c) Nothing in this section shall prohibit a dental hygienist from possessing, administering, dispensing, or prescribing a fluoride supplement, topically applied fluoride, and chlorhexidine gluconate oral rinse pursuant to RSA 317-A:21-c, I(g).

II-a. Midwives certified pursuant to RSA 326-D, from obtaining, possessing, or administering prescription drugs to meet the immediate medical needs of their patients. Such authority to obtain, possess, or administer shall be limited to those drugs listed in RSA 326-D:12. Nothing shall prohibit a pharmacist, in good faith, from selling and dispensing drugs listed in RSA 326-D:12 to midwives certified pursuant to RSA 326-D.

III. The sale of prescription drugs by licensed manufacturers or wholesalers to persons or entities legally authorized to possess such drugs.

IV. The possession of prescription drugs for such agricultural, technical, or industrial uses as may be approved by the board, the Federal Drug Enforcement Administration, or by other state or federal statutes or regulations.

V. The sale and distribution of nonprescription drugs as defined in RSA 318:1, XVIII by non-pharmacy retail stores and outlets. Retail stores and outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule shall be adopted by the board under this chapter which shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist. The commissioner of the department of health and human services may make a determination that a specific product may only be dispensed upon a written prescription of a practitioner.

VI. The department of health and human services from possessing and distributing "biological drugs" to the public within the meaning of RSA 141-C:17.

VII. The dispensing of noncontrolled prescription drugs at a clinic by a licensed health professional legally authorized to administer immunizations or dispense medications, or by registered nurses in clinics of nonprofit family planning agencies under contract with the department of health and human services, provided that:

(a) The drugs are dispensed under a written protocol established by a licensed physician, physician assistant, or by an advanced practice registered nurse, which provides for responsible supervision over the activities in question and mentions the name of each health care provider for whom the physician, physician assistant, or advanced practice registered nurse is assuming

supervisory responsibility. A written and signed copy of the protocol showing the date it was approved shall be kept at the clinic at all times and shall be made available during any inspection conducted under RSA 318:8.

(b) The drugs appear on the current vaccine schedule recommended by the federal advisory committee on immunization practices or the current formulary approved pursuant to RSA 326-B.

(c) The drugs are dispensed or administered only to bona fide clients of the clinic for their personal needs pursuant to written eligibility criteria established by the licensed physician, physician assistant, or advanced practice registered nurse who established the written and signed protocol.

(d) Nothing in this section shall be construed to negate any authority of the board of pharmacy pursuant to RSA 318:8.

(e) [Repealed].

VII-a. (a) The possession and administration, with written parental authorization, of flu vaccine, immunizations, and mantoux tests for the purpose of disease prevention and tuberculosis screening by registered nurses employed or contracted by public school systems.

(b) The possession and administration of epinephrine for the emergency treatment of anaphylaxis by licensed practical nurses or registered nurses employed or contracted by public school systems or by licensed campus medical professionals in postsecondary educational institutions or independent schools.

(c) The possession, provision, and administration of a bronchodilator, spacer, or nebulizer by a school nurse or designated unlicensed assistive personnel pursuant to RSA 200:53 through RSA 200:57.

VII-b. The management of medication therapy and administration of non-controlled prescription drugs including injectable medications, biologicals, and immunizations by qualified pharmacists pursuant to collaborative pharmacy practice agreements.

VIII. A registered nurse or physician assistant from:

(a) Making dilutions from concentrated solutions or pre-weighed or pre-measured packets.

(b) Adding prepared sterile additives.

(c) Reconstituting or diluting medications following manufacturers specific directions.

(d) Entering an institutional pharmacy in an institutional setting specially designated for this purpose by the institution in the absence of a pharmacist to obtain those drugs needed in an emergency situation.

IX. A pharmacy student serving an internship from performing the duties of a pharmacist in the presence of, and under the direction and supervision of, a licensed pharmacist.

X. The possession, for emergency use only, by emergency medical care providers licensed under RSA 153-A of such noncontrolled prescription drugs as are specified by the state emergency medical services medical control board, with the concurrence of the pharmacy board, provided that there has been prior establishment of medical control for possession of such drugs. The emergency medical care provider may only administer such prescription drugs upon receipt of orders to do so from a supervising physician or an emergency/trauma advanced practice registered nurse. Such orders may be transmitted either directly or by telephone or by radio or by other communication medium, or by standing order of local medical control delineated in a protocol as defined in RSA 153-A.

XI. A nurse licensed under RSA 326-B who is an employee of a home health care or hospice agency licensed pursuant to RSA 151:2, and is acting in the course of his or her employment, from possessing such noncontrolled prescription drugs as are approved by the board of nursing



and agreed upon jointly by the board of registration in medicine and the pharmacy board and from administering such preapproved noncontrolled prescription drugs according to written protocols approved annually by such employer's professional advisory committee which includes a physician licensed by the board of registration in medicine.

XII. A registered or certified pharmacy technician from performing functions and duties supervised by a licensed pharmacist as authorized by rules adopted by the board under RSA 541-A.

XII-a. A registered or certified pharmacy technician from performing transport for the authorized transfer of prescription drugs between pharmacies.

XIII. A nurse licensed under RSA 326-B, who is an employee of a home health care or hospice agency licensed pursuant to RSA 151:2 and is acting in the course of employment, from organizing the prescription and nonprescription drugs of clients into containers designed to aid clients in carrying out a prescriber's directions, provided that the organizing of drugs is documented in the client's nursing record and that the original prescription containers remain in the client's possession.

XIV. A nurse, licensed under RSA 326-B, who is an employee of a health facility, licensed by the state of New Hampshire, and acting in the course of his or her employment, from organizing the prescription and non-prescription drugs of clients into containers designed to aid clients in carrying out prescriber's directions; provided, that the organizing of the drugs is documented in the client's nursing record and that the original prescriptions will be kept at the facility or client's home and the medication container is set up on a weekly basis.

XV. The placement of automated pharmacy systems in long-term care facilities, hospices, and state correctional institutions, for the purpose of storage and dispensing of controlled and non-controlled prescription drugs under the supervision and control of a licensed pharmacist. Only pharmacies registered by the Federal Drug Enforcement Administration may provide controlled substances for storage in and dispensing from automated pharmacy systems.

XVI. Law enforcement officers who are acting within the scope of their employment and official duties, from possessing prescription drugs for the purpose of collection, storage, and disposal of such prescription drugs, in conjunction with a pharmaceutical drug take-back program established pursuant to RSA 318-E.

XVII. Persons who possess prescription drugs pursuant to a lawful prescription or who are acting as an authorized agent for a person holding a lawful prescription, from delivering any unwanted or unused prescription drugs to law enforcement officers for the purpose of disposal of such prescription drugs in conjunction with a pharmaceutical drug take-back program established pursuant to RSA 318-E.

XVIII. A research organization licensed by the board pursuant to RSA 318:51-f, and researchers representing such organization, from possessing prescription drugs for research operations.

**Source.** 1921, 122:27. PL 210:43. 1931, 123:5. 1941, 207:1. RL 256:43. 1949, 280:2. RSA 318:42. 1967, 82:2. 1973, 453:10. 1981, 484:19. 1988, 158:4. 1991, 189:1; 382:19. 1992, 245:2. 1993, 333:2. 1994, 333:8-10. 1995, 65:1; 286:26; 310:181, 182. 1996, 56:1; 267:21; 277:3. 1997, 326:2. 1998, 67:4, 5. 1999, 213:4; 345:7. 2000, 91:1; 188:5; 271:6, 7. 2001, 15:2. 2002, 281:7. 2003, 310:64. 2004, 49:1. 2005, 274:5; 293:7. 2006, 164:5. 2007, 202:9-11. 2009, 54:2, 5; 152:1. 2010, 37:1. 2011, 63:9. 2012, 36:1. 2013, 121:5, eff. Jan. 1, 2014. 2015, 45:2, eff. July 17, 2015; 203:4, eff. July 1, 2015. 2016, 42:2; 45:2 eff. July 2, 2016. 2019, 264:8, 9, eff. Sept. 17, 2019; 287:11, eff. July 19, 2019.

**Section 318:43**

**318:43 Repealed by 1979, 155:34, eff. Aug. 5, 1979. –**

**Section 318:44**

**318:44 Repealed by 1979, 155:35, eff. Aug. 5, 1979. –**

**Section 318:45**

**318:45 Repealed by 2019, 264:15, I, eff. Sept. 17, 2019. –**

**Section 318:45-a**

**318:45-a Continuous Quality Improvement. –**

I. Each licensed pharmacy shall establish a continuous quality improvement program (CQI). The purpose of the program shall be to assess errors that occur in the pharmacy during the review, preparation, and dispensing of prescription medications and to allow the pharmacy to take appropriate action to prevent or reduce the likelihood of a recurrence. The program is non-punitive and seeks to identify weaknesses in processes and systems, in order to make appropriate corrections to improve them.

II. A CQI program may be comprised of staff members of the pharmacist, including pharmacists, registered pharmacist interns, licensed advanced pharmacy technicians, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the pharmacist in charge or the consultant pharmacist of record.

III. A CQI program shall require that the pharmacist in charge or the consultant pharmacist of record ensure that a review of quality-related events occurs at least every 3 months, contain a planned process to record and assess quality related events, include a process for documenting actions to improve the quality of patient care, and maintain a summary of the documented actions. The review should consider environment and systems-based contributing factors.

IV. (a) The pharmacy shall either:

(1) Report incidents and unsafe events as quality-related events through a contracted patient safety organization (PSO) recognized by the Agency for Healthcare Research and Quality (AHRQ) whose primary mission is pharmacy continuous quality improvement; or

(2) Document incidents and unsafe events as quality-related events in an internal program in the pharmacy in a written record or computer database created solely for that purpose.

(b) The quality-related event shall be documented by the individual who discovers the event or the individual to whom it is initially reported. Documentation of quality-related events shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacies shall maintain such records at least until the event has been considered and incorporated in a summary of documented actions.

V. As a component of its CQI program, each licensed pharmacy shall assure that, following a quality-related event, all reasonably necessary steps have been taken to prevent or minimize patient harm.

VI. CQI programs shall be confidential. The summarization document shall analyze process improvements undertaken following a quality-related event. No patient names or employee

names shall be included in this summarization. The summarization shall be maintained for 4 years and be made available within 3 business days of a request by the board's inspectors. Continuous quality improvement records shall be considered peer-review documents and not subject to discovery in civil litigation or administrative actions.

VII. The board may establish by rules adopted under RSA 541-A program requirements and recordkeeping requirements of a pharmacy CQI program.

**Source.** 2017, 221:1, eff. Sept. 8, 2017. 2019, 58:6, eff. July 1, 2019.

## **Section 318:46, 318:47**

**318:46, 318:47 Repealed by 2019, 264:15, II, eff. Sept. 17, 2019. –**

## **Section 318:47-a**

**318:47-a Prescription Labels.** – Whenever a pharmacist dispenses a noncontrolled drug pursuant to a prescription, he or she shall affix to the container in which such drug is dispensed a label showing at least the name and address of the pharmacy and the name or initials of the dispensing pharmacist or pharmacist-in-charge; the prescription identification number assigned by the pharmacy; the date dispensed; any directions as may be stated on the prescription; the name of the prescribing practitioner; the name of the patient; all pertinent auxiliary labels; and, unless otherwise indicated by the prescribing physician, dentist, veterinarian, or advanced practice registered nurse, the name, strength, and quantity of the drug dispensed. All drugs dispensed to a patient that have been filled using a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities. A biological product, as defined in RSA 318:47-dd, I, shall also be labeled as provided in RSA 318:47-dd, VII. No person shall alter, deface, or remove any label so affixed. A compounded drug product shall also be labeled as provided in RSA 318:14-a, II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

**Source.** 1979, 155:30. 1985, 324:13. 1994, 333:12. 2002, 281:5. 2009, 54:5. 2013, 121:6, eff. Jan. 1, 2014. 2018, 164:2, eff. Jan. 1, 2019.

## **Section 318:47-b**

**318:47-b Labeling Exemption.** – Labeling requirements as specified in 318:47-a are exempted when medication is dispensed to institutionalized patients and as provided for under RSA 141-C:17.

**Source.** 1979, 155:30. 2008, 271:8, eff. June 26, 2008.

## **Section 318:47-c**

**318:47-c Prescriptions. –**

I. (a) A prescription may be written, oral, or electronically transmitted. All oral prescriptions shall be immediately reduced to writing by the pharmacist, authorized technician, or licensed advanced pharmacy technician receiving the oral prescription and shall indicate at least the name of the patient; the name, strength, and quantity of the drug prescribed; any directions specified by the prescriber; the name of the practitioner prescribing the medication; the date the prescription was ordered; a statement that the prescription was presented orally; and the name of the pharmacist who took the oral order. The pharmacist who dispensed an original prescription shall indicate on the face of the prescription at least the assigned prescription identification number; the date of dispensing; the quantity actually dispensed; and his or her name or unique identifiers. The prescription shall be filed numerically by the assigned identification number for a period not less than 4 years. Such prescription files shall be open to inspection by the pharmacist board and its agents.

(b) A patient shall be entitled to receive a paper prescription instead of an oral or electronically transmitted prescription.

II. (a) A prescription that is electronically generated by a licensed prescriber, transmitted and received at the pharmacy by computer systems shall contain at least the name of the patient, the name, strength, and quantity of the drug prescribed, any directions specified by the prescriber, the name of the practitioner prescribing the medication, and shall be dated and signed using an electronic signature by the prescribing practitioner on the day issued. Such electronic signature shall be made in accordance with RSA 294-E.

(b) Electronic prescribing shall not interfere with a patient's freedom to choose a pharmacy.

(c) Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered by or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.

(d) Electronic prescribing software may show information regarding a payor's formulary, co-payment, or benefit plan as long as nothing is designed to preclude or make more difficult the act of a prescribing practitioner or patient selecting any particular pharmacy or pharmaceutical.

(e) No person who has access to electronic prescription information solely by transmitting or facilitating the transmission of prescriptions between the licensed prescriber generating the prescription and the pharmacy receiving the prescription, or any intermediary, shall retain the prescription or any information it contains for longer than is mandated by federal or state law, after which time the prescription information shall be destroyed. No such person shall sell, use, or otherwise make available the prescription information for any purpose other than transmission of prescriptions, prescription refills, and clinical information displayed to the prescriber or pharmacist.

**Source.** 1979, 155:30. 1985, 324:14. 2005, 177:134. 2007, 320:2. 2008, 217:2. 2010, 259:8, eff. July 6, 2010. 2019, 58:7, eff. July 1, 2019.

**Section 318:47-d**

**318:47-d Pharmacies; Substituting Generic Drugs.** – Pharmacies, including mail-order pharmacies, may substitute generically equivalent drug products for all legend and non-legend prescriptions unless the prescribing practitioner handwrites "medically necessary" on each paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the brand name drug product is medically necessary. In this section, "drug product" does not include a biological product.

**Source.** 2002, 123:1. 2008, 23:1, eff. July 11, 2008. 2018, 164:3, eff. Jan. 1, 2019.

## **Section 318:47-dd**

### **318:47-dd Pharmacies; Substituting Biological Products. –**

I. In this section:

(a) "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(b) "Proper name" means the nonproprietary name for a biological product designated by the federal Food and Drug Administration license for use upon each package of the product.

(c) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration:

(1) Has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. section 262(k)(4); or

(2) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

II. The board shall maintain a link on its website to the federal Food and Drug Administration's Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

III. A pharmacist may substitute a biological product pursuant to this section only if it has been licensed by the federal Food and Drug Administration as an interchangeable biological product for the prescribed biological product.

IV. When a pharmacist dispenses an interchangeable biological product for the prescribed biological product, the pharmacist or his or her designee shall inform the patient.

V. A pharmacist shall not substitute an interchangeable biological product pursuant to this section if the prescriber indicates that substitution is not authorized by specifying on the prescription "medically necessary" on a paper prescription, or uses electronic indications when transmitted electronically, or gives instructions when transmitted orally that the biological product prescribed is medically necessary.

VI. (a) Within 3 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) An interoperable electronic medical records system;

(2) An electronic prescribing technology; or

- (3) A pharmacy benefit management system; or
- (4) A pharmacy record.

(b) Entry into an electronic records system as described in this paragraph is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that the communication shall not be required where:

- (1) There is no federal Food and Drug Administration-approved interchangeable biological product for the biological product prescribed; or
- (2) A refill prescription is not changed from product dispensed on the prior filling of the prescription.

VII. The label of all biological products dispensed by a pharmacist shall include the proper name and the name of the manufacturer of the product.

**Source.** 2018, 164:4, eff. Jan. 1, 2019.

### **Section 318:47-e**

**318:47-e Repealed by 2019, 264:15, III, eff. Sept. 17, 2019. –**

### **Section 318:47-f**

**318:47-f Prescription Information to be Kept Confidential.** – Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this section shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this section is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this section.

**Source.** 2006, 328:1, eff. June 30, 2006.

## **Section 318:47-g**

### **318:47-g Patient Assistance Program. –**

I. Following the close of each calendar year, any clearinghouse that provides information to New Hampshire residents about pharmaceutical manufacturers' patient assistance programs shall, to the extent that the clearinghouse collects such information, provide aggregate information to the commissioner of the department of health and human services relative to either:

- (a) The number of people in New Hampshire who may qualify for any manufacturer or government program during the calendar year; or
- (b) The number of patients served during the calendar year.

II. An individual company may provide additional information about the individual company's patient assistance program; however, the commissioner shall combine all information from all sources, including individual companies and the clearinghouse, and shall report only aggregate information to the public.

**Source.** 2006, 328:1, eff. June 30, 2006.

## **Section 318:47-h**

### **318:47-h Price of Filling Prescriptions. –**

I. A pharmacy benefits manager or insurer shall require a contracted pharmacy to charge an enrollee or insured person the pharmacy's usual and customary price of filling the prescription or the contracted copayment, whichever is less.

II. Once it has settled a claim for filling a prescription for an enrollee or insured person and notified the pharmacy of the amount the pharmacy benefits manager or insurer will pay to the pharmacy for that prescription, the pharmacy benefits manager or insurer shall not lower the amount to be paid to the pharmacy by the pharmacy benefits manager or the insurer for such settled claim; provided, however, that this paragraph shall not apply if the claim was submitted fraudulently or with inaccurate or misrepresented information.

III. The board shall adopt rules under RSA 541-A establishing procedures to receive complaints of violations of paragraphs I and II. Such rules shall include:

- (a) Criteria and procedure to refer complaints to the insurance department.
- (b) Method for tracking the status of complaints referred to the insurance department and receiving department of insurance reports on the status.
- (c) Procedures for reporting to the senate president, the speaker of the house of representatives, and the chairpersons of the house and senate committees with oversight of pharmacy benefit manager regulation, the number of complaints received, the number and nature of complaints referred to the insurance department, and the status of referred complaints.

**Source.** 2008, 29:1. 2010, 202:1, eff. Aug. 21, 2010. 2016, 221:5, eff. June 9, 2016.

## **Section 318:47-i**

**318:47-i Emergency Prescription. –** In the event a pharmacist receives a request for a prescription that requires a prior authorization that has neither been approved nor denied, and such medication is determined by the pharmacist to be essential to the maintenance of life or to

the continuation of therapy in a chronic condition, or the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort, the pharmacist may dispense a one-time emergency prescription of a maximum 72-hour supply of the prescribed medication to be reimbursed according to RSA 420-J:7-b, IX. A product that is packaged in a dosage form that is fixed and unbreakable may be dispensed as a 72-hour supply.

**Source.** 2014, 311:2, eff. Jan. 1, 2015.

### **Section 318:47-j**

**318:47-j Medicaid Coverage for Telehealth Services.** – Under this chapter, Medicaid coverage for telehealth services shall comply with the provisions of 42 C.F.R. section 410.78 and RSA 167:4-d.

**Source.** 2015, 246:2, eff. July 6, 2015 at 12:01 a.m.

### **Section 318:47-k**

**318:47-k Repealed by 2017, 23:2, effective Dec. 1, 2017. –**

### **Section 318:47-l**

**318:47-l Hormonal Contraceptives; Dispensing.** –

I. In this section, "standing order" means a written and signed protocol authored by one or more physicians licensed under RSA 329:12 or one or more advanced practice registered nurses licensed under RSA 326-B:18. Such agreement shall specify a protocol allowing the pharmacist licensed under RSA 318:18 to dispense hormonal contraceptives under the delegated prescriptive authority of the physician or APRN, specify a mechanism to document screening performed and the prescription in the patient's medical record, and include a plan for evaluating and treating adverse events. Any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

II. Licensed pharmacists following standing orders may dispense hormonal contraceptives to persons in this state without a prior prescription.

III. A pharmacist, pharmacy, physician, or APRN issuing or following standing orders shall be prohibited from seeking personal financial benefit by participating in any incentive-based program or accepting any inducement that influences or encourages therapeutic or product changes or the ordering of tests or services.

IV. Prior to dispensing hormonal contraceptives under this section, a pharmacist shall complete an Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to hormonal contraceptives. In addition, pharmacists shall comply with the most current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use as adopted by the Centers for Disease Control and Prevention.

V. The pharmacist shall provide each recipient of hormonal contraceptives pursuant to this section with a standardized information sheet written in plain language, which shall include, but is not limited to, the indication for the use of the hormonal contraceptive, the importance of



follow-up care, and health care referral information.

VI. The board shall adopt rules, pursuant to RSA 541-A, relative to:

- (a) Education and training required under paragraph IV.
- (b) Content and format of the information sheet required under paragraph V, in consultation with the commissioner of the department of health and human services.
- (c) A model statewide protocol, with the consent of the board of medicine, the board of nursing, and the department of health and human services to be used for the purposes of paragraph I.
- (d) Other matters necessary to the proper administration of this section.

VII. The board of medicine shall not deny, revoke, suspend, or otherwise take disciplinary action against a physician based on a pharmacist's failure to follow standing orders provided the provisions of this section and the rules adopted under this section are satisfied. The board of nursing shall not deny, revoke, suspend, or otherwise take disciplinary action against an APRN based on a pharmacist's failure to follow standing orders provided the provisions of this section and the rules adopted under this section are satisfied. The board of pharmacy shall not deny, revoke, suspend, or otherwise take disciplinary action against a pharmacist who follows standing orders based on a defect in those standing orders provided the provisions of this section and the rules adopted under this section are satisfied.

**Source.** 2018, 205:2, eff. Aug. 7, 2018.

## **Possession and Sale of Drugs and Devices for Administration of Drugs**

### **Section 318:48 to 318:51**

**318:48 to 318:51 Repealed by 1963, 276:2, eff. July 1, 1963 –**

### **Section 318:51-a**

#### **318:51-a Licensing of Manufacturers and Wholesalers Required. –**

I. No person shall manufacture legend drugs or controlled drugs as that term is defined in RSA 318-B:1, VI and no person as a wholesaler, distributor, or reverse distributor shall supply the same without first having obtained a license to do so from the board. Such license shall expire biennially on June 30 of every even-numbered year. An application together with a reasonable fee as established by the board shall be filed biennially by midnight on June 30 of every even-numbered year.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board of pharmacy:

- (a) That the applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.
- (b) That the applicant has sufficient land, buildings, and such security equipment so as to properly carry on the business described in his application.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

V. (a) The manufacturer, wholesaler, distributor, reverse distributor, or broker to which a license has been issued shall, within 30 days of any change of information supplied in the original application, notify the board.

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

(1) Current New Hampshire license number of the manufacturer, wholesaler, distributor, reverse distributor, or broker.

(2) Name of the manufacturer, wholesaler, distributor, reverse distributor, or broker, old and new, if applicable.

(3) Address of the manufacturer, wholesaler, distributor, reverse distributor, or broker, old and new, if applicable.

(4) [Repealed.]

(c) A new license shall be required for a change of ownership of an established manufacturer, wholesaler, distributor, reverse distributor, or broker to a successor business entity which results in a change in the controlling interest in the manufacturer, wholesaler, distributor, reverse distributor, or broker.

**Source.** 1985, 324:15. 1989, 258:3. 2011, 111:2, 3, eff. July 30, 2011. 2019, 264:10, 15, IV, eff. Sept. 17, 2019.

### **Section 318:51-b**

#### **318:51-b Licensing of Limited Retail Drug Distributors Required. –**

I. No person shall operate as a limited retail drug distributor, as defined in RSA 318:1, VII-a, without first having obtained a license to do so from the board. Such license shall expire biennially on June 30 of each odd-numbered year. An application together with a reasonable fee as established by the board shall be filed biennially by midnight June 15 of every odd-numbered year.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board that:

(a) The applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) The applicant has sufficient space and security equipment as to properly carry on the business described in the application.

(c) The license granted by this chapter shall at all times be displayed in a conspicuous place in the facility for which it is issued.

(d) The applicant, other than a distributor of legend devices or medical gases, has a written contract with a pharmacist licensed in the state to serve as a consultant on all matters relating to the storage and dispensing of prescription drugs.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section is subject to the provisions of RSA 318:29.

**Source.** 2000, 271:5. 2007, 202:12, eff. Jan. 1, 2008. 2019, 264:11, eff. Sept. 17, 2019.

## **Section 318:51-c**

### **318:51-c Licensing of Outsourcing Facilities Identified as Section 503B Facilities by the United States Food and Drug Administration. –**

I. No person shall compound legend drugs or controlled drugs, as defined in RSA 318-B:1, VI, and no person acting as or employed by an outsourcing facility shall supply such drugs, without first having obtained a license from the board. Such license shall expire biennially on June 30 of each odd-numbered year. An application together with a fee established by the board shall be filed biennially by June 15 of every odd-numbered year.

II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the pharmacy board:

(a) That the applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.

(b) That the applicant has sufficient land, buildings, and security equipment as to properly carry on the business described in the application.

III. No license shall be granted to any person who has within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined in this chapter or RSA 318-B, or to any person who is a drug-dependent person.

IV. Any person licensed pursuant to this section shall be subject to the provisions of RSA 318:29.

V. (a) The outsourcing facility to which a license has been issued shall, within 30 days of any change of information supplied in the original application, notify the board.

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

(1) Current New Hampshire license number of the outsourcing facility.

(2) Name of the outsourcing facility, old and new, if applicable.

(3) Address of the outsourcing facility, old and new, if applicable.

(4) Names, addresses, and titles of new corporate officers, partners, or owners.

(c) A new license shall be required for a change of ownership of an established outsourcing facility to a successor business entity which results in a change in the controlling interest in the outsourcing facility.

VI. The outsourcing facility to which a license has been issued shall, within 30 days of any written warnings or disciplinary action from any state or federal licensing or enforcement agency, notify the board and provide a copy of the action.

**Source.** 2015, 180:3, eff. July 1, 2015. 2019, 264:12, eff. Sept. 17, 2019.

## **Section 318:51-d**

**318:51-d Repealed by 2015, 180:4, eff. July 22, 2017. –**

## **Section 318:51-e**

### **318:51-e Rulemaking. –**

The board shall adopt rules pursuant to RSA 541-A relative to:

I. The application procedure for licensing of outsourcing facilities;

II. Content of the application;

- III. The standards for licensing of outsourcing facilities;
- IV. The establishment of fees for licensing outsourcing facilities;
- V. Standards for denial and revocation of license;
- VI. Inspection requirements;
- VII. Dispensing and distribution requirements of prescription drugs;
- VIII. Record keeping requirements; and
- IX. Requirements for outsourcing facilities.

**Source.** 2015, 180:3, eff. July 1, 2015.

## **Section 318:51-f**

### **318:51-f Licensure of Research Organizations. –**

- I. No research organization shall procure or conduct research operations with prescription drugs by researchers without first having obtained a license from the board. Such license shall expire biennially on June 30 of each odd-numbered year. An application together with a reasonable fee as established by the board shall be filed biennially by June 15 of every odd-numbered year.
- II. No license shall be issued under this section unless the applicant has furnished proof satisfactory to the board of pharmacy:
  - (a) That the applicant is of good moral character or, if that applicant is an association or corporation, that the managing officers are of good moral character.
  - (b) That the applicant has sufficient space and security equipment as to properly carry on the research operations described in the application.
- III. The license granted under this section shall at all times be displayed in a conspicuous place in the research organization facility for which it is issued.
- IV. No license shall be issued under this section to research organizations for sale, dispensing, or distribution of prescription drugs.
  - (a) Prescription drugs are to be used solely for research purposes only.
  - (b) Use of controlled drugs is prohibited under the license for research organizations issued under this section.
  - (c) No research organization shall distribute prescription drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.
  - (d) The research organization shall effectively destroy all prescription drugs in due course by means of conducting routine research operations or disposal by approved methods.
  - (e) The research organization shall maintain up-to-date and accurate records indicating:
    - (1) The amount of prescription drug destroyed.
    - (2) The date on which the prescription drug was destroyed.
    - (3) The manner or method by which the prescription drug was destroyed.
  - (f) Inventories and disposal transactions shall be maintained for 2 years and made available for inspection by the board's inspectors within a period of 72 hours from notice.
- V. No license shall be granted to any research organization if any of its managing officers or researchers have within 5 years been convicted of a violation of any law of the United States, or of any state, relating to drugs, as defined by this chapter or RSA 318-B, or is an impaired person.
- VI. Any licensee under this section is subject to the provisions of RSA 318:29.
- VII. (a) The licensee shall, within 30 days of any change of information supplied in the original license application, notify the board.

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

- (1) Current New Hampshire license number of the research organization.
- (2) Name of managing officers and researchers, old and new, if applicable.
- (3) Address of the research organization, old and new, if applicable.

VIII. A new license shall be required for a change of ownership of an established research organization to a successor business entity which results in a change in the controlling interest in the research organization.

**Source.** 2015, 203:5, eff. July 1, 2015. 2019, 264:13, eff. Sept. 17, 2019.

### **Section 318:51-g**

#### **318:51-g Licensure of Drug or Device Distribution Agents. –**

I. No person shall act as a prescription drug or device distribution agent, which includes controlled drugs as the term is defined in RSA 318-B:1, VI, without first having obtained a license to do so from the board.

II. Any person licensed pursuant to this section shall be subject to the provisions of RSA 318:29.

III. For purposes of this section:

(a) A drug or device distribution agent shall include virtual manufacturers, virtual wholesaler distributors, jobbers or brokers (including sales/marketing offices), and third-party logistics companies, and any other agent involved in the handling or distribution of prescription drugs, medical gases, or prescription medical devices or equipment in the supply chain that affects the pedigree of the products.

(b) "Broker or jobber" is any party that mediates between a buyer and a seller for the sale or shipment of prescription drugs, gases, equipment, or devices.

(c) "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.

(d) "Third-party logistics provider" is a person that contracts with a wholesale distributor or a 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, gas, device, or equipment.

(e) "Virtual manufacturer" is anyone that owns the NDA or ANDA for a prescription drug, gas, device, or equipment that contracts with others for the actual manufacturing.

(f) "Virtual wholesale distributor" is anyone engaged in wholesale distribution of prescription drugs, gases, devices, or equipment.

**Source.** 2019, 264:14, eff. Sept. 17, 2019.

### **Section 318:52**

**318:52 Repealed by 1971, 135:2, eff. July 20, 1971. –**

### **Section 318:52-a**

**318:52-a Fraud or Deceit. –**

It is unlawful to obtain or attempt to obtain a drug or device sold by prescription of a physician, dentist, optometrist, podiatrist, veterinarian, naturopathic doctor, physician assistant, or advanced practice registered nurse that bears a statement that it is to be dispensed or sold only by or on the prescription of a physician, dentist, optometrist, podiatrist, veterinarian, naturopathic doctor, physician assistant, or advanced practice registered nurse by:

- I. Fraud, deceit, misrepresentation or subterfuge;
- II. The forgery or alteration of a prescription or of any written order;
- III. The concealment of a material fact;
- IV. The use of a false name or the giving of a false address; or
- V. Submission of an electronic or on-line medical history form that fails to establish a valid practitioner-patient relationship.

**Source.** 1965, 275:1. 1994, 333:13. 2009, 54:5. 2010, 74:2, eff. Jan. 1, 2011; 259:10, eff. July 6, 2010; 259:12, eff. Jan. 1, 2011 at 12:01 a.m.

**Section 318:52-b**

**318:52-b Destruction of Used Instruments in Health Care Facilities. –** It shall be unlawful for any possessor of a hypodermic syringe, needle, or any instrument adapted for the administration of controlled drugs, in health care facilities, to dispose of or discard any such instrument in any manner other than that provided in this section. Disposables which can cause injury, such as needles or syringes with needles, shall be placed intact in puncture resistant containers that are adapted with a secured lid which prevents easy access to the contents.

**Source.** 1970, 48:2. 1989, 34:1. 1990, 129:1, eff. June 18, 1990.

**Section 318:52-c**

**318:52-c Sale of Hypodermic Syringes and Needles. –**

I. No person shall sell, furnish, or give to any person, under 18 years of age, an instrument commonly known as a hypodermic syringe, hypodermic needle, or any instrument adapted for the administration of drugs by injection without the written or oral prescription of a licensed physician, physician assistant, dentist, veterinarian, podiatrist, or advanced practice registered nurse. Such prescription shall contain the name and address of the patient, the date of the prescription, the description of the instrument prescribed, and the number of instruments prescribed.

II. The following conditions shall apply to all purchases of hypodermic syringes or needles:

- (a) Retailers and dispensers of hypodermic syringes, needles, or any instrument adapted for the administration of drugs by injection shall provide to each purchaser at the time of purchase information regarding the safe disposal of hypodermic syringes or needles, including local disposal locations or a telephone number to call for such information, if appropriate.
- (b) Retailers and dispensers shall also provide purchasers with information on drug addiction treatment, including a local telephone number to get assistance, if appropriate.

**Source.** 1971, 135:1. 1973, 453:12. 1981, 484:15. 1989, 34:2. 1992, 102:1. 1994, 333:14. 1999, 213:5. 2000, 176:1. 2005, 177:135. 2009, 54:5. 2012, 171:26, XII, eff. Aug. 10, 2012. 2017, 117:2, eff. June 16, 2017.

### **Section 318:52-d**

**318:52-d Repealed by 2017, 117:6, eff. June 16, 2016. –**

### **Section 318:52-e**

**318:52-e Control or Possession of Hypodermic or Like Instruments Without Prescription Prohibited for Minors.** – No person under 18 years of age shall have under such person's control or possess a hypodermic syringe, hypodermic needle, or any instrument adapted for the administration of drugs by injection, unless the person has received a written or oral prescription issued under RSA 318:52-c. For the purpose of this subdivision, no such prescription shall be valid which has been outstanding for more than one year.

**Source.** 1971, 135:1. 1973, 453:15. 1981, 484:16. 1989, 34:4. 1994, 333:15. 1999, 213:6. 2000, 176:3, eff. Jan. 1, 2001.

### **Section 318:53, 318:54**

**318:53, 318:54 Repealed by 1963, 276:2, eff. July 1, 1963 –**

## **Penalty**

### **Section 318:55**

**318:55 Fines and Imprisonment; Penalties.** –

I. Any person violating the provisions of this chapter, except as otherwise provided, shall be guilty of a misdemeanor if a natural person, or guilty of a felony if any other person.

II. In addition to the penalties under paragraph I, the board may impose a civil penalty not to exceed \$5,000 per violation upon any person who willfully or repeatedly violates any provision of this chapter.

III. For any order issued in resolution of a disciplinary proceeding before the board, the board may require that any licensee, permittee, registrant, or certificate holder found guilty of a charge involving any drug law or rule to pay to the board a sum not to exceed the reasonable cost of investigation and prosecution of the proceeding. The sum shall not exceed \$5,000. The costs to be assessed shall be fixed by the board and any sums recovered shall be paid to the state treasurer for deposit in the general fund.

**Source.** 1909, 162:4. 1921, 122:30. PL 210:54. 1933, 61:2. RL 256:55. RSA 318:55. 1973, 528:203; 529:70. 1989, 258:4. 2007, 202:13, eff. Jan. 1, 2008.

## **Unused Prescription Drug Program**

## **Section 318:56**

**318:56 Unused Prescription Drug Program Established.** – There is established the unused prescription drug program for the purpose of allowing the donation of unused prescription drugs and medical devices to uninsured or underinsured individuals. The program shall be administered by the New Hampshire pharmacy board.

**Source.** 2006, 152:1, eff. July 21, 2006.

## **Section 318:57**

### **318:57 Definitions. –**

In this subdivision:

- I. "Board" means the New Hampshire pharmacy board.
- II. "Medical device" means an instrument, apparatus, implement, machine, or similar article, or any attachment or component part thereof, that has been prescribed by a physician or other authorized health care practitioner.
- III. "Patient" means a person to whom a drug or a medical device has been prescribed, that patient's authorized representative, or the executor or administrator of the patient's estate.
- IV. "Prescription drug" means a drug as defined in RSA 318:1, XVII, excluding any controlled drug as defined in RSA 318-B:1, VI.
- V. "Program" means the unused prescription drug program.

**Source.** 2006, 152:1, eff. July 21, 2006.

## **Section 318:58**

### **318:58 Donating, Accepting, and Redispersing Unused Drugs. –**

- I. Any patient, or other person or entity authorized to possess prescription drugs and medical devices pursuant to RSA 318, including manufacturers and wholesalers licensed under RSA 318:51-a or other law, including any nursing home or long-term care facility licensed under RSA 151 or any correctional facility, may donate unused prescription drugs and medical devices to the program.
- II. Any person authorized to dispense prescription drugs and medical devices pursuant to RSA 318 or other law may redispense such drugs and devices for the purposes of the program.
- III. The following facilities and services may accept donations of unused prescription drugs and medical devices for the program:
  - (a) Any pharmacy as defined in RSA 318:1, XI;
  - (b) Any hospital, nursing home, hospice, or outpatient clinic licensed pursuant to RSA 151;
  - (c) New Hampshire hospital, Glencliff home, New Hampshire veterans home, and the state and county correctional facilities; and
  - (d) Any licensed prescriber of prescription drugs pursuant to RSA 318:42, II.
- III-a. Any facility authorized to accept prescription drugs and devices for the program may temporarily store the drugs and devices appropriately but separately from the usual storage of such drugs and devices for the sole purpose of redispersing to individuals as provided in this section.



IV. The following prescription drugs and medical devices may be accepted and redispensed through the program; provided, that they have not been in the possession of the patient or other member of the public:

(a) Unused prescription drugs, including manufacturer's samples, that have not reached their expiration date, are contained in unopened unit dose or other tamper-evident packaging, and show no evidence of contamination; and

(b) Medical devices that have not been opened or adulterated.

V. Unused prescription drugs and medical devices may not be resold, but the facility or service redispensing such drug or device may charge a handling fee for the service not to exceed \$15.

VI. A facility or service may redispense unused prescription drugs and medical devices under the program to uninsured or underinsured persons as defined by the board, but redispensing to other patients is permitted if no uninsured or underinsured person is available.

VII. Participation in the program shall be voluntary and individuals in the program shall be informed that the prescription drugs and medical devices have been redispensed.

**Source.** 2006, 152:1. 2007, 263:12. 2010, 89:1, 2. 2011, 41:1, eff. July 8, 2011; 99:1, eff. July 26, 2011.

### **Section 318:58-a**

**318:58-a Repealed by 2018, 147:2, eff. Nov. 30, 2018. –**

### **Section 318:59**

#### **318:59 Rulemaking. –**

The board shall, not later than December 31, 2010, adopt rules, pursuant to RSA 541-A, for the program relative to:

I. Standards and procedures for the donation, acceptance, storage, and redispensing of unused prescription drugs and medical devices.

II. Eligibility of individuals to receive unused drugs.

III. The maximum allowable handling fee for redispensing drugs and devices.

IV. Content and format of all forms required under this subdivision.

V. Further definition of persons and entities which may donate unused prescription drugs and medical devices.

**Source.** 2006, 152:1. 2010, 89:3. 2011, 41:2, eff. July 8, 2011.

### **Section 318:60**

#### **318:60 Limited Immunity. –**

I. Accepting or dispensing of a prescription drug manufactured by the prescription drug manufacturer that is donated by any entity pursuant to this subdivision shall not subject a prescription drug manufacturer to criminal or civil liability for injury, death, or loss to person or property for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug, or for damages related to improper storage of the donated prescription drug or use after the expiration date. Except as provided in this section,

nothing in this subdivision shall in any way limit liability that would have existed under the original prescription.

II. Pharmacies, pharmacists, and other persons or entities acting in good faith, participating in the unused prescription drug program, and students and faculty of medical and pharmacy education institutions, with respect to the duties they perform as part of the program, shall not be subject to criminal or civil liability for injury, death, or loss to person or property for damages related to improper storage of the donated prescription drug or use after the expiration date, provided they comply with rules adopted by the board.

**Source.** 2006, 152:1. 2010, 89:4, eff. July 24, 2010.

## **Pharmacy Rights During Audit**

### **Section 318:61**

**318:61 Definition.** – In this subdivision, "responsible party" means the entity responsible for payment of claims for health care services other than the individual to whom the health care services were rendered or that individual's guardian or legal representative.

**Source.** 2013, 159:1, eff. Jan. 1, 2014.

### **Section 318:62**

#### **318:62 Pharmacy Rights During Audit. –**

Notwithstanding any other provision of law, whenever a managed care company, insurance company, third-party payer, or any entity that represents a responsible party conducts an audit of the records of a pharmacy, the pharmacy has a right to all of the following:

- I. To have at least 7 days' advance notice of the initial on-site audit for each audit cycle. A pharmacy that requests an additional 7 days prior to the commencement of an audit shall be granted 7 additional days.
- II. To have any audit that involves clinical judgment be done with a pharmacist who is licensed and is employed or working under contract with the auditing entity.
- III. Not to have clerical or record-keeping errors, including typographical errors, scrivener's errors, and computer errors, on a required document or record, in the absence of any other evidence, deemed fraudulent. This subdivision does not prohibit recoupment of fraudulent payments.
- IV. If required under the terms of the contract, to have the auditing entity provide a pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media.
- V. To have the properly documented records of a hospital or any person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug, in compliance with state laws.
- VI. If an on-site audit is conducted for a reason other than an identified problem, the audit shall be limited to no more than 250 selected prescriptions and the third party plan or audit company must provide a masked list of prescriptions to the pharmacy to assist in preparation. The list is

considered masked if the last 2 numbers of the prescription are marked with an "X." This procedure allows the pharmacy to pull the book the audited prescription is in, however it does not allow the pharmacy to pull the specific prescription audited. Additionally, all of the invoices for actual dispensed prescriptions, with prices redacted, may be obtained from the pharmacy's wholesaler or distributor upon approval from the pharmacy.

VII. To be subject to no more than 2 audits in one calendar year, unless fraud or misrepresentation is reasonably suspected.

VIII. Except for cases of Food and Drug Administration regulation or drug manufacturer safety programs, to be free of recoupments based on any of the following unless defined within the billing requirements set forth in the pharmacy provider manual:

(a) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the pharmacy board or by the provider manual or contract.

(b) A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the board.

IX. To be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity.

X. To have the period covered by an audit limited to 24 months from the date a claim was submitted to, or adjudicated by, a managed care company, an insurance company, a third-party payer, or any entity that represents responsible parties, unless a longer period is permitted by a federal plan under federal law.

XI. Not to be subject to the initiation or scheduling of audits during the first 5 calendar days of any month for any pharmacy that averages in excess of 600 prescriptions per week due to the high volume of prescriptions filled during that time and for patient care considerations, without the express consent of the pharmacy. The pharmacy shall cooperate with the auditor to establish an alternate date should the audit fall within the days excluded.

XII. Not to have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans.

XIII. The auditor shall not include dispensing fees in the calculations of overpayments unless the prescription is considered a misfill. A misfill shall be defined as a prescription not dispensed, a medication error, a prescription whereby the prescriber denied authorization, or where an extra dispensing fee was charged.

XIV. (a) Auditors shall only have access to previous audit reports on a particular pharmacy if the previous audit was conducted by the same entity, except as required for compliance with state or federal law.

(b) Additionally, pharmacies subject to an audit may use the following records at the time of the audit to validate a claim for a prescription, refill, or change in a prescription:

(1) Electronic or physical copies of records of a health care facility, or a health care provider with prescribing authority.

(2) Any prescription that complies with state law.

**Source.** 2013, 159:1, eff. Jan. 1, 2014.

## **Section 318:63**

**318:63 Mandatory Appeals Process. –**

- I. Each entity that conducts an audit of a pharmacy shall establish an appeals process under which a pharmacy may appeal an unfavorable audit report to the entity.
- II. If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings unless outlined in the contract.
- III. Each entity conducting an audit shall provide a copy, if required under contractual terms, of the audit findings to the plan sponsor after completion of any appeals process.

**Source.** 2013, 159:1, eff. Jan. 1, 2014.

**Section 318:64**

**318:64 Pharmacy Audit Recoupments. –**

- I. Recoupments of any disputed funds shall occur only after final internal disposition of an audit, including the appeals process, unless fraud or misrepresentation is reasonably suspected or the discrepant amount exceeds \$10,000.
- II. Recoupment on an audit shall be refunded to the responsible party as contractually agreed upon by the parties.
- III. The entity conducting the audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:
  - (a) The responsible party and the entity conducting the audit have entered into a contract that explicitly states the percentage charge or assessment to the responsible party.
  - (b) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

**Source.** 2013, 159:1, eff. Jan. 1, 2014.

**Section 318:65**

**318:65 Audit Information and Reports. –** An audit report shall be delivered to the pharmacy within 75 days, unless otherwise agreed to, after the conclusion of the audit. A pharmacy shall be allowed at least 30 days, unless otherwise agreed to, following receipt of the audit report to appeal any discrepancy found in the audit. A final audit report shall be delivered to the pharmacy within 90 days, unless otherwise agreed to, after receipt of the appeal. A charge-back, recoupment, or other penalty may not be assessed until the appeal process has been exhausted and the final report issued except as specified in RSA 318:64. Except as provided by state or federal law or contract, audit information may not be shared. Auditors may have access only to previous audit reports on a particular pharmacy conducted by that same entity.

**Source.** 2013, 159:1, eff. Jan. 1, 2014.

**Section 318:66**

**318:66 Applicability. –** This subdivision shall not apply to any audit, review, or investigation that is based on suspected or alleged fraud, willful misrepresentation, or abuse. Nothing in this

subdivision shall apply to claims that were paid for in part or in whole by Medicare or Medicaid program funds.

**Source.** 2013, 159:1, eff. Jan. 1, 2014.

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# **TITLE XXX OCCUPATIONS AND PROFESSIONS**

## **CHAPTER 318-B CONTROLLED DRUG ACT**

### **Section 318-B:1**

#### **318-B:1 Definitions. –**

The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

I. "Abuse of drugs" means the use of controlled drugs solely for their stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and not as a therapeutic agent recommended by a practitioner in the course of medical treatment or in a program of research operated under the direction of a physician, pharmacologist, physiologist, chemist, or advanced practice registered nurse.

I-a. "Administer" means an act whereby a single dose of a drug is instilled into the body of or given to a person or animal for immediate consumption or use.

I-aa. "Advanced emergency medical care provider" means a person licensed to provide advanced emergency medical care under RSA 151-B.

I-b. "Advanced practice registered nurse" means a person licensed to practice as an advanced practice registered nurse in this state pursuant to RSA 326-B:18.

II. "Amphetamine-type drugs" means amphetamine, optical isomers thereof, salts of amphetamine and its isomers, and chemical compounds which are similar thereto in physiological effect, and which show a like potential for abuse.

II-a. "Anabolic steroid" includes any of the following or any isomer, ester, salt, or derivative of the following that acts in the same manner on the human body:

- (a) Clostebol;
- (b) Dehydrochlormethyltestosterone;
- (c) Ethylestrenol;
- (d) Fluoxymesterone;
- (e) Mesterolone;

- (f) Methandienone;
- (g) Methandrostenolone;
- (h) Methenolone;
- (i) Methyltestosterone;
- (j) Nandrolone;
- (k) Norethandrolone;
- (l) Oxandrolone;
- (m) Oxymesterone;
- (n) Oxymetholone;
- (o) Stanozolol; and
- (p) Testosterone.

III. "Barbiturate-type drugs" means barbituric acid and its salts, derivatives thereof and chemical compounds which are similar thereto in physiological effect, and which show a like potential for abuse.

IV. "Cannabis-type drug" means all parts of any plant of the Cannabis genus of plants, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plants, fiber produced from such stalks, oil or cake made from the seeds of such plants, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seeds of such plants which are incapable of germination.

V. "Cocaine-type drugs" means coca leaves, cocaine, ecgonine, and chemical compounds which are similar thereto in chemical structure or which are similar thereto in physiological effect and which show a like potential for abuse.

V-a. "Commissioner" means the commissioner of the department of health and human services.

VI. "Controlled drugs" means any drug or substance, or immediate precursor, which is scheduled pursuant to RSA 318-B:1-a.

VI-a. "Controlled drug analog" means a substance that has a chemical structure substantially similar to that of a controlled drug and that was specifically designed to produce an effect substantially similar to that of a controlled drug. The term shall not include a drug manufactured or distributed in conformance with the provisions of an approved new drug application or an exemption for investigational use within the meaning of section 505 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1052 (21 U.S.C. 355).

VI-b. "Crack cocaine", also known as cocaine base or rock cocaine, means the free base form of cocaine in which the molecule is not chemically combined as an acid salt.

VII. "Dentist" means a person authorized by law to practice dentistry in this state.

VII-a. "Department" means the department of health and human services.

VIII. "Dispense" means to distribute, leave with, give away, dispose of, deliver, or sell one or more doses of and shall include the transfer of more than a single dose of a medication from one container to another and the labelling or otherwise identifying a container holding more than a single dose of a drug.

IX. "Drug dependence" means a state of physical addiction or psychic dependence, or both, upon a drug following use of that drug upon a repeated periodic or continuous basis except:

- (a) Upon a morphine-type drug as an incident to current medical treatment of a demonstrable physical disorder, other than produced by the use of the drug itself, or
- (b) Upon amphetamine-type, ataractic, barbiturate-type, hallucinogenic or other stimulant and

depressant drugs as an incident to current medical treatment of a demonstrable physical or psychological disorder, or both, other than produced by the drug itself.

X. "Drug-dependent person" means any person who has developed a state of psychic or physical dependence, or both, upon a controlled drug following administration of that drug upon a repeated periodic or continuous basis. No person shall be classified as drug dependent who is dependent:

(a) Upon a morphine-type drug as an incident to current medical treatment of a demonstrable physical disorder other than drug dependence, or

(b) Upon amphetamine-type, ataractic, barbiturate-type, hallucinogenic or other stimulant and depressant drugs as an incident to current medical treatment of a demonstrable physical or psychological disorder, or both, other than drug dependence.

X-a. "Drug paraphernalia" means all equipment, products and materials of any kind which are used or intended for use or customarily intended for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this chapter. It includes, but is not limited to:

(a) Kits used or intended for use or customarily intended for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived.

(b) Kits including but not limited to cocaine kits, used or intended for use or customarily intended for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.

(c) Isomerization devices used or intended for use or customarily intended for use in increasing the potency of any species of plant which is a controlled substance.

(d) Testing equipment used or intended for use or customarily intended for use in identifying, or analyzing the strength, effectiveness or purity of controlled substances.

(e) Scales and balances used or intended for use or customarily intended for use in weighing or measuring controlled substances.

(f) Dilutents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, used or intended for use or customarily intended for use in cutting controlled substances.

(g) Separation gins and sifters used or intended for use or customarily intended for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana.

(h) Blenders, bowls, containers, spoons and mixing devices used or intended for use or customarily intended for use in compounding controlled substances.

(i) Capsules, balloons, envelopes and other containers used or intended for use or customarily intended for use in packaging small quantities of controlled substances.

(j) Containers and other objects used or intended for use or customarily intended for use in storing or concealing controlled substances.

(k) Objects used or intended for use or customarily intended for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as:

(1) Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls.

(2) Water pipes.

(3) Carburetion tubes and devices.

(4) Smoking and carburetion masks.

- (5) Chamber pipes.
- (6) Carburetor pipes.
- (7) Electric pipes.
- (8) Air-driven pipes.
- (9) Chillums.
- (10) Bongs.

(11) Ice pipes or chillers.

XI. "Federal food and drug laws" means the Federal Food, Drug and Cosmetic Act, as amended (Title 21 U.S.C. § 301 et seq.).

XI-a. "Fentanyl class drug" shall mean the following drugs: fentanyl, 3-methylfentanyl, 3-methylthiofentanyl, acetylfentanyl, acetyl-alpha-methylfentanyl, alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyl-3-methylfentanyl, beta-hydroxyfentanyl, para-fluorofentanyl, thiofentanyl, alfentanil, carfentanil, remifentanil, sufentanil, and all optical isomers of these substances. Drugs which become controlled after September 1, 2015, pursuant to RSA 318-B:1-a; and are known or scheduled with a common name that includes the term "fentanyl", or "fentanil" shall also be considered as belonging to this class, along with optical isomers of same. Drugs may be added or removed from this classification by action of the general court.

XII. "Comprehensive Drug Abuse Prevention and Control Act of 1970" means the applicable law of the United States relating to opium, coca leaves and other narcotic drugs.

XIII. "Hallucinogenic drugs" are psychodysleptic drugs which assert a confusional or disorganizing effect upon mental processes or behavior and mimic acute psychotic disturbances. Exemplary of such drugs are mescaline, peyote, psilocybin and d-lysergic acid diethylamide.

XIV. "Laboratory" means a scientific or medical establishment entrusted with the custody of controlled drugs and the use of controlled drugs for scientific and medical purposes and for purposes of instruction, research or analysis.

XIV-a. "Law enforcement officer" means any officer of the state or political subdivision of the state who is empowered by law to conduct investigations of or to make arrests for offenses enumerated in this chapter.

XV. "Manufacturer" means a person who, by compounding, mixing, cultivating, growing or other process, produces or prepares controlled drugs, but shall not mean a pharmacist who compounds controlled drugs to be sold or dispensed on prescription.

XVI. "Morphine-type drugs" means morphine and chemical compounds which are similar thereto in physiological effect and which show a like potential for abuse.

XVII. "Narcotic drugs" means cocaine-type and morphine-type drugs, and drugs other than cannabis-type regulated under the Comprehensive Drug Abuse Prevention and Control Act of 1970.

XVIII. "Nurse" means a person licensed to perform nursing as defined in RSA 326-B.

XIX. "Official written order" means an order written on a form provided for that purpose by the United States Attorney General under the laws of the United States making provision therefor, if such order forms are authorized and required by federal law, or conforming to the requirements of such a form and provided by the department of health and human services, or, if no such order form is provided, on an official form provided for that purpose by the department of health and human services.

XIX-a. "Optometrist" means a person authorized by law to practice optometry in this state pursuant to RSA 327.

XX. "Other stimulant and depressant drugs" means controlled drugs other than amphetamine-



type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenics and morphine-type which are found to exert a stimulant and depressant effect upon the higher functions of the central nervous system and which are found to have a potential for abuse.

XXI. "Person" means any corporation, association or partnership, or one or more individuals.

XXII. "Pharmacist" means a person authorized by law to practice pharmacy pursuant to RSA 318.

XXIII. "Pharmacy" means an establishment licensed pursuant to RSA 318.

XXIV. "Physician" means a person authorized by law to practice medicine in this state pursuant to RSA 329.

XXIV-a. "Podiatrist" means a person authorized by law to practice podiatry in this state pursuant to RSA 315.

XXV. "Potential for abuse" means that there is a likelihood that a drug will be used solely for its stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system as distinguished from use recommended by a practitioner as a therapeutic agent in a course of medical treatment or in a program of research operated under the direction of a physician, pharmacologist, or advanced practice registered nurse.

XXVI. "Practitioner" means any person who is lawfully entitled to prescribe, administer, dispense or distribute controlled drugs to patients.

XXVI-a. "Practitioner-patient relationship" means a medical connection between a licensed practitioner and a patient that includes an in-person exam, a history, a diagnosis, a treatment plan appropriate for the licensee's scope of practice, and documentation of all prescription drugs including name and dosage. A licensee may prescribe for a patient whom the licensee does not have a practitioner-patient relationship under the following circumstances: for a patient of another licensee for whom the prescriber is taking call; for a patient examined by another New Hampshire licensed practitioner; or for medication on a short-term basis for a new patient prior to the patient's first appointment. The definition of a practitioner-patient relationship shall not apply to a practitioner licensed in another state who is consulting to a New Hampshire licensed practitioner with whom the patient has a relationship.

XXVII. "Prescribe" means order or designate a remedy or any preparation containing controlled drugs.

XXVIII. "Prescription" means an oral, written, or facsimile or electronically transmitted order for any controlled drug or preparation issued by a licensed practitioner to be compounded and dispensed by a pharmacist and delivered to a patient for a medicinal or therapeutic purpose arising from a practitioner-patient relationship.

XXIX. "Registry number" means the number assigned to each person registered under the federal narcotic laws.

XXIX-a. "Residual amount" means an unusable amount of a controlled substance in or on a hypodermic syringe or needle.

XXX. "Sale" means barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant, or employee.

XXXI. "State food, drug and cosmetic laws" means RSA 146.

XXXII. "Veterinarian" means a person authorized by law to practice veterinary medicine in this state pursuant to RSA 332-B.

XXXIII. "Wholesaler" means a person who supplies or distributes controlled drugs that he himself has not produced or prepared to hospitals, practitioners, pharmacies, other wholesalers, manufacturers or federal, state and municipal agencies.

**Source.** 1969, 421:1. 1975, 255:2. 1977, 547:1-4. 1981, 513:1. 1985, 190:98; 293:1, 2; 324:17, 18. 1988, 6:1. 1989, 195:1; 361:1. 1993, 333:3. 1994, 186:1; 333:16-18. 1995, 310:155, 156, 181. 1996, 267:22. 2000, 176:4. 2001, 15:3; 282:8. 2005, 293:8. 2008, 217:3, 4. 2009, 54:5. 2011, 63:4. 2016, 2:1, eff. Jan. 21, 2016. 2017, 117:3, eff. June 16, 2017.

## **Section 318-B:1-a**

### **318-B:1-a Scheduling by the Commissioner. –**

I. The commissioner may add, delete, or reschedule all substances, by rule, pursuant to RSA 541-A, after hearing and after consulting with the pharmacy board. In making a determination regarding a substance, the commissioner shall consider the following:

- (a) Actual or relative potential for abuse;
- (b) Scientific evidence of its pharmacological effect, if known;
- (c) State of current scientific knowledge regarding the substance;
- (d) History and current pattern of abuse;
- (e) Scope, duration, and significance of abuse;
- (f) Risk to the public health;
- (g) Potential of the substance to produce psychic or physical dependence liability; and
- (h) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

II. After considering the factors in paragraph I, the commissioner shall make findings relative to the substance and adopt a rule controlling the substance if he finds the substance has a potential for abuse.

III. In addition to the provisions of RSA 541-A, the commissioner shall give due notice of the time, place and purpose of all hearings required under this chapter to podiatrists, osteopaths, hospitals, pharmacists, physicians, dentists, veterinarians, advanced registered nurse practitioners, optometrists, laboratories, registered manufacturers, suppliers and to the general public by such means as he shall deem adequate. From and after the hearing date, the sale or dispensation (except by prescription) of a drug or chemical containing any quantity of such substance as is the subject matter of the hearing shall be suspended pending a determination as to whether such substance is to be designated as a controlled drug. Designation as a controlled drug shall result in the continued suspension of the sale or dispensation (except by prescription) of any drug or chemical containing any quantity of such substance until the effective date of the designation. The substance shall thereafter be a controlled drug subject to this chapter. If any substance is so designated, the commissioner shall publish the designation in a newspaper of general circulation in the state once each week for 3 successive weeks.

IV. Substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

V. If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the commissioner, the commissioner shall similarly control the substance under this chapter after the expiration of 30 days from publication in the Federal Register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless, within that 30 day period, the commissioner objects to inclusion, rescheduling, or deletion. In that case, the commissioner shall publish the reasons for objection and afford all interested persons an opportunity to be heard. At the conclusion of the hearing, the commissioner shall publish his decision, which shall be final unless altered by law. Upon

publication of objection to inclusion, rescheduling, or deletion under this chapter by the commissioner, control under this chapter shall be stayed until the commissioner publishes his decision.

VI. Authority to control under this section shall not extend to distilled spirits, wine, malt beverages, or tobacco.

VII. Controlled drugs shall be scheduled by whatever official, common, usual, chemical or trade name designated.

VIII. The commissioner shall revise and republish the schedules in RSA 318-B:1-b semi-annually for 2 years from the effective date of this section, and thereafter annually.

**Source.** 1985, 293:3. 1993, 333:4. 1994, 333:19. 1995, 310:183, eff. Nov. 1, 1995.

### **Section 318-B:1-b**

#### **318-B:1-b Schedule Tests. –**

I. Schedule I Tests. The commissioner shall place a substance in schedule I if he finds that the substance:

- (a) Has high potential for abuse; and
- (b) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

II. Schedule II Tests. The commissioner shall place a substance in schedule II if he finds that:

- (a) The substance has high potential for abuse;
- (b) The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and
- (c) The abuse of the substance may lead to severe psychic or physical dependence.

III. Schedule III Tests. The commissioner shall place a substance in schedule III if he finds that:

- (a) The substance has a potential for abuse less than the substances listed in schedules I and II of the current chapter 21, Code of Federal Regulations;
- (b) The substance has currently accepted medical use in treatment in the United States; and
- (c) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

IV. Schedule IV Tests. The commissioner shall place a substance in schedule IV if he finds that:

- (a) The substance has a low potential for abuse relative to substances listed in schedule III of the current chapter 21, Code of Federal Regulations;
- (b) The substance has currently accepted medical use in treatment in the United States; and
- (c) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in schedule III of the current chapter 21, Code of Federal Regulations.

V. Schedule V Tests. The commissioner shall place a substance in schedule V if he finds that:

- (a) The substance has a low potential for abuse relative to substances listed in schedule IV of the current chapter 21, Code of Federal Regulations;
- (b) The substance has currently accepted medical use in treatment in the United States; and
- (c) The substance has limited physical dependence liability or psychological dependence liability relative to the substances in schedule IV of the current chapter 21, Code of Federal Regulations.

**Source.** 1985, 293:3. 1995, 310:183, eff. Nov. 1, 1995.

## **Section 318-B:1-c**

[RSA 318-B:1-c contingently repealed by 1998, 359:2; see contingent repeal note set out below.]

### **318-B:1-c Flunitrazepam. –**

I. The legislature intends that the provisions of paragraph III of this section shall remain in effect until such time as flunitrazepam is scheduled by the commissioner of the department of human services in accordance with and pursuant to RSA 318-B.

II. The legislature finds that flunitrazepam, marketed under the trade name rohypnol, which has a sedative, hypnotic, and amnesiac effect, has no acceptable medical uses in the United States and carries a high potential for abuse. Therefore, flunitrazepam meets the criteria for placement on schedule I of controlled drugs.

III. Notwithstanding the provisions of RSA 318-B:1-a, relative to scheduling by rulemaking of the commissioner of the department of health and human services, flunitrazepam shall be scheduled as a schedule I controlled drug.

**Source.** 1998, 359:1. 2005, 177:138, eff. July 1, 2005.

## **Section 318-B:2**

### **318-B:2 Acts Prohibited. –**

I. It shall be unlawful for any person to manufacture, possess, have under his control, sell, purchase, prescribe, administer, or transport or possess with intent to sell, dispense, or compound any controlled drug, or controlled drug analog, or any preparation containing a controlled drug, except as authorized in this chapter.

I-a. It shall be unlawful for any person to manufacture, sell, purchase, transport or possess with intent to sell, dispense, compound, package or repack (1) any substance which he represents to be a controlled drug or controlled drug analog, or (2) any preparation containing a substance which he represents to be a controlled drug or controlled drug analog, except as authorized in this chapter.

I-b. It shall be unlawful for a qualifying patient or designated caregiver as defined under RSA 126-X:1 to sell cannabis to another person who is not a qualifying patient or designated caregiver. A conviction for the sale of cannabis to a person who is not a qualifying patient or designated caregiver shall not preclude or limit a prosecution or conviction of any person for sale of cannabis or any other offense defined in this chapter.

II. It shall be unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver, drug paraphernalia, knowing that it will be used or is customarily intended to be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, ingest, inhale, or otherwise introduce into the human body a controlled substance.

II-a. It shall be unlawful for any person, at retail, to sell or offer for sale any drug paraphernalia listed in RSA 318-B:1, X-a.

III. It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publication any advertisement, knowing that the purpose of the advertisement, when viewed as a whole, is to promote the sale of objects intended for use or customarily intended for use as drug paraphernalia.

IV. In determining whether an object is drug paraphernalia under this chapter, a court or other authority should consider, in addition to all other logically relevant factors, the following:

- (a) Statements by an owner or by anyone in control of the object concerning its use;
- (b) Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance;
- (c) The proximity of the object, in time and space, to a direct violation of this chapter;
- (d) The proximity of any residue of controlled substances;
- (e) The existence of any residue of controlled substances on the object;
- (f) Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he knows intend to use the object to facilitate a violation of this chapter; the innocence of an owner, or of anyone in control of the object, as to a direct violation of this chapter shall not prevent a finding that the object is intended for use as drug paraphernalia;
- (g) Instructions, oral or written, provided with the object concerning its use;
- (h) Descriptive materials accompanying the object which explain or depict its use;
- (i) National and local advertising concerning its use;
- (j) The manner in which the object is displayed for sale;
- (k) Direct or circumstantial evidence of the ratio of sales of the objects to the total sales of the business enterprise;
- (l) Whether the object is customarily intended for use as drug paraphernalia and the existence and scope of other legitimate uses for the object in the community; and
- (m) Expert testimony concerning its use.

V. No person shall obtain or attempt to obtain a controlled drug:

- (a) By fraud, deceit, misrepresentation, or subterfuge;
- (b) By the forgery or alteration of a prescription or of any written order;
- (c) By the concealment of a material fact;
- (d) By the use of a false name or the giving of a false address; or
- (e) By submission of an electronic or on-line medical history form that fails to establish a valid practitioner-patient relationship.

VI. No person shall willfully make a false statement in any prescription, order, report, or record required hereby.

VII. No person shall, for the purpose of obtaining a controlled drug, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, practitioner, or other authorized person.

VIII. No person shall make or utter any false or forged prescription or false or forged written order.

IX. No person shall affix any false or forged label to a package or receptacle containing controlled drugs.

X. Possession of a false or forged prescription for a controlled drug by any person, other than a pharmacist in the pursuance of his profession, shall be prima facie evidence of his intent to use the same for the purpose of illegally obtaining a controlled drug.

XI. It shall be unlawful for any person 18 years of age or older to knowingly use, solicit, direct, hire or employ a person 17 years of age or younger to manufacture, sell, prescribe, administer, transport or possess with intent to sell, dispense or compound any controlled drug or any preparation containing a controlled drug, except as authorized in this chapter, or to manufacture, sell, transport or possess with intent to sell, transport or possess with intent to sell, dispense,

compound, package or repackaged (1) any substance which he represents to be a controlled drug or controlled drug analog, or (2) any preparation containing a substance which he represents to be a controlled drug or controlled drug analog, except as authorized in this chapter. It shall be no defense to a prosecution under this section that the actor mistakenly believed that the person who the actor used, solicited, directed, hired or employed was 18 years of age or older, even if such mistaken belief was reasonable. Nothing in this section shall be construed to preclude or limit a prosecution or conviction for a violation of any other offense defined in this chapter or any other provision of law governing an actor's liability for the conduct of another.

XII. A person is a drug enterprise leader if he conspires with one or more persons as an organizer, supervisor, financier, or manager to engage for profit in a scheme or course of conduct to unlawfully manufacture, sell, prescribe, administer, dispense, bring with or transport in this state methamphetamine, lysergic acid diethylamide, phencyclidine (PCP) or any controlled drug classified in schedule I or II, or any controlled drug analog thereof. A conviction as a drug enterprise leader shall not merge with the conviction for any offense which is the object of the conspiracy. Nothing in this section shall be construed to preclude or limit a prosecution or conviction of any person for conspiracy or any other offense defined in this chapter.

XII-a. It shall be unlawful for any person to knowingly acquire, obtain possession of or attempt to acquire or obtain possession of a controlled drug by misrepresentation, fraud, forgery, deception or subterfuge. This prohibition includes the situation in which a person independently consults 2 or more practitioners for treatment solely to obtain additional controlled drugs or prescriptions for controlled drugs.

XII-b. It shall be unlawful for any person to knowingly obtain, or attempt to obtain, or to assist a person in obtaining or attempting to obtain a prescription for a controlled substance without having formed a valid practitioner-patient relationship.

XII-c. It shall be unlawful for any person to, by written or electronic means, solicit, facilitate or enter into any agreement or contract to solicit or facilitate the dispensing of controlled substances pursuant to prescription orders that do not meet the federal and state requirements for a controlled drug prescription, and without an established valid practitioner-patient relationship.

XII-d. It shall be unlawful for any pharmacy to ship finished prescription products, containing controlled substances, to patients residing in the state of New Hampshire, pursuant to any oral, written or online prescription order that was generated based upon the patient's submission of an electronic or online medical history form. Such electronic or online medical questionnaires, even if followed by telephonic communication between practitioner and patient, shall not be deemed to form the basis of a valid practitioner-patient relationship.

XII-e. It shall be unlawful for any pharmacist to knowingly dispense a controlled substance pursuant to any oral, written, or electronic prescription order, which he or she knows or should have known, was generated based upon the patient's submission of an electronic or online medical history form. Such electronic or online medical questionnaires, even if followed by telephonic communication between practitioner and patient, shall not be deemed to form the basis of a valid practitioner-patient relationship.

XII-f. It shall be unlawful for any person to prescribe by means of telemedicine a controlled drug classified in schedule II through IV, except as provided in RSA 318-B:2, XVI, (a) and (b).

XIII. Nothing in this section shall be deemed to preclude or limit a prosecution for theft as defined in RSA 637.

XIV. It shall be an affirmative defense to prosecution for a possession offense under this chapter that the person charged had a lawful prescription for the controlled drug in question or was, at

the time charged, acting as an authorized agent for a person holding a lawful prescription. An authorized agent shall mean any person, including but not limited to a family member or caregiver, who has the intent to deliver the controlled drug to the person for whom the drug was lawfully prescribed.

XV. Persons who have lawfully obtained a controlled substance in accordance with this chapter or a person acting as an authorized agent for a person holding a lawful prescription for a controlled substance may deliver any unwanted or unused controlled substances to law enforcement officers acting within the scope of their employment and official duties for the purpose of collection, storage, and disposal of such controlled drugs in conjunction with a pharmaceutical drug take-back program established pursuant to RSA 318-E.

XVI. (a) The prescribing of a non-opioid controlled drug classified in schedule II through IV by means of telemedicine shall be limited to prescribers as defined in RSA 329:1-d, I and RSA 326-B:2, XII(a), who are treating a patient with whom the prescriber has an in-person practitioner-patient relationship, for purposes of monitoring or follow-up care, or who are treating patients at a state designated community mental health center pursuant to RSA 135-C or at a Substance Abuse and Mental Health Services Administration (SAMHSA)-certified state opioid treatment program, and shall require an initial in-person exam by a practitioner licensed to prescribe the drug. Subsequent in-person exams shall be by a practitioner licensed to prescribe the drug at intervals appropriate for the patient, medical condition, and drug, but not less than annually. (b) The prescribing of an opioid controlled drug classified in schedule II through IV by means of telemedicine shall be limited to prescribers as defined in RSA 329:1-d, I and RSA 326-B:2, XII(a), who are treating patients at a SAMHSA-certified state opioid treatment program. Such prescription authority shall require an initial in-person exam by a practitioner licensed to prescribe the drug and subsequent in-person exams shall be by a practitioner licensed to prescribe the drug at intervals appropriate for the patient, medical condition, and opioid, but not less than annually.

**Source.** 1969, 421:1. 1977, 547:5. 1981, 513:2. 1983, 36:1; 292:1, 2. 1988, 6:2, 3. 1989, 207:1; 361:2, 3. 1990, 129:2. 2000, 176:5. 2008, 145:1; 217:5, 6. 2011, 63:5. 2013, 242:3. 2015, 246:3, 4. 2016, 221:1, 2, eff. Aug. 8, 2016.

### **Section 318-B:2-a**

**318-B:2-a Repealed by 1994, 333:34, eff. Jan. 1, 1995. –**

### **Section 318-B:2-b**

#### **318-B:2-b Counterfeit Drugs; Affirmative Defense. –**

It is an affirmative defense to prosecution under RSA 318-B:2, I-a that the actor is:

- I. A physician or advanced practice registered nurse who sells, dispenses, or prescribes a substance which he represents to be or contain a controlled drug, but which in fact neither is nor contains a controlled drug, to a patient under his care for a bona fide therapeutic purpose; or
- II. A pharmacist who sells or dispenses a substance which he represents to be or contain a controlled drug, but which in fact neither is nor contains a controlled drug, to a person at the direction of and upon the written prescription of an attending physician or advanced practice registered nurse, provided any written prescription is properly executed, dated, and signed by the

person prescribing on the day when issued and bears the full name and address of the patient for whom the drug is dispensed; or

III. A nurse or intern who, at the explicit direction of and under the supervision of an attending physician, administers a substance which he represents to be or contain a controlled drug, but which in fact neither is nor contains a controlled drug, to a patient for a bona fide therapeutic purpose; or

IV. An advanced emergency medical care provider who, upon receipt directly or by phone or by radio or by other communication medium of directions to do so from the supervising physician or an emergency/trauma advanced practice registered nurse, administers a substance which he represents to be or to contain a controlled drug, but which in fact neither is nor contains a controlled drug, to a patient for a bona fide therapeutic purpose.

**Source.** 1983, 36:2. 1992, 48:7. 1994, 333:20. 2009, 54:5, eff. July 21, 2009.

### **Section 318-B:2-c**

#### **318-B:2-c Personal Possession of Marijuana. –**

I. In this section:

(a) "Marijuana" includes the leaves, stems, flowers, and seeds of all species of the plant genus cannabis, but shall not include the resin extracted from any part of such plant and every compound, manufacture, salt, derivative, mixture, or preparation from such resin including hashish, and further, shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks, fiber, oil or cake, or the sterilized seed of such plant which is incapable of germination. Marijuana shall not include hemp grown, processed, marketed, or sold under RSA 439-A.

(b) "Personal-use amount of a regulated marijuana-infused product" means one or more products that is comprised of marijuana, marijuana extracts, or resins and other ingredients and is intended for use or consumption, such as, but not limited to, edible products, ointments, and tinctures, which was obtained from a state where marijuana sales to adults are legal and regulated under state law, and which is in its original, child-resistant, labeled packaging when it is being stored, and which contains a total of no more than 300 milligrams of tetrahydrocannabinol.

II. Except as provided in RSA 126-X, any person who knowingly possesses 3/4 of an ounce or less of marijuana, including adulterants or dilutants, shall be guilty of a violation, and subject to the penalties provided in paragraph V.

III. Except as provided in RSA 126-X, any person who knowingly possesses 5 grams or less of hashish, including adulterants or dilutants, shall be guilty of a violation, and subject to the penalties provided in paragraph V.

IV. Except as provided in RSA 126-X, any person 21 years of age or older possessing a personal-use amount of a regulated marijuana-infused product shall be guilty of a violation, and subject to the penalties provided in paragraph V. Persons 18 years of age or older and under 21 years of age who knowingly possess marijuana-infused products shall be guilty of a misdemeanor.

V. (a) Except as provided in this paragraph, any person 18 years of age or older who is convicted of violating paragraph II or III, or any person 21 years of age or older who is convicted of violating paragraph IV shall be subject to a fine of \$100 for a first or second offense under this



paragraph, or a fine of up to \$300 for any subsequent offense within any 3-year period; however, any person convicted based upon a complaint which alleged that the person had 3 or more prior convictions for violations of paragraph II, III or IV, or under reasonably equivalent offenses in an out-of-state jurisdiction since the effective date of this paragraph, within a 3-year period preceding the fourth offense shall be guilty of a class B misdemeanor. The offender shall forfeit the marijuana, regulated marijuana-infused products, or hashish to the state. A court shall waive the fine for a single conviction within a 3-year period upon proof that person has completed a substance abuse assessment by a licensed drug and alcohol counselor within 60 days of the conviction. A person who intends to seek an assessment in lieu of the fine shall notify the court, which shall schedule the matter for review after 180 days. Should proof of completion of an assessment be filed by or before that time, the court shall vacate the fine without a hearing unless requested by a party.

(b) Any person under 18 years of age who is convicted of violating paragraph II or III shall forfeit the marijuana or hashish and shall be subject to a delinquency petition under RSA 169-B:6.

VI. (a) Except as provided in this section, no person shall be subject to arrest for a violation of paragraph II, III, or IV and shall be released provided the law enforcement officer does not have lawful grounds for arrest for a different offense.

(b) Nothing in this chapter shall be construed to prohibit a law enforcement agency from investigating or charging a person for a violation of RSA 265-A.

(c) Nothing in this chapter shall be construed as forbidding any police officer from taking into custody any minor who is found violating paragraph II, III, or IV.

(d) Any person in possession of an identification card, license, or other form of identification issued by the state or any state, country, city, or town, or any college or university, who fails to produce the same upon request of a police officer or who refuses to truthfully provide his or her name, address, and date of birth to a police officer who has informed the person that he or she has been found to be in possession of what appears to the officer to be 3/4 of an ounce or less of marijuana, a personal-use amount of a regulated marijuana-infused product, or 5 grams or less of hashish, may be arrested for a violation of paragraph II, III, or IV.

VII. All fines imposed pursuant to this section shall be deposited into the alcohol abuse prevention and treatment fund established in RSA 176-A:1 and utilized for evidence-informed substance abuse prevention programs.

VIII. (a) No record that includes personally identifiable information resulting from a violation of this section shall be made accessible to the public, federal agencies, or agencies from other states or countries.

(b) Every state, county, or local law enforcement agency that collects and reports data for the Federal Bureau of Investigation Uniform Crime Reporting Program shall collect data on the number of violations of paragraph II, III, or IV. The data collected pursuant to this paragraph shall be available to the public. A law enforcement agency may update the data annually and may make this data available on the agency's public Internet website.

**Source.** 2017, 248:2, eff. Sept. 16, 2017. 2019, 306:3, eff. July 30, 2019.

## **Section 318-B:2-d**

**318-B:2-d Plea by Mail. –**

I. Any person 18 years of age or older who is charged with a violation of RSA 318-B:2-c, II, III, or IV may enter a plea of guilty, nolo contendere, or not guilty, by mail in a circuit court, district division.

II. Such defendant shall receive, in addition to the summons, a fine notice entitled "Notice of Fine" which shall contain the amount of the fine for a violation of RSA 318-B:2-c, II, III, or IV. A defendant who is issued a summons and notice of fine and who wishes to plead guilty or nolo contendere shall enter his or her plea on the summons and return it with payment of the fine within 30 days of the date of the summons. Payment by credit card may be accepted in lieu of cash payment.

III. If the defendant wishes to enter a plea of not guilty, he or she shall enter such plea on the summons and return it within 30 days of the date of the summons. The circuit court, district division shall schedule a trial.

IV. Whenever a defendant willfully fails to pay a fine in connection with a conviction for a violation of RSA 318-B:2-c, II, III, or IV or payment of such fine cannot be collected, the defendant shall be defaulted and the court may impose an additional fine of \$100.

**Source.** 2017, 248:2, eff. Sept. 16, 2017.

**Section 318-B:2-e**

**318-B:2-e Negligent Storage of Marijuana-Infused Products. –**

I. In addition to any other penalties provided for by law, any person who negligently stores marijuana-infused products, where the negligent storage causes such products to be possessed by a person under 18 years of age, shall be guilty of a misdemeanor. The storing of marijuana-infused products obtained legally in any state in an original childproof container shall be prima facie evidence that a person did not act negligently. Failure to store marijuana-infused products obtained legally in any state in an original childproof container shall be prima facie evidence of negligence.

II. As used in this section, "marijuana-infused products" means products that are comprised of marijuana, marijuana extracts, or resins that have been combined with other ingredients and are intended for use or consumption, including but not limited to, edible products, drinks, ointments, and tinctures.

**Source.** 2017, 248:2, eff. Sept. 16, 2017.

**Section 318-B:3**

**318-B:3 Licensing of Manufacturers and Wholesalers Required. –** No person shall manufacture controlled drugs, and no person as a wholesaler shall supply the same, without first having obtained a license to do so as provided in RSA 318:51-a.

**Source.** 1969, 421:1. 1973, 198:1. 1985, 324:19. 1990, 129:3, eff. June 18, 1990.

**Section 318-B:4**

**318-B:4 Repealed by 1985, 324:25, eff. Jan. 1, 1986. –**

### **Section 318-B:5**

#### **318-B:5 Sale by Manufacturer or Wholesaler. –**

A duly licensed manufacturer or wholesaler may sell and dispense controlled drugs only to any of the following persons, and only on official written orders:

I. To a manufacturer, wholesaler, or pharmacist.

II. To a practitioner.

III. To that person in each hospital designated as in charge of controlled drugs, but only for use by that hospital, pursuant to the restrictions of the board of pharmacy license.

IV. To that person in each laboratory designated as in charge of controlled drugs, but only for use in that laboratory for scientific and medical purposes.

V. To a person in the employ of the United States government or of any state, territorial, district, county, municipal, or insular government purchasing, receiving, possessing, or dispensing controlled drugs by reason of his official duties, upon an exempt official order form as required by the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended.

VI. To a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed, or to a physician or surgeon, duly licensed in some state, territory, or the District of Columbia to practice his profession, or to a retired commissioned medical officer of the United States Army, Navy, or Public Health Service employed upon such ship or aircraft for the medical needs of persons on board such ship or aircraft, or to a physician, surgeon, or retired commissioned medical officer of the United States Army, Navy, or Public Health Service employed upon such ship or aircraft only in pursuance of a special order form approved by the Attorney General of the United States.

VII. To a person in a foreign country if the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, are complied with.

**Source.** 1969, 421:1. 1977, 547:7, 8. 1983, 292:4, eff. Aug. 17, 1983.

### **Section 318-B:6**

**318-B:6 Possession Lawful. –** Possession of or control of controlled drugs obtained as authorized shall be lawful if in the regular course of business, occupation, profession, employment, or duty of the possessor. A person who obtains controlled drugs under the provisions of RSA 318-B:5 or otherwise shall not administer, dispense, or otherwise use such drugs within the state, except within the scope of his employment or official duty, and then only for scientific or medical purposes and subject to the provisions of this chapter.

**Source.** 1969, 421:1. 1983, 292:5, eff. Aug. 17, 1983.

### **Section 318-B:7**

**318-B:7 Written Orders. –** An official written order for any controlled drug in schedule II shall be signed in triplicate by the person giving said order or by his duly authorized agent. The original shall be presented to the person who sells or dispenses the controlled drug or drugs

named therein. In the event of the acceptance of such order by said person, each party to the transaction shall preserve his copy of such order for a period of 2 years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter. It shall be deemed compliance with this section if the parties to the transaction have complied with the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, or the federal food and drug laws, respecting the requirements governing the use of order forms.

**Source.** 1969, 421:1. 1977, 547:9. 1983, 292:6. 1985, 293:4, eff. Aug. 13, 1985.

### **Section 318-B:8**

**318-B:8 Limitation on Use.** – A person in charge of controlled drugs in a hospital or of a laboratory, or in the employ of this state or of any other state or of any political subdivision thereof, or a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed, or a physician or surgeon duly licensed in some state, territory, or the District of Columbia to practice his profession, or a retired commissioned medical officer of the United States Army, Navy, or Public Health Service employed upon such ship or aircraft who obtains controlled drugs under the provisions of RSA 318-B:5, or otherwise, shall not administer, nor dispense, nor otherwise use such drugs within the state, except within the scope of his employment or official duty, and then only for scientific or medical purposes and subject to the provisions of this chapter.

**Source.** 1969, 421:1, eff. Aug. 31, 1969.

### **Section 318-B:9**

#### **318-B:9 Sale by Pharmacists. –**

I. A pharmacist, in good faith and in the course of his or her professional practice, may sell and dispense controlled drugs exempt under the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, and federal food and drug laws from prescription requirements. A pharmacist, in good faith, may sell and dispense controlled drugs requiring prescriptions to any person upon the written or electronically transmitted prescription of a practitioner, provided it is properly executed, dated and when required by law, manually or electronically signed by the person prescribing on the day when issued and bears the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, or upon oral prescription, in pursuance of regulations promulgated by the Department of Justice of the United States, under the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended where applicable, provided said oral prescription is promptly reduced to writing by the pharmacist or authorized technician, stating the name of the practitioner so prescribing, the date, the full name and address of the patient for whom, or the owner of the animal for which, the drug is dispensed, and, in all instances, the full name, address and registry number under the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, or federal food and drug laws of the person so prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed. The person filling the prescription shall indicate the date of filling and his or her name on the face or record of the prescription. The

prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of 4 years so as to be readily accessible for the inspection of any officers engaged in the enforcement of this chapter. The prescription as to a controlled drug may be refilled pursuant to the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. The person refilling a prescription for a controlled drug shall record on the prescription record the date of refill, the quantity dispensed, and his or her initials.

II. The legal owner of any stock of controlled drugs in a pharmacy, upon discontinuance of dealing in said drugs, may sell said stock to a manufacturer, wholesaler, or registered pharmacy but only upon an official written order, and in accordance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, and regulations where applicable. A licensed pharmacy only upon an official written order may sell controlled drugs in schedule II to a practitioner to be used for medical purposes.

III. Prescriptions issued by practitioners for controlled drugs shall be executed in clear, concise, readable form. Each prescription shall contain the following information and comply with the following requirements:

- (a) The full name and complete address of the patient or of the owner of the animal for which the drug is prescribed.
- (b) The day, month, and year the prescription is issued.
- (c) The name of the controlled drug prescribed. Only one controlled drug shall appear on a prescription blank.
- (d) The strength of the controlled drug prescribed.
- (e) The specific directions for use of the controlled drug by the patient.
- (f) No refills shall be authorized for controlled drugs in schedule II of the current chapter 21, Code of Federal Regulations.
- (g) The federal Drug Enforcement Administration registration number of the practitioner.
- (h) The practitioner shall manually or electronically sign the prescription on the date of issuance.
- (i) The practitioner's full name shall be printed, rubber stamped, or typewritten above or below the manual or electronic signature.
- (j) A practitioner shall not issue a prescription in order to obtain controlled substances for the purpose of general dispensing to his or her patients.
- (k) A practitioner shall not issue a prescription to himself or herself or his or her immediate family which includes a spouse, children or parents.
- (l) A prescription shall be deemed invalid if it is not filled within 6 months from the date prescribed.

IV. No prescription shall be filled for more than a 34-day supply upon any single filling for controlled drugs of schedules II or III; provided, however, that for controlled drugs, in schedules II or III, that are commercially packaged for dispensing directly to the patient, such as metered sprays and inhalers, liquids packaged in bottles with calibrated droppers, and certain topical preparations packaged with metered dispensing pumps may be filled for greater than a 34-day supply, but not more than 60 days, utilizing the smallest available product size, in order to maintain the dosing integrity of the commercially packaged containers; and, provided that with regard to amphetamines and methylphenidate hydrochloride, a prescription may be filled for up to a 60-day supply if either such prescription specifies it is being used for the treatment of attention deficit disorder, attention deficit disorder with hyperactivity, or narcolepsy.

V. Notwithstanding the provisions of RSA 318-B:26, it shall be a misdemeanor for a practitioner to issue or a pharmacist to fill a prescription that does not meet the requirements of this section.

VI. A pharmacist employed by a pharmacy located in a hospital may dispense cannabis-type drugs prescribed under RSA 318-B:10, VI, to any person upon the written prescription of an attending physician, provided it is properly executed, dated, and signed by the person prescribing on the day when issued and bears the full name and address of the patient for whom the drug is dispensed. The pharmacist filling the prescription shall write the date of filling and his own signature on the face of the prescription.

**Source.** 1969, 421:1. 1977, 547:10. 1979, 398:5. 1981, 107:2; 226:1-3. 1983, 292:7. 1985, 293:5, 6. 1997, 30:1. 2005, 177:136, 137. 2008, 222:1, eff. Jan. 1, 2009.

## **Section 318-B:10**

### **318-B:10 Professional Use of Narcotic Drugs. –**

I. A practitioner other than a veterinarian, in good faith, in the course of his professional practice, and for a legitimate medical purpose, may administer and prescribe controlled drugs, or the practitioner may cause the same to be administered by a nurse or intern under his direction and supervision. In a bona fide emergency situation, the practitioner may dispense a controlled drug to a patient under his care but only in a quantity not to exceed a 48-hour supply for all schedule II substances or a 7-day supply of schedule III, IV, or V substances.

II. A veterinarian, in good faith, in the course of his professional practice only, and not for use by a human being, may administer and prescribe controlled drugs, and the veterinarian may cause them to be administered to an animal under his care, but only in a quantity not to exceed a 48-hour supply of a schedule II substance or a 7-day supply of schedule III, IV, or V substances.

III, IV. [Repealed.]

V. An advanced emergency medical care provider licensed under RSA 153-A may possess, for emergency use only, such controlled prescription drugs as are specified by the state emergency medical services medical control board, with the concurrence of the pharmacy board, provided that there has been prior establishment of medical control for the possession of such drugs. The advanced emergency medical care provider may only administer such controlled prescription drugs upon receipt of orders to do so from a supervising physician or an emergency trauma advanced practice registered nurse, practicing within such nurse practitioner's specialty. Such orders may be transmitted either directly or by telephone or by radio or by other communication medium, or by standing order of local medical control delineated in a protocol as defined in RSA 153-A.

VI. Notwithstanding any other law to the contrary, an attending physician, in good faith and in the course of the attending physician's professional practice only, may prescribe and administer federal Food and Drug Administration approved and classified cannabis-type drugs, or the attending physician may cause such drugs to be administered by a nurse or intern under such physician's direction and supervision.

VII. (a) The department of health and human services is hereby declared to be the state methadone authority.

(b) The commissioner of the department of health and human services shall adopt and have in effect rules, pursuant to RSA 541-A, relative to methadone detoxification and maintenance programs as follows:

(1) Application procedure and standards for approval for certification and re-certification of providers to operate methadone detoxification and maintenance programs, including certification

period, for each type of certification. The department shall utilize accreditation reports obtained from national accreditation bodies that are approved by the United States Department of Health and Human Services Substance Abuse and Mental Health Services Administration in certifying methadone detoxification and maintenance programs in New Hampshire.

- (2) Eligibility of individuals for admission to such programs.
- (3) Qualifications of program personnel.
- (4) Program content, including, but not limited to, services to be offered by the program.
- (5) Mandatory records and reports to the department.
- (6) Security measures to prevent diversion of methadone to illegal use.
- (7) Confidentiality and disclosure of identifying information, records and reports.
- (8) Financial responsibility.
- (9) Any other provisions necessary to implement the purposes of this paragraph.

(c) Providers may operate a methadone detoxification or methadone maintenance program, or both, in the state of New Hampshire only if the providers are certified to operate pursuant to rules adopted under subparagraph VII(b).

(d) For the purposes of this paragraph:

(1) "Heroin" means an illegal semi-synthetic drug produced from the morphine contained in sap of the opium poppy, and known to have the potential for devastating addictive properties in vulnerable individuals.

(2) "Methadone" means a legal drug, methadone hydrochloride, which is a synthetic opioid that has been demonstrated to be an effective treatment agent for heroin abuse and dependence.

(3) "Methadone detoxification treatment" means the dispensing of methadone or similar substance in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to the withdrawal from the sustained use of heroin.

(4) "Methadone maintenance program" means a substance abuse treatment program substituting methadone or any of its derivatives, over time, to relieve withdrawal symptoms of heroin dependence, to reduce craving, and to permit normal functioning and engagement in rehabilitative services.

(e) Nothing in this paragraph shall prohibit a licensed health care practitioner from administering, prescribing, or dispensing a controlled drug under paragraph I.

(f) The department shall assess a fee to be paid by providers of methadone detoxification and maintenance programs for certification and administration by the department. The fee shall be \$8 per client based on the annual client census of the previous calendar year. If the provider had no clients in the previous calendar year, then the fee shall be \$1,000. All moneys collected by the department from fees authorized under this subparagraph shall be deposited into the general fund.

(g) The commissioner of the department of health and human services shall report by July 31, 2010, and each July 31 thereafter, to the chairpersons of the house and senate ways and means committees, the house and senate committees having jurisdiction over health and human services, and the oversight committee on health and human services under RSA 126-A:13, on the number of methadone detoxification and maintenance program clinics certified under RSA 318-B:10, VII, the number of clients, the average annual census data, the amount of fees assessed providers, and any recommendations for changes to the fee structure.

VIII. (a) Notwithstanding paragraph VII or any other law to the contrary, methadone may be administered, prescribed, and dispensed to pregnant and postpartum heroin addicts and

administered as part of an alcohol and drug abuse treatment program, which may include extended detoxification and which is approved by the commissioner of health and human services.

(b) The commissioner of health and human services shall adopt rules pursuant to RSA 541-A, relative to:

- (1) Eligibility for the program.
- (2) Length of time in the program.
- (3) Requirements for participation in prenatal and postnatal care.
- (4) Security measures to prevent diversion of methadone to illegal use.
- (5) Any other provisions necessary to implement the purposes of this paragraph.

IX. If, in the judgment of a physician licensed under RSA 329, appropriate pain management warrants a high dosage of controlled drugs and the benefit of the relief expected outweighs the risk of the high dosage, the licensed physician may administer or cause to be administered such a dosage, even if its use may increase the risk of death, so long as it is not furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it falls within rules of the board of medicine.

**Source.** 1969, 421:1. 1973, 392:3. 1977, 106:2; 547:11, 12. 1981, 107:1. 1983, 292:8, 9, 21, I, II. 1985, 293:7; 324:20. 1992, 48:8. 1994, 186:2; 333:21. 1995, 286:25. 1996, 252:1, 2; 267:23. 1998, 149:1. 1999, 345:8. 2000, 268:2; 271:1. 2009, 54:5, eff. July 21, 2009; 205:1, 2, eff. July 15, 2009. 2017, 156:157, eff. July 1, 2017.

## **Section 318-B:11**

### **318-B:11 Preparations Exempted. –**

I. Not Dependence Forming or of Sustaining Character. The department of health and human services may by rule exempt from the application of this chapter, to such extent as it determines to be consistent with the public welfare, pharmaceutical preparations found by the department of health and human services after due notice and hearing:

- (a) Either to possess no physiological or psychological dependence forming or sustaining character, or to possess physiological or psychological dependence forming or sustaining character not sufficient to warrant imposition of all the requirements of this chapter, and,
- (b) Not to permit recovery of the minute quantity of a controlled drug from the pharmaceutical preparation having such a physiological or psychological dependence forming or sustaining character, with such relative technical chemical separation simplicity and degree of quantitative yield as to create a risk of improper use.

II. Exempt Under Federal Law. In exercising the authority granted in paragraph I, the commissioner of the department of health and human services by rule and without special findings, may grant exempt status to such pharmaceutical preparations as are or may be determined to be exempt under the Comprehensive Drug Abuse Prevention and Control Act of 1970 and regulations and permit the administering, dispensing, or selling of such preparations under the same conditions as permitted by the Comprehensive Drug Abuse Prevention and Control Act of 1970 and regulations and the federal food and drug laws and regulations.

III. Revocation. If the department of health and human services shall find after due notice and a hearing, as required by RSA 318-B:1, VI, that any exempt pharmaceutical preparation does possess a degree of physiological or psychological dependence character that results in material



abusive use, it shall by designation publish, once each week for 3 successive weeks, the findings in a newspaper of general circulation in the state. The findings shall be effective, and the exempt status shall cease to apply to such pharmaceutical preparation, 7 days after the date of the publication of the findings. The suspension procedure specified in RSA 318-B:1, VI, shall also apply to such exempt preparation after the hearing date.

**Source.** 1969, 421:1. 1977, 547:13. 1985, 190:99, 100. 1995, 310:181, 182, eff. Nov. 1, 1995.

## **Section 318-B:12**

### **318-B:12 Records to be Kept; Confidentiality. –**

I. Practitioners, including physicians, podiatrists, dentists, veterinarians, optometrists, advanced practice registered nurses, manufacturers, wholesalers, pharmacists, clinics, hospitals, and laboratories, shall keep separate records, so as not to breach the confidentiality of patient records, to show the receipt and disposition of all controlled drugs. Such records shall meet the requirements of the department of health and human services and federal laws and regulations relative to the receipt, manufacture, inventory, distributions, sale, dispensing, loss, theft, and any other disposition of controlled drugs. The records shall indicate at least the name, dosage form, strength, and quantity of the controlled drug; the name and address of any person to whom the drug was administered, dispensed, sold or transferred and the date of any and all transactions involved with the controlled drug.

II. Prescription orders and records required by this chapter and stocks of controlled drugs shall be open for inspection only to federal, state, county and municipal law enforcement officers; all officers, agents, inspectors, and representatives of the board of pharmacy who are charged with the responsibility to enforce this chapter; all peace officers within the state; the attorney general; and all county attorneys whose duty it is to enforce the laws of this state or of the United States relating to controlled drugs. No officer having knowledge by virtue of his office of any such prescription, order, or record shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosecution or proceeding the person to whom such prescriptions, orders or records relate is a party.

III. Practitioners including physicians, podiatrists, dentists, veterinarians, optometrists, advanced practice registered nurses, manufacturers, wholesalers, pharmacies, clinics, hospitals, laboratories, and any other person required by federal law to conduct biennial controlled substance inventories, shall do so in accordance with 21 U.S.C. section 1304.11(c) inventory requirements every odd-numbered year. The pharmacy board, established in RSA 318:2, may adopt rules, pursuant to RSA 541-A, relative to the board's responsibility for ensuring compliance with this paragraph.

IV. Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise required by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a

pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force. Nothing in this paragraph shall prohibit the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a licensed pharmacy; the transfer of prescription information between licensed pharmacies; the transfer of prescription records that may occur in the event a pharmacy ownership is changed or transferred; care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy or other information about the drug being dispensed, treatment options, or clinical trials. Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes. In addition to other appropriate remedies under this chapter, a violation of this paragraph is an unfair or deceptive act or practice within the meaning of RSA 358-A:2. Any right or remedy set forth in RSA 358-A may be used to enforce the provisions of this paragraph.

**Source.** 1969, 421:1. 1977, 547:14. 1983, 292:10. 1985, 324:21. 1990, 129:4. 1993, 333:5, 6. 1994, 333:22, 23. 1995, 310:181. 2006, 328:2, eff. June 30, 2006. 2019, 8:1, eff. July 9, 2019.

### **Section 318-B:12-a**

**318-B:12-a Treatment for Drug Abuse.** – Any minor 12 years of age or older may voluntarily submit himself to treatment for drug dependency as defined in RSA 318-B:1, IX, or any problem related to the use of drugs at any municipal health department, state institution or facility, public or private hospital or clinic, any licensed physician or advanced practice registered nurse practicing within such nurse practitioner's specialty, or other accredited state or local social welfare agency, without the consent of a parent, guardian, or any other person charged with the care or custody of said minor. Such parent or legal guardian shall not be liable for the payment for any treatment rendered pursuant to this section. The treating facility, agency or individual shall keep records on the treatment given to minors as provided under this section in the usual and customary manner, but no reports or records or information contained therein shall be discoverable by the state in any criminal prosecution. No such reports or records shall be used for other than rehabilitation, research, or statistical and medical purposes, except upon the written consent of the person examined or treated. Nothing contained herein shall be construed to mean that any minor of sound mind is legally incapable of consenting to medical treatment provided that such minor is of sufficient maturity to understand the nature of such treatment and the consequences thereof.

**Source.** 1971, 136:1. 1994, 333:24. 2009, 54:5, eff. July 21, 2009.

### **Section 318-B:13**

#### **318-B:13 Labels. –**

I. Whenever a manufacturer sells or dispenses a controlled drug, and whenever a wholesaler sells or dispenses a controlled drug in a package prepared by him, he shall securely affix to each package in which the drug is contained a label showing in legible English the name and address

of the vendor and the quantity, kind, and form of controlled drug contained therein. If any controlled drug is determined by rule of the department of health and human services to be habit forming, the container label shall show clearly the statement "Warning-May be Habit Forming". No person, except a pharmacist for the purpose of filling a prescription under this chapter, shall alter, deface, or remove any label so affixed.

II. Whenever a pharmacist dispenses any controlled drug on prescription issued by a practitioner, he or she shall affix to the container in which such drug is dispensed a label showing the name, address, and registry number of the pharmacy and name or the initials of the pharmacist; the name of the prescribing practitioner; the prescription identification number; the name of the patient; the date dispensed; any directions as may be stated on the prescription; and the name and strength and quantity of the drug dispensed. All drugs dispensed to a patient that have been filled using a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities. No person shall alter, deface, or remove any label so affixed.

III. Whenever a practitioner other than a pharmacist, but including a physician, dentist, podiatrist, optometrist, veterinarian, or advanced practice registered nurse dispenses a controlled drug, he shall indicate on the container in which such drug is dispensed at least the name of the practitioner; the name and address of the patient, or, in the case of an animal, the name and address of the owner and the species of animal; the date dispensed; the name, strength, and quantity of drug dispensed; and the directions for administering the medication.

IV. A compounded drug product shall also be labeled as provided in RSA 318:14-a.

**Source.** 1969, 421:1. 1977, 547:15, 16. 1983, 292:11. 1985, 324:22. 1993, 333:7. 1994, 333:25. 1995, 310:181. 2002, 281:6. 2009, 54:5. 2013, 121:7, eff. Jan. 1, 2014.

## **Section 318-B:14**

**318-B:14 Repealed by 2010, 173:2, eff. Jan. 1, 2011. –**

## **Section 318-B:15**

### **318-B:15 Persons and Corporations Exempted. –**

The provisions of this chapter restricting the possession and having control of controlled drugs shall not apply to:

I. Common carriers or to warehousemen while engaged in lawfully transporting or storing such drugs, or to an employee of the same acting within the scope of his employment; or to public officers or their employees in the performance of their official duties requiring possession or control of controlled drugs; or to temporary incidental possession by employees or agents or persons lawfully entitled to possession, or by persons whose possession is for the purpose of aiding public officers in performing their official duties.

II. Persons possessing prescription drugs dispensed to them pursuant to a lawful prescription or who are acting as an authorized agent for a person holding a lawful prescription. For purposes of this section, an authorized agent shall mean any person, including but not limited to a family member or caregiver, who has the intent to deliver the prescription drug to the person to whom the prescription drugs are lawfully prescribed. This exemption does not extend to persons possessing drugs with an intent to sell.

III. Law enforcement officers engaged in the collection, storage, and disposal of controlled drugs in conjunction with a pharmaceutical drug take-back program established under RSA 318-E.

IV. (a) A health care professional authorized to prescribe an opioid antagonist may prescribe, dispense, or distribute, directly or by standing order, an opioid antagonist to a person at risk of experiencing an opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose. Any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

(b) A person or organization may, if acting pursuant to the provisions of subparagraph (a), store and possess an opioid antagonist, dispense or distribute an opioid antagonist, and administer an opioid antagonist to another person who the person believes is suffering an opioid-related overdose.

(c) No health care professional who, acting in good faith and with reasonable care, prescribes, dispenses, or distributes an opioid antagonist directly or by standing order and no person who, acting in good faith and with reasonable care, stores, dispenses, or distributes an opioid antagonist or administers an opioid antagonist to another person who the person believes is suffering an opioid-related drug overdose shall be subject to any criminal or civil liability, or any professional disciplinary action, for any action authorized by this paragraph or any outcome resulting from an action authorized by this paragraph.

(d) In this paragraph:

(1) "Opioid antagonist" means any drug that binds to opioid receptors and blocks or disinhibits the effects of opioids acting on those receptors.

(2) "Opioid-related drug overdose" means a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid, or another substance with which an opioid was combined, or that a layperson would reasonably believe to be an opioid-related drug overdose that requires medical assistance.

**Source.** 1969, 421:1. 2010, 173:1. 2011, 63:6. 2015, 65:1, eff. June 2, 2015.

## **Section 318-B:16**

**318-B:16 Common Nuisances.** – Any store, shop, warehouse, dwellinghouse, building, vehicle, boat, aircraft, or any place whatever which is resorted to by drug-dependent persons for the purpose of using controlled drugs or which is used for the illegal keeping or selling of the same shall be deemed a common nuisance. No person shall knowingly keep or maintain such a common nuisance.

**Source.** 1969, 421:1, eff. Aug. 31, 1969.

## **Section 318-B:16-a**

[RSA 318-B:16-a effective January 1, 2020.]

**318-B:16-a Controlled Drugs Containing Opiates; Warning Label Required.** – Any controlled drug containing opiates dispensed by a health care provider or pharmacy shall have an

orange sticker with the word "opioid" in easily legible font placed on the cap or dispenser and shall have a warning label stating "Risk of addiction and overdose." The health care provider or pharmacist shall also provide each person with a handout which shall be developed and approved by the governor's commission on alcohol and drug abuse, prevention, treatment, and recovery which shall include guidance on associated risks of opioid use and how to mitigate them. This section shall not apply to pharmacists or a pharmacy that dispenses a drug containing an opioid that is administered to a patient treated in a health care facility required to be licensed under RSA 151. A patient may remove the cap sticker or warning label.

**Source.** 2019, 210:1, eff. Jan. 1, 2020.

### **Section 318-B:17**

#### **318-B:17 Disposal of Controlled Drugs in Possession of Law Enforcement Officer. –**

All controlled drugs, the lawful possession of which is not established or the title to which cannot be ascertained, which have come into the custody of a law enforcement officer shall be forfeited and disposed of as follows:

I. The superior court shall order such controlled drugs forfeited and destroyed. A record of the place where the drugs were seized, of the kinds and quantities of drugs so destroyed, and of the time, place and manner of destruction shall be kept, and return under oath, reporting said destruction, shall be made to the superior court and to the Drug Enforcement Administration, if controlled drugs are involved, by the officer who destroys them.

I-a. The circuit court having jurisdiction over a misdemeanor or violation controlled drug offense may order such controlled drugs forfeited and destroyed upon written motion. Such order shall not be entered until after the period for appeal of the offense has expired.

I-b. The circuit court shall require the same record and reporting of the officer who is destroying the controlled drugs as is required under paragraph I for the superior court, with the exception of notification to the Drug Enforcement Administration.

I-c. All unwanted or unused controlled drugs which have come into the custody of a law enforcement officer, pursuant to a pharmaceutical drug take-back program, shall be disposed of in accordance with the disposal requirements for controlled drugs set forth under RSA 318-E.

II, III. [Repealed.]

**Source.** 1969, 421:1. 1983, 292:13. 1995, 310:181. 1998, 362:1, 2. 2003, 80:1. 2011, 63:7, 8. 2013, 222:1, eff. Jan. 1, 2014.

### **Section 318-B:17-a**

**318-B:17-a Disposal of Controlled Drugs in Possession of Practitioner. –** No person other than the pharmacy board, its officers, agents, and inspectors is authorized to destroy any outdated, deteriorated, excessive or otherwise unwanted or confiscated controlled drugs which are in the possession of a practitioner, veterinarian, pharmacy, peace officer, nursing home, manufacturer, wholesaler, clinic, or laboratory or hospital. No payment shall be made to any person or institution for any drug surrendered for destruction. A record shall be maintained which indicates the name, strength, and quantity of all drugs destroyed; the place and manner of destruction; the date and time destroyed; the name of the practitioner or institution surrendering

the drugs; and the signature and title of the person witnessing destruction. Such records shall conform to any federal requirements and shall be open to inspection by all federal or state officers charged with the enforcement of federal or state controlled drug laws. This section shall not apply to residual amounts in hypodermic syringes and needles.

**Source.** 1977, 547:17. 1983, 292:14, eff. Aug. 17, 1983. 2017, 117:4, eff. June 16, 2017.

### **Section 318-B:17-b**

#### **318-B:17-b Forfeiture of Items Used in Connection With Drug Offense. –**

I. Interests in the following property, upon petition of the attorney general, shall be subject to forfeiture to the state and said property interest shall be vested in the state:

(a) All materials, products and equipment of any kind, including, but not limited to, firearms, scales, packaging equipment, surveillance equipment and grow lights, which are used or intended for use in procurement, manufacture, compounding, processing, concealing, trafficking, delivery or distribution of a controlled drug in felonious violation of this chapter.

(b) Property interest in any conveyance, including but not limited to aircraft, vehicles, or vessels, which is used or intended for use in the procurement, manufacture, compounding, processing, concealing, trafficking, delivery or distribution of a controlled drug in felonious violation of this chapter.

(c) Any moneys, coin, currency, negotiable instruments, securities or other investments knowingly used or intended for use in the procurement, manufacture, compounding, processing, concealing, trafficking, delivery or distribution of a controlled drug in felonious violation of this chapter and all proceeds, including moneys, coin, currency, negotiable instruments, securities or other investments, and any real or personal property, traceable thereto. All moneys, coin, currency, negotiable instruments, securities and other investments found in proximity to controlled substances are presumed to be forfeitable under this paragraph. The claimant of the property shall bear the burden of rebutting this presumption.

(d) Any books, records, ledgers and research material, including formulae, microfilm, tapes and any other data which are used or intended for use in felonious violation of this chapter.

(e) Any real property, including any right, title, leasehold interest, and other interest in the whole of any lot or tract of land and any appurtenances or improvements, which real property is knowingly used or intended for use, in any manner or part, in the procurement, manufacture, compounding, processing, concealing, trafficking, delivery or distribution of a controlled drug in felonious violation of this chapter.

I-a. The state shall have a lien on any property subject to forfeiture under this section upon seizure thereof. Upon forfeiture, the state's title to the property relates back to the date of seizure.

I-b. Property may be seized for forfeiture by any law enforcement agency designated by the department of justice, as follows:

(a) Upon process issued by any justice, associate justice or special justice of the municipal, district or superior court. The court may issue a seizure warrant on an affidavit under oath demonstrating that probable cause exists for its forfeiture or that the property has been the subject of a previous final judgment of forfeiture in the courts of any state or of the United States. The application for process and the issuance, execution and return of process shall be subject to applicable state law. The court may order that the property be seized and secured on such terms and conditions as are reasonable in the discretion of the court. Such order may

include an order to a financial institution or to any fiduciary or bailee to require the entity to impound any property in its possession or control and not to release it except upon further order of the court. The order may be made on or in connection with a search warrant;

(b) Physically, without process on probable cause to believe that the property is subject to forfeiture under this chapter; or

(c) Constructively, without process on probable cause to believe that the property is subject to forfeiture under this chapter, by recording a notice of pending forfeiture in the registry of deeds in the county where the real property is located or at the town clerk's office where the personal property is located stating that the state intends to seek forfeiture of the identified property pursuant to this chapter.

(d) A seizure for forfeiture without process under subparagraph (b) or (c) is reasonable if made under circumstances in which a warrantless seizure or arrest would be valid in accordance with state law.

I-c. Upon seizure of any items or property interests the property shall not be subject to alienation, sequestration or attachment but is deemed to be in the custody of the department of justice subject only to the order of the court.

II. (a) Upon the seizure of any personal property under paragraph I, the person making or directing such seizure shall inventory the items or property interests and issue a copy of the resulting report to any person or persons having a recorded interest, or claiming an equitable interest in the item within 7 days of said seizure.

(b) Upon seizure of any real property under paragraph I, the person making or directing such seizure shall notify any person having a recorded interest or claiming an equitable interest in the property within 7 days of said seizure.

(c) The seizing agency shall cause an appraisal to be made of the property as soon as possible and shall promptly send to the department of justice a written request for forfeiture. This request shall include a statement of all facts and circumstances supporting forfeiture of the property, including the names of all witnesses then known, and the appraised value of the property.

(d) The department of justice shall examine the facts and applicable law of the cases referred pursuant to subparagraph (c), and if it is probable that the property is subject to forfeiture, shall cause the initiation of administrative or judicial proceedings against the property. If upon inquiry and examination, the department of justice determines that such proceedings probably cannot be sustained or that the ends of justice do not require the institution of such proceedings, the department shall make a written report of such findings and send a copy to the seizing agency, and, if appropriate, shall also authorize and direct the release of the property.

(e) The department of justice shall, within 60 days of the seizure, file a petition in the superior court having jurisdiction under this section. If no such petition is filed within 60 days, the items or property interest seized shall be released or returned to the owners.

II-a. Pending forfeiture and final disposition, the law enforcement agency making the seizure shall:

(a) Place the property under seal; or

(b) Remove the property to a storage area for safekeeping; or

(c) Remove the property to a place designated by the court; or

(d) Request another agency to take custody of the property and remove it to an appropriate location within the state; or

(e) In the case of moneys, file a motion for transfer of evidence under RSA 595-A:6. Upon the court's granting of the motion the moneys shall be immediately forwarded to an interest-bearing

seized asset escrow account to be administered by the attorney general. Upon resolution of the forfeiture proceeding the moneys deposited shall be transferred to the drug forfeiture fund or returned to the owners thereof as directed by the court. Unless otherwise ordered by a court in a specific case, interest on all moneys deposited in the seized asset escrow account shall be deposited annually into the drug forfeiture fund established under RSA 318-B:17-c.

III. The court may order forfeiture of all items or property interests subject to the provisions of paragraph I, except as follows:

(a) No item or property interest shall be subject to forfeiture unless the owner or owners thereof were consenting parties to a felonious violation of this chapter and had knowledge thereof.

(b) No items or property interests shall be subject to forfeiture unless involved in an offense which may be charged as a felony.

IV. (a) The department of justice may petition the superior court in the name of the state in the nature of a proceeding in rem to order forfeiture of items or property interests subject to forfeiture under the provisions of this section. Such petition shall be filed in the court having jurisdiction over any related criminal proceedings which could be brought under this chapter.

(b) Such proceeding shall be deemed a civil suit in equity in which the state shall have the burden of proving all material facts by a preponderance of the evidence and in which the owners or other persons claiming an exception pursuant to paragraph III shall have the burden of proving such exception.

(c) The court shall issue summonses to all persons who have a recorded interest or claim an equitable interest in said items or property interests seized under this chapter and shall schedule a hearing on the petition to be held within 90 days of the date specified by the court on the summonses.

(d) At the request of any party to the forfeiture proceeding, the court may grant a continuance until the final resolution of any criminal proceedings which were brought against a party under this chapter and which arose from the transaction which gave rise to the forfeiture proceeding. No asset forfeiture may be maintained against a person's interest in property if that person has been found not guilty of the underlying felonious charge.

(e) At the hearing, the court shall hear evidence and make findings of fact and rulings of law as to whether the property is subject to forfeiture under this chapter. Except in the case of proceeds, upon a finding that the property is subject to forfeiture the court shall determine whether the forfeiture of the property is not excessive in relation to the underlying criminal offense. In making this determination the court shall consider whether in addition to any other pertinent considerations:

(1) There is a substantial connection between the property to be forfeited and the underlying drug offense;

(2) Criminal activities conducted by or through the use of the property were extensive; and

(3) The value of the property to be forfeited greatly outweighs the value of the drugs that were or would have been likely to be distributed, the costs of the investigation and prosecution, and the harm caused by the criminal conduct.

The court shall, thereupon, make a final order, from which all parties shall have a right of appeal.

V. Final orders for forfeiture of property under this section shall be implemented by the department of justice and shall provide for disposition of the items or property interests by the state in any manner not prohibited by law, including retention for official use by law enforcement or other public agencies or sale at public auction. The department of justice shall pay the reasonable expenses of the forfeiture proceeding, seizure, storage, maintenance of



custody, advertising, court costs, and notice of sale from any money forfeited and from the proceeds of any sale or public auction of forfeited items. All outstanding recorded liens on said items or property interests seized shall be paid in full upon conclusion of the court proceedings from the proceeds of any sale or public auction of forfeited items. The balance remaining shall be distributed by the department of justice as follows:

(a) Of the first \$500,000:

(1) Forty-five percent shall be returned to the fiscal officer or officers of the municipal, county, state, or federal government which provided the law enforcement agency or agencies responsible for the seizure. Moneys returned to each fiscal officer shall be deposited in a special account and shall be used primarily for meeting expenses incurred by law enforcement agencies in connection with drug-related investigations. Except as provided in RSA 31:95-b, such funds shall be available for expenditure without further appropriation by the legislative body of the municipal, county, state or federal government, and shall not be transferred or expended for any other purpose. Moneys returned to a state law enforcement agency shall be deposited in a special nonlapsing account established within the office of the state treasurer and shall be in addition to all other state appropriations to such agency;

(2) Ten percent shall be deposited into a special nonlapsing account established within the office of the state treasurer for the department of health and human services; and

(3) Forty-five percent shall be deposited in a revolving drug forfeiture fund, administered by the department of justice pursuant to RSA 318-B:17-c; and

(b) Of any balance remaining:

(1) Ten percent shall be deposited in the manner prescribed in subparagraph V(a)(2) of this section; and

(2) Ninety percent shall be deposited in the manner prescribed in subparagraph V(a)(3) of this section.

The total amount of payments made to the special account for the department of health and human services pursuant to subparagraphs V(a)(2) and V(b)(1) of this section shall not exceed \$400,000 in any fiscal year and any excess over \$400,000 which would otherwise be paid to such special account under this section shall be deposited in the general fund. The revolving drug forfeiture fund shall at no time exceed \$1,000,000. All sums in the revolving drug forfeiture fund in excess of \$1,000,000 shall be credited to the general fund.

**Source.** 1981, 166:2. 1983, 292:15. 1985, 327:1-4. 1986, 232:1. 1988, 94:1. 1989, 380:1, 2. 1992, 182:1. 1994, 343:1-3. 1995, 310:177. 2014, 204:11. 2016, 329:5, 7, eff. Jan. 1, 2017.

### **Section 318-B:17-c**

#### **318-B:17-c Drug Forfeiture Fund. –**

I. There is hereby established within the office of the state treasurer a special revolving fund to be designated as the drug forfeiture fund. This fund shall be administered by the attorney general and may be used to pay the costs of local, county and state drug related investigations, as well as drug control law enforcement programs within New Hampshire. The fund may also be used to pay extraordinary costs of local, county and state drug prosecutions and trial expenses.

II. Law enforcement agencies may apply to the department of justice for grants from the forfeiture fund. Such grants shall be utilized exclusively for meeting expenses associated with drug related investigations. The attorney general shall report 60 days after the close of each fiscal

year to the governor and council and to the fiscal committee of the general court a detailed accounting of the grants provided to law enforcement agencies under this paragraph by agency, including the department of safety, and the amount forwarded to the department of health and human services, bureau of drug and alcohol services, for the preceding fiscal year. The attorney general's report shall also include a detailed accounting of the costs of investigations, enforcement programs, and prosecutions paid under paragraph I.

III. The attorney general shall adopt rules, pursuant to RSA 541-A, relative to:

- (a) The administration of the drug forfeiture fund.
- (b) The grant application procedures and forms to be used by law enforcement agencies.

**Source.** 1985, 327:5. 1986, 232:2. 1989, 380:3. 2012, 247:29. 2016, 329:8, eff. June 24, 2016.

### **Section 318-B:17-d**

**318-B:17-d Repealed by 2016, 329:9, eff. Jan. 1, 2017. –**

### **Section 318-B:17-e**

**318-B:17-e Drug Asset Forfeiture Guidelines Required.** – The department of justice shall adopt and maintain drug asset forfeiture guidelines. The attorney general shall submit the guidelines and any proposed amendments to such guidelines to the house judiciary and family law committee and to the senate judiciary committee for review and comment at least as often as annually. The attorney general shall submit any proposed amendments to the guidelines for legislative review and comment prior to their becoming effective.

**Source.** 1994, 343:4. 1995, 9:39, eff. June 11, 1995.

### **Section 318-B:17-f**

**318-B:17-f Forfeiture Reports.** –

The attorney general shall submit a biennial report to the governor, senate president, and speaker of the house relative to the seizure of any items or property interests under RSA 318-B:17-b.

Such report shall include:

- I. A full and complete description of any items or property interests seized including the property's location and value.
- II. The name and address of all known persons having a legal or equitable interest in the property.
- III. Any findings of fact relative to the justice of the forfeiture as determined under RSA 318-B:17-b, IV(e).

The attorney general has the authority to exclude any information which would reveal the identity of an informant or compromise an ongoing investigation.

**Source.** 1994, 343:5, eff. Aug. 7, 1994.

### **Section 318-B:18**

**318-B:18 Notice of Conviction to be Sent to Licensing Board.** – On the conviction of any person for violation of any provision of this chapter, a copy of the judgment and sentence, and of the opinion of the superior court if any opinion is filed, shall be sent by the clerk of the court to the board by whom the convicted defendant has been licensed or registered to practice his profession or to carry on his business. The board may summarily suspend, limit or revoke the license or registration of the convicted defendant to practice his profession or to carry on his business.

**Source.** 1969, 421:1. 1983, 292:17, eff. Aug. 17, 1983.

### **Section 318-B:19, 318-B:20**

**318-B:19, 318-B:20 Repealed by 1983, 292:21, eff. Aug. 17, 1983. –**

### **Section 318-B:21**

**318-B:21 Certain Communications Not Privileged.** – Information communicated to a practitioner in an effort unlawfully to procure a controlled drug, or unlawfully to procure the administration of any such drug, shall not be deemed a privileged communication.

**Source.** 1969, 421:1. 1983, 292:18, eff. Aug. 17, 1983.

### **Section 318-B:22**

**318-B:22 Exceptions and Exemptions Not Required to be Negated.** – In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of this chapter, it shall not be necessary to negate any exception, excuse, proviso, or exemption contained herein, and the burden of proof of any such exception, excuse, proviso or exemption shall be upon the defendant.

**Source.** 1969, 421:1, eff. Aug. 31, 1969.

### **Section 318-B:23**

**318-B:23 Enforcement and Cooperation.** – It is hereby made the duty of the department of health and human services, its officers, agents, inspectors, and representatives; the pharmacy board, its officers, agents, inspectors and representatives; and of all peace officers within the state, and of all county attorneys, to enforce all provisions of this chapter, except those specifically delegated, and to cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to controlled drugs.

**Source.** 1969, 421:1. 1977, 547:18. 1995, 310:181, eff. Nov. 1, 1995.

### **Section 318-B:24**

**318-B:24 Rulemaking. –**

I. The commissioner of the department of health and human services, in conjunction with the pharmacy board, shall adopt rules, pursuant to RSA 541-A, relative to:

- (a) Investigations and hearings on controlled drugs under RSA 318-B:1, VI.
- (b) Official forms required by RSA 318-B:1, XIX.
- (c) Licenses under RSA 318-B:4.
- (d) Revocation procedures under RSA 318-B:11.
- (e) Labels under RSA 318-B:13.
- (f) [Repealed.]

II. The commissioner of the department of health and human services and the pharmacy board are hereby required to adopt rules under this chapter to conform with regulations promulgated by the Secretary of the Treasury of the United States, his delegate, the Secretary of Health and Human Services of the United States, or the United States Attorney General under the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the federal food and drug laws.

**Source.** 1969, 421:1. 1977, 547:19. 1985, 190:101; 324:23. 1995, 310:182. 2012, 171:26, XIII, eff. Aug. 10, 2012.

**Section 318-B:25**

**318-B:25 Authority for Inspection. –** All officers, agents, inspectors and representatives of the department of health and human services who are charged with the responsibility to enforce this chapter; all officers, agents, inspectors, and representatives of the pharmacy board who are charged with the responsibility to enforce this chapter; all peace officers within the state; the attorney general and all county attorneys; and federal, state, county and municipal law enforcement officers are authorized to enter during normal business hours upon the premises used by a practitioner for the purpose of his practice and to inspect such original records or prescriptions or both for controlled drugs as defined herein. Every practitioner, his clerk, agent, or servant shall exhibit to such person on demand every such original record or prescription or both so kept on file.

**Source.** 1969, 421:1. 1977, 547:20. 1983, 292:19. 1985, 324:24. 1995, 310:181, eff. Nov. 1, 1995.

**Section 318-B:26**

**318-B:26 Penalties. –**

I. Any person who manufactures, sells, prescribes, administers, or transports or possesses with intent to sell, dispense, or compound any controlled drug, controlled drug analog or any preparation containing a controlled drug, except as authorized in this chapter; or manufactures, sells, or transports or possesses with intent to sell, dispense, compound, package or repackage (1) any substance which he represents to be a controlled drug, or controlled drug analog, or (2) any preparation containing a substance which he represents to be a controlled drug, or controlled drug analog, shall be sentenced as follows, except as otherwise provided in this section:

- (a) In the case of a violation involving any of the following, a person shall be sentenced to a

maximum term of imprisonment of not more than 30 years, a fine of not more than \$500,000, or both. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a maximum term of life imprisonment, a fine of not more than \$500,000, or both:

(1) Five ounces or more of a mixture or substance containing any of the following, including any adulterants or dilutants:

(A) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; or

(B) Cocaine other than crack cocaine, its salts, optical and geometric isomers, and salts of isomers; or

(C) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(2) Lysergic acid diethylamide, or its analog, in a quantity of 100 milligrams or more including any adulterants or dilutants, or phencyclidine (PCP), or its analog, in a quantity of 10 grams or more including any adulterants or dilutants.

(3) Heroin or its analog, crack cocaine, or a fentanyl class drug in a quantity of 5 grams or more, including any adulterants or dilutants.

(4) Methamphetamine or its analog, in a quantity of 5 ounces or more, including adulterants or dilutants.

(b) In the case of a violation involving any of the following, a person may be sentenced to a maximum term of imprisonment of not more than 20 years, a fine of not more than \$300,000, or both. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a term of imprisonment of not more than 40 years, a fine of not more than \$500,000, or both:

(1) A substance or mixture referred to in subparagraph I(a)(1) of this section, other than crack cocaine, in a quantity of 1/2 ounce or more, including any adulterants or dilutants;

(2) A substance classified in schedule I or II other than those specifically covered in this section, or the analog of any such substance, in a quantity of one ounce or more including any adulterants or dilutants;

(3) Lysergic acid diethylamide, or its analog, in a quantity of less than 100 milligrams including any adulterants or dilutants, or where the amount is undetermined, or phencyclidine (PCP) or its analog, in a quantity of less than 10 grams, including any adulterants or dilutants, or where the amount is undetermined;

(4) Heroin or its analog, crack cocaine, or a fentanyl class drug in a quantity of one gram or more, including any adulterants or dilutants;

(5) Methamphetamine or its analog, in a quantity of one ounce or more including any adulterants or dilutants;

(6) Marijuana in a quantity of 5 pounds or more including any adulterants or dilutants, or hashish in a quantity of one pound or more including any adulterants and dilutants;

(7) Flunitrazepam in a quantity of 500 milligrams or more.

(c) In the case of a violation involving any of the following, a person may be sentenced to a maximum term of imprisonment of not more than 7 years, a fine of not more than \$100,000, or both. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a maximum term of imprisonment of not more than 15 years, a fine of not more than \$200,000, or both:

(1) A substance or mixture referred to in subparagraph I(a)(1) of this section, other than crack cocaine, in a quantity less than 1/2 ounce including any adulterants or dilutants;

(2) A substance or mixture classified as a narcotic drug in schedule I or II other than those specifically covered in this section, or the analog of any such substance, in a quantity of less than one ounce including any adulterants or dilutants;

(3) Methamphetamine, or its analog in a quantity of less than one ounce including any adulterants or dilutants;

(4) Heroin or its analog, crack cocaine, or a fentanyl class drug in a quantity of less than one gram, including any adulterants or dilutants;

(5) Marijuana in a quantity of one ounce or more including any adulterants or dilutants, or hashish in a quantity of 5 grams or more including any adulterants or dilutants;

(6) Flunitrazepam in a quantity of less than 500 milligrams;

(7) Any other controlled drug or its analog, other than those specifically covered in this section, classified in schedules I, II, III or IV.

(d) In the case of a violation involving any of the following, a person may be sentenced to a maximum term of imprisonment of not more than 3 years, a fine of not more than \$25,000, or both. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person may be sentenced to a maximum term of imprisonment of not more than 6 years, a fine of not more than \$50,000, or both:

(1) Marijuana in a quantity of less than one ounce including any adulterants or dilutants, or hashish in a quantity of less than 5 grams including any adulterants or dilutants;

(2) Any schedule V substance or its analog.

II. Any person who knowingly or purposely obtains, purchases, transports, or possesses actually or constructively, or has under his or her control, any controlled drug or controlled drug analog, or any preparation containing a controlled drug or controlled drug analog, except as authorized in this chapter, shall be sentenced as follows, except as otherwise provided in this section:

(a) In the case of a controlled drug or its analog, classified in schedules I, II, III, or IV, other than those specifically covered in this section, the person shall be guilty of a class B felony, except that notwithstanding the provisions of RSA 651:2, IV(a), a fine of not more than \$25,000 may be imposed. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person shall be guilty of a class A felony, except that notwithstanding the provisions of RSA 651:2, IV(a), a fine of up to \$50,000 may be imposed.

(b) In the case of a controlled drug or its analog classified in schedule V, the person shall be sentenced to a maximum term of imprisonment of not more than 3 years, a fine of not more than \$15,000, or both. If a person commits any such violation after one or more prior offenses as defined in RSA 318-B:27, such person shall be guilty of a class B felony, except that notwithstanding the provisions of RSA 651:2, IV(a), a fine of not more than \$25,000 may be imposed.

(c) In the case of more than 3/4 ounce of marijuana or more than 5 grams of hashish, including any adulterants or dilutants, the person shall be guilty of a misdemeanor. In the case of marijuana-infused products possessed by persons under the age of 21 or marijuana-infused products as defined in RSA 318-B:2-e, other than a personal-use amount of a regulated marijuana-infused product as defined in RSA 318-B:2-c, I(b), that are possessed by a person 21 years of age or older, the person shall be guilty of a misdemeanor.

(d) In the case of 3/4 ounce or less of marijuana or 5 grams or less of hashish, including any adulterants or dilutants, the person shall be guilty of a violation pursuant to RSA 318-B:2-c. In the case of a person 21 years of age or older who possesses a personal-use amount of a regulated marijuana-infused product as defined in RSA 318-B:2-c, I(b), the person shall be guilty of a

violation pursuant to RSA 318-B:2-c.

(e) In the case of a residual amount of a controlled substance, as defined in RSA 318-B:1, XXIX-a, a person shall be guilty of a misdemeanor if the person is not part of a service syringe program under RSA 318-B:43.

III. A person shall be guilty of a misdemeanor who:

(a) Except as provided in RSA 318-B:2-c, controls any premises or vehicle where he or she knows a controlled drug or its analog is illegally kept or deposited;

(b) Aids, assists or abets a person in his presence in the perpetration of a crime punishable under paragraph II of this section, knowing that such person is illegally in possession of a controlled drug or its analog.

(c) Manufactures with the intent to deliver, delivers or possesses with the intent to deliver any drug paraphernalia when such paraphernalia is knowingly manufactured, delivered or possessed for one or more of the uses set forth in RSA 318-B:2, II.

(d) Places an advertisement in violation of RSA 318-B:2, III.

III-a. [Repealed.]

IV. Any person who attempts or conspires to commit any offense defined in this chapter is punishable by imprisonment or a fine or both, which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

V. Any person who violates this chapter by manufacturing, selling, prescribing, administering, dispensing, or possessing with intent to sell, dispense, or compound any controlled drug or its analog, in or on or within 1,000 feet of the real property comprising a public or private elementary, secondary, or secondary vocational-technical school, may be sentenced to a term of imprisonment or fine, or both, up to twice that otherwise authorized by this section. Except to the extent a greater minimum sentence is otherwise provided by this chapter, a sentence imposed under this paragraph shall include a mandatory minimum term of imprisonment of not less than one year. Neither the whole nor any part of the mandatory minimum sentence imposed under this paragraph shall be suspended or reduced.

VI. Except as otherwise provided in this paragraph, a person convicted under RSA 318-B:2, XII as a drug enterprise leader shall be sentenced to a mandatory minimum term of not less than 25 years and may be sentenced to a maximum term of not more than life imprisonment. The court may also impose a fine not to exceed \$500,000 or 5 times the street value of the controlled drug or controlled drug analog involved, whichever is greater. Upon conviction, the court shall impose the mandatory sentence unless the defendant has pleaded guilty pursuant to a negotiated agreement or, in cases resulting in trial, the defendant and the state have entered into a post-conviction agreement which provides for a lesser sentence. The negotiated plea or post-conviction agreement may provide for a specified term of imprisonment within the range of ordinary or extended sentences authorized by law, a specified fine, or other disposition. In that event, the court at sentencing shall not impose a lesser term of imprisonment or fine than that expressly provided for under the terms of the plea or post-conviction agreement.

VII. Any person who violates RSA 318-B:2, XI may be sentenced to a maximum term of imprisonment of not more than 20 years, a fine of not more than \$300,000, or both. If any person commits such a violation after one or more prior offenses, as defined in RSA 318-B:27, such person may be sentenced to a term of imprisonment of not more than 40 years, a fine of not more than \$500,000, or both.

VIII. Any person who knowingly or purposely obtains or purchases (1) any substance which he represents to be a controlled drug or controlled drug analog, or (2) any preparation containing a

substance which he represents to be a controlled drug or controlled drug analog, except as authorized in this chapter, shall be guilty of a misdemeanor. If any person commits such a violation after one or more prior offenses as defined in RSA 318-B:27, such person shall be guilty of a class B felony.

IX. Any person who manufactures, sells, or dispenses methamphetamine, lysergic acid, diethylamide phencyclidine (PCP) or any other controlled drug classified in schedules I or II, or any controlled drug analog thereof, in violation of RSA 318-B:2, I or I-a, is strictly liable for a death which results from the injection, inhalation or ingestion of that substance, and may be sentenced to imprisonment for life or for such term as the court may order. For purposes of this section, the person's act of manufacturing, dispensing, or selling a substance is the cause of a death when:

(a) The injection, inhalation or ingestion of the substance is an antecedent but for which the death would not have occurred; and

(b) The death was not:

(1) Too remote in its occurrence as to have just bearing on the person's liability; or

(2) Too dependent upon conduct of another person which was unrelated to the injection, inhalation or ingestion of the substance or its effect, as to have a just bearing on the person's liability. It shall not be a defense to a prosecution under this section that the decedent contributed to his own death by his purposeful, knowing, reckless or negligent injection, inhalation or ingestion of the substance or by his consenting to the administration of the substance by another. Nothing in this section shall be construed to preclude or limit any prosecution for homicide. A conviction arising under this section shall not merge with a conviction of one as a drug enterprise leader or for any other offense defined in this chapter.

IX-a. A qualifying patient or designated caregiver as defined in RSA 126-X:1 who sells cannabis to a person who is not a qualifying patient or a designated caregiver shall be guilty of a class B felony and shall be sentenced to a maximum term of imprisonment of not more than 7 years, a fine of not more than \$300,000, or both.

X. Any penalty imposed for violation of this chapter shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

XI. Any person who violates any provision of this chapter for which a penalty is not provided by paragraphs I through IX shall be guilty of a class B felony if a natural person, or guilty of a felony if any other person.

XII. The penalty categories set forth in this section based upon the weight of the drug involved are material elements of the offense; however, the culpability requirement shall not apply to that element of the offense.

XIII. Any person who violates any provision of this chapter shall be fined a minimum of \$350 for a first offense and \$500 for a second or subsequent offense, except that any person who violates the provisions of RSA 318-B:26, II(c) or RSA 318-B:26, II(d) shall be fined \$350. This paragraph shall not apply to violations of RSA 318-B:2-c.

**Source.** 1969, 421:1. 1970, 48:3. 1973, 528:204. 1977, 547:21. 1981, 114:2; 513:3, 4. 1988, 6:4. 1989, 195:2; 207:2-5. 1991, 364:2. 1993, 291:1. 1994, 186:3-11. 1998, 359:3, 4. 2005, 177:52. 2006, 241:2. 2013, 242:4. 2016, 2:2-4, eff. Jan. 21, 2016; 307:1-3, eff. Aug. 20, 2016. 2017, 117:5, eff. June 16, 2017; 248:3-5, eff. Sept. 16, 2017.

### **Section 318-B:26-a**



**318-B:26-a Chemical Analyses. –**

I. Upon the request of the attorney general, a county attorney or any law enforcement agency, the laboratory employee performing the chemical analysis shall prepare a certificate. The employee shall sign the certificate subject to the penalties under this paragraph and shall include in the certificate an attestation as to the result of the analysis. The presentation of this certificate to a court by any party to a proceeding shall be evidence that all of the requirements and provisions of this section have been complied with. This certificate shall contain a statement establishing the following: the type of analysis performed; the result achieved; any conclusions reached based upon that result; that the subscriber is the person who performed the analysis and made the conclusions; the subscriber's training or experience to perform the analysis; and the nature and condition of the equipment used. When properly executed, the certificate shall, subject to paragraph II of this section and notwithstanding any other provision of law, be admissible evidence of the composition, quality, and quantity of the substance submitted to the laboratory for analysis, and the court shall take judicial notice of the signature of the person performing the analysis and of the fact that he or she is that person. A person shall be guilty of a class B felony if he or she knowingly makes any false entry in any certificate required under this paragraph.

II. Whenever a party intends to proffer in a criminal proceeding a certificate executed pursuant to this section, notice of an intent to proffer that certificate and all reports relating to the analysis in question, including a copy of the certificate, shall be conveyed to the opposing party or parties at least 25 days before the proceeding begins. An opposing party who intends to object to the admission into evidence of a certificate shall give notice of objection and the specific grounds for the objection within 10 days upon receiving the adversary's notice of intent to proffer the certificate. Whenever a notice of objection is filed, admissibility of the certificate shall be determined not later than 10 days before the beginning of the trial. A proffered certificate shall be admitted in evidence unless it appears from the notice of objection and specific grounds for that objection that the composition, quality, or quantity of the substance submitted to the laboratory for analysis will be contested at trial. A failure to comply with the time limitations regarding the notice of objection required by this section shall constitute a waiver of any objection to the admission of the certificate. The time limitations set forth in this section shall not be relaxed except upon a showing of good cause.

**Source.** 1981, 207:1. 1983, 19:2. 1988, 6:5, eff. July 1, 1988. 2017, 253:1, eff. July 1, 2017.

**Section 318-B:26-b**

**318-B:26-b Repealed by 2016, 212:2, eff. Nov. 1, 2016. –**

**Section 318-B:27**

**318-B:27 Prior Offenses. –** In the case of any person charged with a violation of any provision of this chapter or RSA 318-D, who has previously been convicted of a misdemeanor or felony level violation of the laws of the United States or any state, territory or the District of Columbia relating to controlled drugs as defined in this chapter, such previous conviction shall be deemed a prior offense. A prior conviction for a violation level offense shall not be deemed a prior offense, except as provided in RSA 318-B:2-c, V(a).

**Source.** 1969, 421:1. 2006, 241:3, eff. Jan. 1, 2007. 2017, 248:6, eff. Sept. 16, 2017.

## **Section 318-B:28**

**318-B:28 Repealed by 1988, 6:6, eff. July 1, 1988. –**

## **Section 318-B:28-a**

**318-B:28-a Annulments of Criminal Records.** – No court shall order an annulment, pursuant to RSA 651:5 or any other provision of law, of any record of conviction for a felony under RSA 318-B until 7 years after the date of conviction.

**Source.** 1985, 205:1. 1988, 238:5, eff. Jan. 1, 1989.

## **Section 318-B:28-b**

### **318-B:28-b Immunity From Liability. –**

I. As used in this section:

(a) "Drug overdose" means an acute condition resulting from or believed to be resulting from the use of a controlled drug which a layperson would reasonably believe requires medical assistance.

(b) "Medical assistance" means professional services provided to a person experiencing a drug overdose by a health care professional licensed, registered, or certified under state law who, acting within his or her lawful scope of practice, may provide diagnosis, treatment, or emergency services for a person experiencing a drug overdose.

(c) "Requests medical assistance" shall include a request for medical assistance as well as providing care to someone who is experiencing a drug overdose while awaiting the arrival of medical assistance to aid the overdose victim.

II. It shall be a defense to an offense of possessing or having under his or her control, a controlled drug in violation of RSA 318-B:2 that a person in good faith and in a timely manner requests medical assistance for another person who is experiencing a drug overdose. A person who in good faith and in a timely manner requests medical assistance for another person who is experiencing a drug overdose shall not be arrested, prosecuted, or convicted for possessing, or having under his or her control, a controlled drug in violation of RSA 318-B:2, if the evidence for the charge was gained as a proximate result of the request for medical assistance.

III. It shall be a defense to an offense of possessing or having under his or her control, a controlled drug in violation of RSA 318-B:2 that a person who is experiencing a drug overdose, in good faith and in a timely manner, requests medical assistance for himself or herself. A person who in good faith requests, or is the subject of a good faith request for medical assistance, shall not be arrested, prosecuted, or convicted for possessing, or having under his or her control, a controlled drug in violation of RSA 318-B:2, if the evidence for the charge was gained as a proximate result of the request for medical assistance.

IV. (a) Nothing in this section shall be construed to limit the admissibility of evidence in connection with the investigation or prosecution of a crime involving a person who is not protected as provided in paragraphs II or III.

(b) Nothing in this section shall be construed to limit the lawful seizure of any evidence or contraband.

(c) Nothing in this section shall be construed to limit or abridge the authority of a law enforcement officer to detain or place into custody a person as part of a criminal investigation, or to arrest a person for an offense not protected by the provisions of paragraphs II or III.

V. No later than January 1, 2016, the commissioner of the department of health and human services shall develop and make available on the department's public Internet website, information for the public explaining the meaning and applicability of the provisions of this section.

**Source.** 2015, 218:2, eff. Sept. 6, 2015.

### **Section 318-B:29**

**318-B:29 Effect of Acquittal or Conviction Under the Comprehensive Drug Abuse Prevention and Control Act of 1970.** – No person shall be prosecuted for a violation of any provision of this chapter if such person has been acquitted or convicted under the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, or under the federal food and drug laws of the same act or omission which it is alleged constitutes a violation of this chapter.

**Source.** 1969, 421:1. 1977, 547:22. 1983, 292:20, eff. Aug. 17, 1983.

### **Section 318-B:30**

**318-B:30 Severability.** – If any provision of this chapter or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or applications of the chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are declared to be severable.

**Source.** 1969, 421:1, eff. Aug. 31, 1969.

## **Controlled Drug Prescription Health and Safety Program**

### **Section 318-B:31**

#### **318-B:31 Definitions. –**

In this subdivision:

I. [Repealed.]

II. "Controlled substance" means controlled drugs as defined in RSA 318-B:1, VI.

III. "Dispense" means to deliver a controlled substance by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

IV. "Dispenser" means a person or entity who is lawfully authorized to deliver a schedule II-IV controlled substance, but does not include:

(a) A licensed hospital pharmacy that dispenses less than a 48-hour supply of a schedule II-IV controlled substance from a hospital emergency department or that dispenses for administration in the hospital;

(b) A practitioner, or other authorized person who administers such a substance;

- (c) A wholesale distributor of a schedule II-IV controlled substance or its analog;
- (d) A prescriber who dispenses less than a 48-hour supply of a schedule II-IV controlled substance from a hospital emergency department to a patient; or
- (e) A veterinarian who dispenses less than a 48-hour supply of a schedule II-IV controlled substance to a patient.

IV-a. "Executive director" means the executive director of the office of professional licensure and certification.

IV-b. "Office" means office of professional licensure and certification, established in RSA 310-A.

V. "Patient" means the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance or other such drug is lawfully dispensed.

VI. "Practitioner" means a physician, dentist, podiatrist, veterinarian, pharmacist, APRN, physician assistant, naturopath, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance in the course of licensed professional practice. "Practitioner" shall also include practitioners with a federal license to prescribe or administer a controlled substance.

VII. "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient to lawfully obtain controlled substances.

VIII. "Prescriber" means a practitioner or other authorized person who prescribes a schedule II, III, and/or IV controlled substance.

IX. "Program" means the controlled drug prescription health and safety program that electronically facilitates the confidential sharing of information relating to the prescribing and dispensing of controlled substances listed in schedules II-IV, established by the board pursuant to RSA 318-B:32.

**Source.** 2012, 196:2. 2015, 48:1, 2. 2016, 309:1, eff. Jan. 1, 2017. 2019, 303:1, 2, 16, I, eff. Sept. 27, 2019.

## **Section 318-B:32**

### **318-B:32 Controlled Drug Prescription Health and Safety Program Established. –**

I. The office shall design, establish, and contract with a third party for the implementation and operation of an electronic system to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II-IV controlled substances, by prescribers and dispensers within the state.

II. The office may establish fees for the establishment, administration, operations and maintenance of the program. The program may also be supported through grants and gifts. The fee charged to individuals requesting their own prescription information shall not exceed the actual cost of providing that information.

III. Prescription information held by the program relating to any individual shall be deleted 3 years after the initial prescription was dispensed. All de-identified data may be kept for statistical and analytical purposes in perpetuity.

IV. The executive director shall establish an advisory council, as provided in RSA 318-B:38.

**Source.** 2012, 196:2. 2015, 48:8. 2016, 2:5, eff. Jan. 21, 2016. 2019, 303:3, eff. Sept. 27, 2019.

### **Section 318-B:33**

#### **318-B:33 Controlled Drug Prescription Health and Safety Program Operation. –**

I. The office shall develop a system of registration for all prescribers and dispensers of schedule II-IV controlled substances within the state. The system of registration shall be established by rules adopted by the office, pursuant to RSA 541-A.

II. All prescribers and dispensers authorized to prescribe or dispense schedule II-IV controlled substances within the state shall be required to register with the program as follows:

(a) Practitioners who prescribe but do not dispense schedule II-IV controlled substances shall register with the program as a prescriber;

(b) Practitioners who dispense but do not prescribe schedule II-IV controlled substances shall register with the program as a dispenser unless exempted pursuant to RSA 318-B:31, IV; and

(c) Practitioners who prescribe and dispense schedule II-IV controlled substances shall register with the program as both a prescriber and a dispenser unless exempted pursuant to RSA 318-B:31, IV.

II-a. Only registered prescribers, dispensers, or their designees, and federal health prescribers and dispensers working in federal facilities located in New Hampshire, Massachusetts, Maine, and Vermont shall be eligible to access the program.

II-b. The chief medical examiner and delegates may register and access the program.

III. Each dispenser shall submit to the program the information regarding each dispensing of a schedule II-IV controlled substance. Any dispenser located outside the boundaries of the state of New Hampshire and who is licensed and registered by the board shall submit information regarding each prescription dispensed to a patient who resides within New Hampshire.

IV. Each dispenser required to report under paragraph III of this section shall submit to the program by electronic means information for each dispensing that shall include, but not be limited to:

(a) Dispenser's Drug Enforcement Administration (DEA) registration number.

(b) Prescriber's DEA registration number.

(c) Date of dispensing.

(d) Prescription number.

(e) Number of refills granted.

(f) National Drug Code (NDC) of drug dispensed.

(g) Quantity dispensed.

(h) Number of days supply of drug.

(i) Patient's name.

(j) Patient's address.

(k) Patient's date of birth.

(l) Patient's telephone number, if available.

(m) Date prescription was written by prescriber.

(n) Whether the prescription is new or a refill.

(o) Source of payment for prescription.

V. (a) Except as provided in subparagraphs (b) and (c), each dispenser shall submit the required information in accordance with transmission methods daily by the close of business on the next business day from the date the prescription was dispensed.

(b) Veterinarians shall submit the information required under subparagraph (a) no more than 7 days from the date the prescription was dispensed.

(c) Dispensers who have a federal Drug Enforcement Administration license, but who do not dispense controlled substances may request a waiver from the requirements of subparagraph (a) from the board.

VI. The program administrator may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided all information required by paragraph IV is submitted in this alternative format and within the established time limit.

VII. The program administrator may grant a reasonable extension to a dispenser that is unable, for good cause, to submit all the information required by paragraph IV within the established time limits.

VIII. Any dispenser who in good faith reports to the program as required by paragraphs III and IV shall be immune from any civil or criminal liability as the result of such good faith reporting.

**Source.** 2012, 196:2. 2015, 48:3. 2016, 2:6, eff. Jan. 21, 2016; 2:7, eff. Sept. 1, 2016. 2018, 158:1, eff. July 29, 2018. 2019, 303:4, 5, eff. Sept. 27, 2019.

### **Section 318-B:34**

#### **318-B:34 Confidentiality. –**

I. Information contained in the program, information obtained from it, and information contained in the records of requests for information from the program, is confidential, is not a public record or otherwise subject to disclosure under RSA 91-A, and is not subject to discovery, subpoena, or other means of legal compulsion for release and shall not be shared with an agency or institution, except as provided in this subdivision. This paragraph shall not prevent a practitioner from using or disclosing program information about a patient to others who are authorized by state or federal law or regulations to receive program information.

II. The office shall establish and maintain procedures to ensure the privacy and confidentiality of patients and patient information.

III. The office may use and release information and reports from the program for program analysis and evaluation, statistical analysis, public research, public policy, and educational purposes, provided that the data are aggregated or otherwise de-identified.

**Source.** 2012, 196:2. 2015, 48:4, 5, eff. July 20, 2015. 2019, 303:6, eff. Sept. 27, 2019.

### **Section 318-B:35**

#### **318-B:35 Providing Controlled Drug Prescription Health and Safety Information. –**

I. The program administrator may provide information in the prescription health and safety program upon request only to the following persons:

(a) By electronic or written request to prescribers, dispensers, and the chief medical examiner and delegates within the state who are registered with the program:

- (1) For the purpose of providing medical or pharmaceutical care to a specific patient;
- (2) For reviewing information regarding prescriptions issued or dispensed by the requester; or
- (3) For the purpose of investigating the death of an individual.

(b) By written request, to:

- (1) A patient who requests his or her own prescription monitoring information.

(2) The board of dentistry, the board of medicine, the board of nursing, the board of registration in optometry, the board of podiatry, the board of veterinary medicine, and the pharmacy board; provided, however, that the request is pursuant to the boards' official duties and responsibilities and the disclosures to each board relate only to its licensees and only with respect to those licensees whose prescribing or dispensing activities indicate possible fraudulent conduct.

(3) Authorized law enforcement officials on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense when presented with a court order based on probable cause. No law enforcement agency or official shall have direct access to query program information.

(4) [Repealed.]

(5) A practitioner or consultant retained by the office to review the system information of an impaired practitioner program participant or a referral who has agreed to be evaluated or monitored through the program and who has separately agreed in writing to the consultant's access to and review of such information.

(c) By electronic or written request on a case-by-case basis to:

(1) A controlled prescription drug health and safety program from another state; provided, that there is an agreement in place with the other state to ensure that the information is used or disseminated pursuant to the requirements of this state.

(2) An entity that operates a secure interstate prescription drug data exchange system for the purpose of interoperability and the mutual secure exchange of information among prescription drug monitoring programs, provided that there is an agreement in place with the entity to ensure that the information is used or disseminated pursuant to the requirements of this state.

(3) [Repealed.]

II. The program administrator shall notify the appropriate regulatory board listed in subparagraph I(b)(2) and the prescriber or dispenser at such regular intervals as may be established by the office if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred. The program administrator shall provide prescription information required or necessary for an investigation.

III. The program administrator shall review the information to identify information that appears to indicate whether a person may be obtaining prescriptions in a manner that may represent misuse or abuse of schedule II-IV controlled substances. When such information is identified, the program administrator shall notify the practitioner who prescribed the prescription.

IV. The program administrator shall make a report, at least annually, commencing on November 1, 2019, to the senate president, the speaker of the house of representatives, the oversight committee on health and human services, established in RSA 126-A:13, the advisory council established in RSA 318-B:38 and the licensing boards of all professions required to use the program relative to the effectiveness of the program.

**Source.** 2012, 196:2. 2015, 48:6, 11. 2016, 2:8, eff. Jan. 21, 2016. 2018, 158:2, 3, eff. July 29, 2018. 2019, 303:7-10, eff. Sept. 27, 2019.

## **Section 318-B:36**

### **318-B:36 Unlawful Act and Penalties. –**

I. Any dispenser or prescriber who fails to submit the information required in RSA 318-B:33 or knowingly submits incorrect information shall be subject to a warning letter and provided with

an opportunity to correct the failure. Any dispenser or prescriber who subsequently fails to correct or fails to resubmit the information may be subject to discipline by the appropriate regulatory board.

II. Any dispenser or prescriber whose failure to report the dispensing of a schedule II-IV controlled substance that conceals a pattern of diversion of controlled substances into illegal use shall be guilty of a violation and subject to the penalties established under RSA 318-B:26 and the office's and appropriate regulatory board's rules as applicable. In addition, such dispenser or prescriber may be subject to appropriate criminal charges if the failure to report is determined to have been done knowingly to conceal criminal activity.

III. Any person who engages in prescribing or dispensing of controlled substances in schedule II-IV without having registered with the program may be subject to discipline by the appropriate regulatory board.

IV. Any person authorized to receive program information who knowingly discloses such information in violation of this subdivision shall be subject to discipline by the appropriate regulatory board and to all other relevant penalties under state and federal law.

V. Any person authorized to receive program information who uses such information for a purpose in violation of this subdivision shall be subject to disciplinary action by the appropriate regulatory board and to all other relevant penalties under state and federal law.

VI. Unauthorized use or disclosure of program information shall be grounds for disciplinary action by the relevant regulatory board.

VII. Any person who knowingly accesses, alters, destroys, or discloses program information except as authorized in this subdivision or attempts to obtain such information by fraud, deceit, misrepresentation, or subterfuge shall be guilty of a class B felony.

**Source.** 2012, 196:2, eff. June 12, 2012. 2019, 303:11, eff. Sept. 27, 2019.

### **Section 318-B:37**

#### **318-B:37 Rulemaking. –**

The office shall adopt rules, pursuant to RSA 541-A, necessary to implement and maintain the program including:

I. The criteria for registration by dispensers and prescribers.

II. The criteria for a waiver pursuant to RSA 318-B:33, VI for dispensers with limited electronic access to the program.

III. The criteria for reviewing the prescribing and dispensing information collected by the program.

IV. The criteria for reporting matters to the applicable health care regulatory board for further investigation.

V. The criteria for notifying practitioners of individuals that are engaged in obtaining controlled substances from multiple practitioners or dispensers.

VI. Content and format of all forms required under this subdivision.

**Source.** 2012, 196:2. 2015, 48:7, eff. July 20, 2015. 2019, 303:12, eff. Sept. 27, 2019.

### **Section 318-B:38**



**318-B:38 Advisory Council Established. –**

I. There is hereby established an advisory council to carry out the duties under this subdivision. Members of the council shall not be compensated for serving on the council, or serve on the council for more than one 5-year term except for the attorney general, or designee, or the commissioner of the department of health and human services, or designee. The members of the council shall be as follows:

- (a) A member of the board of medicine, appointed by such board.
- (b) A member of the pharmacy board, appointed by such board.
- (c) A member of the board of dental examiners, appointed by such board.
- (d) A member of the New Hampshire board of nursing, appointed by such board.
- (e) A member of the board of veterinary medicine, appointed by such board.
- (f) A physician appointed by the New Hampshire Medical Society.
- (g) A dentist appointed by the New Hampshire Dental Society.
- (h) A chief of police appointed by the New Hampshire Association of Chiefs of Police.
- (i) A community pharmacist appointed jointly by the New Hampshire Pharmacists Association, the New Hampshire Independent Pharmacy Association, and the New Hampshire Association of Chain Drug Stores.
- (j) Two public members appointed by the governor's commission on alcohol and drug abuse prevention, treatment, and recovery, one of whom may be a member of the commission.
- (k) A hospital administrator appointed by the New Hampshire Hospital Association.
- (l) A nurse practitioner appointed by the New Hampshire Nurse Practitioner Association.
- (m) A veterinarian appointed by the New Hampshire Veterinary Medical Association.
- (n) The attorney general, or designee.
- (o) The commissioner of the department of health and human services, or designee.
- (p) A member of the senate, appointed by the president of the senate.
- (q) Two members of the house of representatives, appointed by the speaker of the house of representatives.

II. The council shall:

- (a) Make recommendations to the office relating to the design, implementation, and maintenance of the program, including recommendations relating to:
  - (1) Rules.
  - (2) Legislation.
  - (3) Sources of funding, including grant funds and other sources of federal, private, or state funds;
- (b) Review the program's annual report and make recommendations to the office regarding the operation of the program.
- (c) Provide ongoing advice and consultation on the implementation and operation of the program, including recommendations relating to:
  - (1) Changes in the program to reflect advances in technology and best practices.
  - (2) Changes to statutory requirements.
  - (3) The design and implementation of an ongoing evaluation component of the program.
- (d) Advise the executive director regarding the implementation of this subdivision.
- (e) Adopt rules necessary for the operation of the council.
- (f) Develop a mission statement for the program and strategic goals for its implementation, develop metrics in conjunction with the legislative budget assistant to measure the program's efficient operation, review the performance of the program against the metrics, and make recommendations to the program and ensure they are incorporated.

III. The council shall meet at least quarterly to effectuate its goals. A chairperson shall be elected by the members. A majority of the members of the council constitutes a quorum for the transaction of business. Action by the council shall require the approval of a majority of the members of the council.

**Source.** 2012, 196:2. 2013, 79:1. 2014, 18:4, eff. July 22, 2014. 2018, 80:12, eff. July 24, 2018. 2019, 303:13, eff. Sept. 27, 2019.

### **Section 318-B:39**

**318-B:39 Repealed by 2016, 213:9, eff. Jan. 1, 2017. –**

### **Section 318-B:40**

**318-B:40 Competency Requirements.** – Except for veterinarians who shall complete continuing education requirements in accordance with RSA 332-B:7-a, XV, all prescribers required to register with the program who possess a United States Drug Enforcement Administration (DEA) license number shall complete 3 contact hours of free appropriate prescriber's regulatory board-approved online continuing education or pass an online examination, in the area of pain management and addiction disorder or a combination, as a condition for initial licensure and license renewal. Verification of successful completion of the examination or of the required continuing education shall be submitted to the prescriber's regulatory board with the licensee's application for initial licensure or renewal. A list of the prescriber's regulatory boards' approved continuing education courses and online examinations in pain management and addiction disorder, shall be available on the office of professional licensure and certification's Internet website.

**Source.** 2016, 2:9, eff. Sept. 1, 2016. 2017, 128:3, eff. Aug. 15, 2017.

### **Section 318-B:41**

**318-B:41 Rulemaking for Prescribing Controlled Drugs. –**

I. (a) Before September 1, 2016, the following boards shall submit to the joint legislative committee on administrative rules final proposed rules for prescribing schedule II, III, and IV opioids, for the management or treatment of pain:

- (1) The board of medicine, concerning physicians and physician assistants.
- (2) The board of dental examiners, concerning dentists.
- (3) The board of nursing, concerning advanced practice registered nurses.
- (4) The board of registration in optometry, concerning optometrists.
- (5) The board of registration in podiatry, concerning podiatrists.
- (6) The naturopathic board of examiners, concerning naturopaths.

(b) The rules required under paragraph I shall, at a minimum, contain mandatory standards for the practice components established in paragraph II.

II. The rules shall, at a minimum, contain mandatory standards for the following practice components:

- (a) Standards for the use of opioids for the management or treatment of all pain:

- (1) Conducting and documenting a detailed history and a physical exam in response to a complaint of pain or anticipated pain.
- (2) Completing a board-approved risk assessment tool to determine whether a patient is an appropriate candidate for a schedule II, III, or IV opioid.
- (3) Establishing and documenting an appropriate pain treatment plan that includes consideration of nonpharmacological modalities and non-opioid therapy.
- (4)(A) Querying the program database when writing an initial schedule II, III, or IV opioid prescription for the management or treatment of a patient's pain or substance use disorder and then periodically, at least twice a year. Such rules shall include exceptions for:
  - (i) Controlled substances administered to a patient in a health care setting;
  - (ii) The program is inaccessible or not functioning properly, due to an internal or external electronic issue; or
  - (iii) An emergency department is experiencing a higher than normal patient volume, and to query the program database would materially delay care.
- (B) When a situation falling under exception (A)(ii) or (iii) is applicable, such exception shall be documented in the patient's medical record.
- (5) Establishing procedures for informed consent outlining the risks and benefits of opioid use.
- (6) Requiring the lowest effective dosage for the fewest number of days with specific dose limits be prescribed for a medical condition or specialty.
- (7) Providing for the enforcement of the prescribing rules by specifying that noncompliance with the rules may constitute unprofessional conduct under the board's practice act.
- (b) Standards for the use of opioids for the management or treatment of acute pain:
  - (1) Limiting the amount of days for an opioid prescription issued in an emergency department, urgent care setting, or walk-in clinic. This specific duration limit shall be set by each board no later than August 1, 2016 taking into consideration the recommendation from a majority vote of a policy group consisting of the chief medical officer of the department of health and human services, a physician designated by the New Hampshire chapter of the American College of Emergency Physicians, a physician designated by the New Hampshire Hospital Association, an advanced practice registered nurse designated by the New Hampshire Nurse Practitioner Association, a physician or advanced practice registered nurse designated by the governor, a board certified surgeon designated by the New Hampshire Medical Society, and an oral surgeon designated by the New Hampshire Dental Society. Five members of the policy group shall constitute a quorum. All policy group meetings shall be open to the public and noticed in the house and senate calendars.
  - (2) In settings where continuity of care is anticipated, each board shall establish finite limits considering dose and duration of opioid prescriptions for treatment of acute pain and appropriate timing of office follow up for persistent, unresolved acute pain.
- (c) Standards for the use of opioids for the management or treatment of chronic pain:
  - (1) Mandatory use of written treatment agreements, such as the agreement developed by the American Academy of Pain Medicine. Treatment agreements shall include conduct that triggers the discontinuation or tapering of opioid prescriptions.
  - (2) Establishing a requirement for periodic review conducted at reasonable intervals to reevaluate treatment plans and use of opioids.
  - (3) Establishing a procedure for, and documenting consideration of, consultation with, or referral to a specialist for patients receiving a high morphine equivalent dose for longer than 90 days.
  - (4) Creating exemptions to the prescribing rules for situations in which an opioid is being

prescribed for the management of chronic pain for:

- (A) Patients with cancer pain;
- (B) Patients with a terminal condition;
- (C) Long-term, nonrehabilitative, residents of a nursing home facility.

III. [Repealed.]

IV. [Repealed.]

V. At a minimum, each board's Internet website shall include online links to board approved:

- (a) Continuing education on the prescribing of opioids.
- (b) Screening tools.
- (c) Treatment agreements.
- (d) Risks and benefits of opioid use.
- (e) Proper storage of opioids.
- (f) Proper disposal of unused opioids.

**Source.** 2016, 213:1, eff. June 7, 2016 except for RSA 318-B:41, pars. II(a)(4) and IV(a)(4) eff. Jan. 1, 2017. 2017, 128:4, eff. Aug. 15, 2017. 2019, 28:1, eff. July 14, 2019.

## **Section 318-B:42**

**318-B:42 Repealed by 2016, 309:3, eff. Nov. 1, 2016. –**

# **Syringe Service Programs**

## **Section 318-B:43**

### **318-B:43 Syringe Service Programs Authorized. –**

I. (a) The following entities, if self-funded, may operate a syringe service program in New Hampshire to prevent the transmission of disease and reduce morbidity and mortality among individuals who inject drugs, and those individuals' contacts:

- (1) Federally qualified health centers.
- (2) Community health centers.
- (3) Public health networks.
- (4) AIDS service organizations.
- (5) Substance misuse support or treatment organizations.
- (6) Community based organizations.

(b) The commissioner of the department of health and human services shall adopt rules, pursuant to RSA 541-A, further defining the entities in subparagraph (a).

II. Any entity operating a syringe service program in New Hampshire shall:

- (a) Provide referral and linkage to HIV, viral hepatitis, and substance use disorder prevention, care, and treatment services, as appropriate.
- (b) Coordinate and collaborate with other local agencies, organizations, and providers involved in comprehensive prevention programs for people who inject drugs to minimize duplication of effort.
- (c) Attempt to be a part of a comprehensive service program that may include, as appropriate:
  - (1) Providing sterile needles, syringes, and other drug preparation equipment and disposal services.

- (2) Educating and counseling to reduce sexual, injection, and overdose risks.
- (3) Providing condoms to reduce risk of sexual transmission of viral hepatitis, HIV, or other STDs.
- (4) Screening for HIV, viral hepatitis, STDs, and tuberculosis.
- (5) Providing naloxone to reverse opioid overdoses.
- (6) Providing referral and linkage to HIV, viral hepatitis, STD and tuberculosis prevention, treatment, and care services, including antiretroviral therapy for hepatitis C virus (HCV) and HIV, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother-to-child transmission, and partner services.
- (7) Providing referral and linkage to hepatitis A virus (HAV) and hepatitis B virus (HBV) vaccination.
- (8) Providing referral and linkage to and provision of substance use disorder treatment including medication assisted treatment for opioid use disorder which combines drug therapy such as methadone, buprenorphine, or naltrexone with counseling and behavioral therapy.
- (9) Providing referral to medical care, mental health services, and other support services.
- (d) Post its address, phone number, program contact information, if appropriate, hours of operation, and services offered on its Internet website.
- (e) Register with the department of health and human services and confirm registration annually on or before November 1 of each subsequent year; provided however, the registration process shall be limited to notification to the department for data collection purposes only.
- (f) Report quarterly to the department, which report shall include the following information regarding the program's activities:
  - (1) Number of needles/syringes distributed.
  - (2) Number of needles/syringes taken back.
  - (3) Number of HIV tests performed or delivered by the program.
  - (4) Number of HCV tests performed/delivered by program.
  - (5) Delivery of substance misuse treatment/care.
  - (6) Delivery of HIV care.
  - (7) Delivery of HCV care.
  - (8) Number of referrals to substance misuse treatment/services.
  - (9) Number of referrals to HIV testing.
  - (10) Number of referrals to HCV testing.
  - (11) Number of referrals to HIV care.
  - (12) Number of referrals to HCV care.

III. Nothing in this section shall be construed to prohibit the department of health and human services from administering and/or disbursing federal or other funds to syringe service programs authorized under this section. The use of state general funds shall be prohibited unless otherwise appropriated by the general court or if deemed necessary to control a disease outbreak pursuant to RSA 141-C:3.

**Source.** 2017, 117:7, eff. June 16, 2017. 2019, 154:1, eff. July 1, 2019.

## **Section 318-B:44**

**318-B:44 Syringe Service Programs; Affirmative Defense.** – It is an affirmative defense, as provided in RSA 626:7, to prosecution for possession of a hypodermic syringe or needle that the

item was obtained through participation in a syringe service program. Nothing in this section shall be construed as an affirmative defense for any offense other than as set forth under RSA 318-B:26, II(f).

**Source.** 2017, 117:7, eff. June 16, 2017.

### **Section 318-B:45**

**318-B:45 Syringe Service Programs in Drug-Free School Zones Prohibited.** – No syringe service program shall be located within a drug-free school zone as defined in RSA 193-B:1, II. Exceptions to this prohibition may be granted by the applicable district school board when a request is initiated by a syringe service program administrator.

**Source.** 2017, 117:7, eff. June 16, 2017. 2018, 254:2, eff. Aug. 11, 2018.

## **Commission to Study the Legalization, Regulation, and Taxation of Marijuana**

### **Section 318-B:46**

**318-B:46 Repealed by 2017, 235:2, eff. Nov. 2, 2018. –**

## **Ephedrine and Pseudoephedrine**

### **Section 318-B:47**

#### **318-B:47 Definitions. –**

In this subdivision:

I. "Distributor" means a person, other than a manufacturer or wholesaler, that sells, delivers, transfers, or in any manner furnishes a drug product to any person that is not the ultimate user or consumer of the product.

II. "Knowingly" means having actual knowledge of the relevant facts.

III. "Manufacturer" means a person that produces, compounds, packages, or in any manner initially prepares a drug product for sale or use.

IV. "Wholesaler" means a person, other than a manufacturer, that sells, transfers, or in any manner furnishes a drug product to any other person for the purpose of being resold.

**Source.** 2018, 124:1, eff. Jan. 1, 2019.

### **Section 318-B:48**

#### **318-B:48 Possession of Ephedrine and Pseudoephedrine; Sale. –**

I. No person shall knowingly and unlawfully possess a drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine with the intent to use the product as a precursor to

manufacture methamphetamine or another controlled substance.

II. A drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine shall not be distributed at retail to the general public unless it is maintained in a locked display case or behind the counter out of the public's reach.

III. (a) A retail establishment shall not knowingly complete a sale to a person if the drug product or combination of drug products purchased would surpass a total of more than 3.6 grams within a 24-hour period or 9 grams within a 30-day period of ephedrine base, pseudoephedrine base, or phenylpropanolamine base or their isomers. The "base" form means the fraction of ephedrine, pseudoephedrine, or phenylpropanolamine present within a formulation containing a salt form of those respective drugs.

(b) This section shall not apply to drug products dispensed pursuant to a valid prescription.

**Source.** 2018, 124:1, eff. Jan. 1, 2019.

## **Section 318-B:49**

### **318-B:49 Electronic Registry System. –**

I. (a) Retail establishments shall use an electronic registry system to record the sale of products made pursuant to RSA 318-B:48. The electronic registry system shall have the capacity to block a sale of nonprescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine that would result in a purchaser exceeding the lawful daily or monthly amount. The system shall contain an override function that may be used by an agent of a retail establishment who is dispensing the drug product and who has a reasonable fear of imminent bodily harm to his or her person or to another person if the transaction is not completed. The system shall create a record of each use of the override mechanism.

(b) The electronic registry system shall be available free of charge to the state of New Hampshire, retail establishments, and local law enforcement agencies.

(c) The electronic registry system shall operate in real time to enable communication among in-state users and users of similar systems in neighboring states.

(d) The state shall use the National Precursor Log Exchange (NPLEx) online portal or its equivalent to host New Hampshire's electronic registry system.

II. (a) Prior to completing a sale under RSA 318-B:48, a retail establishment shall require the person purchasing the drug product to present a current, valid government-issued identification document. The retail establishment shall record in the electronic registry system:

(1) The name and address of the purchaser;

(2) The name of the drug product and quantity of ephedrine, pseudoephedrine, and phenylpropanolamine sold in grams;

(3) The date and time of purchase;

(4) The form of identification presented, the issuing government entity, and the corresponding identification number; and

(5) The name of the person selling or furnishing the drug product.

(b)(1) If the retail establishment experiences an electronic or mechanical failure of the electronic registry system and is unable to comply with the electronic recording requirement, the retail establishment shall maintain a written log or an alternative electronic recordkeeping mechanism until the retail establishment is able to comply fully with this subdivision.

(2) If the region of the state where the retail establishment is located does not have broadband

Internet access, the retail establishment shall maintain a written log or an alternative electronic recordkeeping mechanism until broadband Internet access becomes accessible in that region. At that time, the retail establishment shall come into compliance with this subdivision.

(c) A retail establishment shall maintain all records of drug product purchases made pursuant to this subdivision for a minimum of 2 years.

III. A retail establishment shall display a sign at the register provided by NPEEx or its equivalent to notify purchasers of drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine that:

(a) The purchase of the drug product or products shall result in the purchaser's identity being listed on a national database; and

(b) The purchaser has the right to request the transaction number for any purchase that was denied pursuant to this subdivision.

**Source.** 2018, 124:1, eff. Jan. 1, 2019.

### **Section 318-B:50**

#### **318-B:50 Penalty; Exemption. –**

I. Any person who violates this subdivision shall be guilty of a class A misdemeanor.

II. This subdivision shall not apply to a manufacturer that has obtained an exemption from the Attorney General of the United States under section 711(d) of the federal Combat Methamphetamine Epidemic Act of 2005.

**Source.** 2018, 124:1, eff. Jan. 1, 2019.

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## **NH Code of Administrative Rules**

### **Ph 100 – Ph 2000**

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#### **CHAPTER Ph 100 ORGANIZATIONAL RULES**

##### **PART Ph 101 PURPOSE AND SCOPE**

Ph 101.01 Purpose and Scope. The rules of this title implement the statutory responsibilities of the New Hampshire board of pharmacy created by RSA 318, as amended, and RSA 318-B, as amended. These provisions regulate the licensing of pharmacies and pharmacists, the practice of pharmacy in the state of New Hampshire, the safekeeping and distribution of pharmaceuticals and legend drugs, and the inspection of pharmacies and other licensed and unlicensed locations where legend drugs are held, stored or offered for sale.



## ***NH Pharmacy Laws & Rules as of 10/29/2019***

Source. #1856, eff 11-9-81; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-A, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-A, eff 2-5-96

### **PART Ph 102 DEFINITIONS**

Ph 102.01 Statutory Definitions Adopted. All terms used in these rules shall have the same meaning as in RSA 318:1, RSA 318-B:1 and RSA 541-A:1.

Source. #1639, eff 11-1-80; amd by #1856, eff 11-9-81; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-A, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-A, eff 2-5-96

#### **Ph 102.02 Other Definitions.**

- (a) "Board" means the New Hampshire board of pharmacy created by RSA 318.
- (b) "Evidence" means all oral or documentary material received by the board. Evidence includes, but is not limited to, testimony under oath or affirmation, documents, exhibits, and sworn statements of witnesses who are unable to appear at the proceedings.
- (c) "Executive secretary" means the board's staff director, a person with delegated authority to perform administrative and clerical functions for the board.
- (d) "Licensed" means a person or place lawfully authorized to engage in the practice of pharmacy under RSA 318:18 and RSA 318:37 and includes "registered" when used to refer to pharmacists or pharmacies.
- (e) "Order" means the whole or any part of the final decision, whether affirmative, negative or declaratory in form, of the board in any matter other than rulemaking, but including licensing. An order has particularized effect on each party to the proceeding.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-A, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-A, eff 2-5-96

### **PART Ph 103 AGENCY ORGANIZATION**

Ph 103.01 Composition. The New Hampshire board of pharmacy is composed of 7 board members, appointed by the governor and council for a term of 5 years, limited to no more than 2 consecutive terms. At least one member shall be a hospital pharmacist, and one member shall be a public member.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-A, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-A, eff 2-5-96, EXPIRED 8-8-10 pursuant to RSA 541-A:17, II

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New. #10117, *eff 4-20-12*

Ph 103.02 Officers. Annually, in September, the board members shall elect, from among their number, a president, a vice president, a secretary and a treasurer.

Source. #6181-A, *eff 2-5-96*

Ph 103.03 Address.

(a) The board shall maintain an office at 121 South Fruit Street, Concord, N.H. 03301. All correspondence with the board shall be addressed as follows:

State of New Hampshire Board of Pharmacy  
121 South Fruit Street  
Concord, New Hampshire 03301.

(b) The telephone number of the board shall be (603) 271-2350. The fax number shall be (603) 271-2856.

Source. #6181-A, *eff 2-5-96*

Ph 103.04 Meetings.

(a) The board shall meet in its office on the third Wednesday of each month. Special meetings shall be held at the call of the president or by any officer.

(b) A majority of the board may take action by telephone poll or written ballot provided that such action is ratified at a subsequent meeting of the board.

Source. #6181-A, *eff 2-5-96*

### **PART Ph 104 PUBLIC INFORMATION**

Ph 104.01 Records. Except as exempted by law, all records of the board may be examined by any person at the board office, during weekdays, excluding holidays, from 8:00 a.m. to 4:00 p.m.

Source. #6181-A, *eff 2-5-96*

Ph 104.02 Copies.

(a) At the time and place identified in Ph 104.01, any person examining a document may make a copy of that document by any means not injurious to the document provided that the person wishing to make the copy supplies the means of doing so in the office of the board. In the event a person does not have a means of copying those documents, the board shall make copies of the documents examined upon request.

(b) The prescribed fee for copies of documents made by this board shall be a minimum of \$5.00 which includes up to 20 pages then 0.25¢ for each additional page thereafter and shall be payable in advance by bank draft, money order, certified check or cash.

Source. #6181-A, *eff 2-5-96*

Ph 104.03 Lists of Licensees/Registrants.

## ***NH Pharmacy Laws & Rules as of 10/29/2019***

(a) Instead of the examination and copying permitted by Ph 104.01 and Ph 104.02, any person may request the board to provide that person with a complete mailing list of the board's licensees/registrants. This request shall be accompanied by the prescribed fee for each list requested and shall be paid by check or money order.

(b) The fees for the lists shall be:

(1) Pharmacist data file by e-mail	\$125.
(2) Pharmacist data file on CD-ROM	\$150.
(3) Pharmacist pre-printed mailing labels	\$200.
(4) Pharmacy Technician data file by e-mail	\$125.
(5) Pharmacy Technician data file on CD-ROM	\$150.
(6) Pharmacy Technician pre-printed mailing labels	\$200.
(7) In-State Pharmacy data file by e-mail	\$ 75.
(8) In-State Pharmacy data file on CD-ROM	\$100.
(9) In-State Pharmacy pre-printed mailing labels	\$150.
(10) Out-of-State Pharmacy data file by e-mail	\$ 75.
(11) Out-of-State Pharmacy data file on CD-ROM	\$100.
(12) Out-of-State Pharmacy pre-printed mailing labels	\$150.
(13) Drug Manufacturer/Wholesaler data file by e-mail	\$ 75.
(14) Drug Manufacturer/Wholesaler data file on CD-ROM	\$100.
(15) Drug Manufacturer/Wholesaler pre-printed mailing labels	\$150.

Source. #6181-A, eff 2-5-96; ss by #9139-A, eff 4-25-08

### CHAPTER Ph 200 PRACTICE AND PROCEDURE

#### PART Ph 201 INTRODUCTION AND DEFINITIONS

Ph 201.01 Procedure Governed. This chapter governs practice and procedure before the board in both adjudicative and non-adjudicative proceedings.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 201.02 Definitions.

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(a) "Adjudicative proceeding" means the procedure to be followed in contested cases, as set forth in RSA 541-A:31 through RSA 541-A:36.

(b) "Board" means the New Hampshire pharmacy board.

(c) "Declaratory ruling" means a ruling by the board as to the specific applicability of any statutory provision or of any rule or order of the board.

(d) "Licensee" means a person, partnership, corporation, or any other legal or commercial entity however organized, duly licensed by the board pursuant to the provisions of RSA 318, RSA 318-B, or other applicable law.

(e) "Opponent" means any person who objects, on the grounds of public or private interest, to the approval, determination, consent, certification or authorization of any petition which the board might have under consideration.

(f) "Party" means each person named or admitted as a party, or properly seeking and entitled as a right to be admitted as a party in an adjudicative proceeding.

(g) "Presiding officer" means the board president or an individual to whom the board president has delegated the authority to preside over an adjudicative proceeding, a rehearing, or a rulemaking hearing.

(h) "Proponent" means any person who supports, on the grounds of public or private interest, the approval, determination, consent, certification or authorization of any petition which the board may have under consideration.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

### **PART Ph 202 FILING AND SERVICE OF DOCUMENTS**

#### **Ph 202.01 Filing of Documents.**

(a) A document shall be considered filed when it is actually received at the board's office in Concord and conforms to the requirements of this chapter.

(b) All documents filed shall be either originals or legible copies bearing original signatures. Only a single copy of routine correspondence, license applications, and consumer complaints against licensees shall be filed.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 202.02 Subscription and Veracity of Documents.

(a) All complaints, petitions, motions, and replies filed with the board shall be signed by the proponent of the document or, if the party appears by a representative, by the representative.

(b) The signature on a document filed with the board shall constitute a certification that:

- (1) The signor has read the document;
- (2) The signor is authorized to file it;
- (3) To the best of the signor's knowledge, information, and belief, there are good grounds to support it; and
- (4) The document has not been filed for purposes of delay or harassment.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 202.03 Service of Documents.

(a) Complaints against licensees of the board shall be filed with the board without service upon the licensee which is the subject of the complaint.

(b) Petitions for rulemaking and petitions for declaratory rulings shall be filed with the board without service upon other persons.

(c) All motions, replies, exhibits, memoranda, or other documents filed in an adjudicatory proceeding shall be served by the proponent upon all parties to the proceeding by:

- (1) Sending a copy of the document by U.S. mail, first class postage prepaid, addressed to the last address given to the board by the party being served, no later than the day the document is filed with the board; or
- (2) Delivering a copy of the document in hand on or before the date it is filed with the board.

(d) All notices, orders, decisions or other documents issued by the board in the course of an adjudicatory proceeding shall be served by the board upon all parties to the proceeding by either:

- (1) Sending a copy of the document by U.S. mail, first class postage prepaid, addressed to the last address given to the board by the party being served; or
- (2) Delivering a copy of the document in hand to the party.

(e) When a party has appeared by a representative, service shall be upon the representative.

(f) Except for exhibits distributed at a prehearing conference or a hearing, every document filed with the board and required to be served upon the parties to an adjudicatory proceeding shall be accompanied by a certificate of service, signed by the person making service, attesting to the method and date of service, and the persons served.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 202.04 Voluntary Production of Information.

(a) Each party and intervenor shall attempt in good faith to make complete and timely response to requests for the voluntary production of information and documents relevant to the hearing.

(b) When a dispute arises concerning a request for the voluntary production of information or documents, any party or intervenor may file a motion to compel the production of the requested information or documents.

Source. #8315-A, eff 3-26-05

Ph 202.05 Motions to Compel Production of Information and Documents.

(a) Any party or intervenor may make a motion seeking an order for compliance with an information or document request. The motion shall be filed at least 20 days before the date scheduled for the hearing and in any event as soon as possible after receiving the notice of the hearing and failing in an attempt to obtain the requested information or documents through voluntary production.

(b) The motion to compel shall:

- (1) Set forth in detail those facts which justify the request for information or documents; and
- (2) List with specificity the information or documents being sought.

(c) Objections to motion to compel shall be filed within 10 days of the delivery of the motion.

(d) The presiding officer shall grant the motion to compel if its proponent has demonstrated that an order for compliance is necessary for a full and fair presentation of evidence at the hearing.

Source. #8315-A, eff 3-26-05

PART Ph 203 HEARINGS AND PROCEEDINGS

Ph 203.01 Mandatory Pre-Hearing Disclosure of Witnesses and Exhibits. At least 5 days before the hearing, the parties and intervenors shall provide to the other parties and intervenors:

(a) A list of witnesses intended to be called at the hearing including the names, their addresses and their telephone numbers;

(b) Brief summaries of the testimony of the witnesses to be called;

(c) A list of documents and exhibits intended to be offered as evidence at the hearing;

(d) A copy of each document intended to be offered as evidence at the hearing; and

(e) An offer to allow the inspection on non-documentary exhibits intended to be offered as evidence at the hearing at times and places of convenience to the parties and intervenors.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 203.02 Representatives.

(a) Any person may represent himself/herself in a proceeding before the board or may be represented by an attorney or a competent individual of good character.

(b) A representative under (a) above shall be someone who:

(1) Is an attorney holding a current and active New Hampshire license who has filed a written appearance with the board containing his or her business address and telephone number; or

(2) Is not a New Hampshire licensed attorney, but has filed a motion for leave to appear as a representative which has been granted by the board.

(c) Motions made pursuant to Ph 203.01 (b)(2) shall:

(1) Describe the proposed representative's qualifications including, but not limited to, the following:

a. Education;

b. Experience serving in a representative capacity before administrative agencies, boards, or commissions; and

c. Present employment.

(2) Provide the proposed representative's daytime address and telephone number; and

(3) Be signed by both the proposed representative and the party who would be represented.

(d) The board shall grant a motion made pursuant to Ph 203.01 (b) (2) if the proposed representative does not have a history of dishonesty or felonious acts.

(e) Nothing in this section shall be construed to permit the unauthorized practice of law.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 203.03 Computation of Time. Any time period specified in this chapter shall begin with the day following the act, event, or default, and shall include the last day of the period, unless it is a Saturday, Sunday, or state legal holiday, in which event the period shall run until the end of the next day which is not

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a Saturday, Sunday, or state legal holiday. When the period prescribed or allowed is less than 7 days, intermediate Saturdays, Sundays, and state legal holidays shall be excluded from the computation.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

**Ph 203.04 Change in Allowed Times.**

(a) Except where a time period is fixed by statute, a party may file a motion to change a time period which shall set forth specific facts to support their request to enlarge or shorten the time provided for the filing of any document, or advance or postpone the time set for any oral hearing, prehearing conference, or other activity.

(b) The board shall grant such motion:

- (1) If all parties consent; or
- (2) For good cause shown from the facts presented.

(c) Good cause under (b) (2) above shall include the following:

- (1) Unavoidable unavailability of witnesses, parties, their attorneys, or their authorized representatives; or
- (2) Other exigent circumstances beyond the control of the parties, their attorneys, or their representatives.

(d) A consent of the parties under (b)(1) above shall be:

- (1) Made in writing;
- (2) Signed by all parties; and
- (3) Filed with the board prior to a scheduled date or the expiration of a time period.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

**Ph 203.05 Recess and Adjournment.**

(a) The presiding officer shall recess or adjourn any proceeding for good cause, which shall include but not be limited to the following:

- (1) Other exigent business of the board;



- (2) The end of the business day; or
- (3) Inclement weather.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 203.06 Waiver.

(a) Any interested person may request the board to waive or suspend provisions of the Ph 200 rules by filing an original and 2 copies of a petition which identifies the rule in question and sets forth specific facts and arguments which support the requested waiver.

(b) Petitions for rule waivers shall address whether:

(1) Adherence to the rule would cause the petitioner hardship. "Hardship" in this context means that because of petitioner's unique circumstances strict adherence to a rule would be unreasonable or result in unfair advantage to another party.

(2) Other good cause for waiving the rule exists, including the following:

- a. Repeal or amendment of the enabling statute for provisions of rules from which a waiver is sought; or
- b. Other circumstances which render a rule inapplicable, unenforceable, or illegal.

(c) If examination of the petition reveals that other persons would be substantially affected by the proposed relief, the board shall require service of the petition on such persons and advise them that they may file a reply to the petition.

(d) Petitions for waiver shall be acted upon by the board within 45 days of receipt. The board shall give written notice of the decision to all interested parties.

(e) A granted waiver shall only apply to the proceedings under review at the time of the petition.

(f) Provisions of Ph 200 rules which include provisions of New Hampshire statutes shall not be waived.

(g) A consent of the parties under (f) above shall:

- (1) Be made in writing;
- (2) Identify the specific rule provision to which the waiver applies;
- (3) Be signed by all parties; and
- (4) Be filed with the board.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600,

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eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95,  
EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 203.07 Docket. The board shall maintain a docket of all proceedings, hearings, and rehearings pending before the board.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 203.08 Consolidation.

(a) A party may file a motion to consolidate whenever 2 or more proceedings involve substantially similar or related issues.

(b) A motion to consolidate may include a request for a single hearing, a single decision, or both.

(c) The board shall grant a motion to consolidate upon finding that:

(1) A requested consolidation would further the interests of fairness and efficiency; and

(2) A requested consolidation would not impair consideration of the issues presented by each individual matter.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 203.09 Severance.

(a) A party may file a motion to sever one or more issues from a proceeding and dispose of those issues in another proceeding whenever it shall appear that injury to the substantive rights of a party or undue delay might be thereby avoided.

(b) The board shall grant a motion for severance upon finding that:

(1) A requested severance would further the interests of fairness and efficiency; and

(2) A requested severance would not impair the proceeding from which the issue or issues are removed.

Source. #8315-A, eff 3-26-05

PART Ph 204 ADJUDICATIVE PROCEEDINGS

Ph 204.01 Applicability. This part shall govern adjudicative proceedings before the board.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.02 Place of an Adjudicative Proceeding. Adjudicative proceedings before the board shall be held at the offices of the board, 121 South Fruit Street, Concord, New Hampshire.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.03 Commencement of Adjudicative Proceeding.

(a) Pursuant to RSA 541-A:31, II, the board shall commence an adjudicative proceeding at any time as a result of the following actions by a licensee:

- (1) Failure to file requisite reports within 30 days of applicable deadlines;
- (2) Failure to pay fees or fines within 60 days of invoice date;
- (3) Engaging in licensed activity with a suspended, revoked, or expired license;
- (4) Failure to allow board personnel access, authorized by law, to the books, papers, records, files or similar documents for purposes of conducting examinations; or
- (5) Any other failure to comply with the laws, rules or orders of the board governing the licensee's activities.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.04 Notice.

(a) Notice of an adjudicative proceeding shall be governed by the following provisions, unless otherwise provided by law:

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- (1) The board shall give written notice to a party at least 30 days prior to a scheduled hearing date by first class mail, postage prepaid, or by personal service upon a party or a party's agent;
- (2) Contents of the notice shall be governed by the provisions of RSA 541-A:31, III.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.05 Continuances.

(a) Any party or intervenor may make an oral or written motion that a hearing be delayed or continued to a later date or time.

(b) A motion for a delay or a continuance shall be granted if the presiding officer determines that a delay or continuance would assist in resolving the case fairly.

(c) If the later date, time and place are known when the hearing is being delayed or continued, the information shall be stated on the record. If the later date, time and place are not known at that time, the presiding officer shall as soon as practicable issue a written scheduling order stating the date, time and place of the delayed or continued hearing.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.06 Emergency Orders.

(a) Pursuant to RSA 318:30-a, if the board finds that public welfare requires emergency action against a licensee, and the board incorporates a finding to that effect in an order, the board shall order the immediate suspension of a license pending an adjudicative proceeding which shall be commenced not later than 30 working days after the date of the board's order suspending the license.

(b) An emergency order shall be served upon the licensee by certified mail-return receipt requested, or by personal service upon the licensee, or by personal service upon the licensee's agent as identified on the most recent license application submitted to the board.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

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### **Ph 204.07 Intervention.**

(a) A person filing a complaint which becomes the subject of a disciplinary hearing shall be served with the hearing notice and notified that he/she may petition to intervene in the proceeding.

(b) The board shall grant one or more petitions for intervention if:

(1) The petition is submitted in writing to the board, with copies mailed to all parties named in the notice of hearing, at least 3 days before the hearing;

(2) The petition states facts demonstrating that the petitioner's rights, duties, privileges, immunities or other substantial interests might be affected by the proceeding; and

(3) The interests of justice and the orderly and prompt conduct of the proceedings would not be impaired by allowing the intervention.

(c) Once granted leave to intervene, an intervenor shall enter the proceeding as it stands at the time. No portion of the proceeding shall be repeated because of the fact of intervention.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

### **Ph 204.08 Access to Board Records.**

(a) Parties shall have access to any statements, documents, or other information in the board's files pertinent to an adjudicative proceeding. However, confidential information pursuant to RSA 318:30,I, including consumer complaints and confidential material otherwise protected by law shall not be disclosed or provided to any party other than the board.

(b) The intervenor shall have access to all materials permitted by Ph 204.07 (a).

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

**Ph 204.09 Filing Requirements.** Copies of all documents, pleadings, motions, objections, requests, memorandums, correspondence, accounts, and the like, which are filed by a party with the board shall be provided to other parties to the same proceeding as follows:

(a) A party shall send copies of all documents filed by first class mail, postage prepaid, to all other parties, or shall deliver such documents in hand to all other parties; and

(b) A party shall certify compliance with Ph 204.08 (a) by submitting a certificate of service with the documents filed.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.10 Stipulations. The parties to an adjudicative proceeding may by written stipulation agree upon facts or issues of proof relating to the subject matter of the proceeding. The stipulation shall be filed with the board and approved by the presiding officer in order to be considered in rendering a decision.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.11 Evidence.

(a) Proceedings shall not be conducted under the rules of evidence, but the evidentiary privileges recognized by the law of New Hampshire shall apply to proceedings under this chapter.

(b) Pursuant to RSA 541-A:33, II, the board shall receive all material and relevant evidence bearing upon the subject matter of the proceeding.

(c) The presiding officer shall determine the admissibility of evidence and shall exclude irrelevant, immaterial or unduly repetitious evidence.

(d) All witnesses appearing before the board shall testify under oath or affirmation and subject to the penalties specified in RSA 641:1 and RSA 641:2.

(e) Oaths or affirmations shall be administered by the presiding officer.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.12 Withdrawal of Presiding Officer.

(a) Upon his or her own initiative or upon the motion of any party or intervenor, the presiding officer shall withdraw from any adjudicative proceeding for good cause.

(b) Good cause shall exist if the presiding officer:

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- (1) Has a direct interest in the outcome of the matter, including but not limited to, a financial or family relationship with any party or intervenor;
- (2) Has made statements or engaged in behavior which objectively demonstrates that he or she had prejudged the facts of the case; or
- (3) Personally believes that he or she cannot fairly judge the facts of the case.

(c) Mere knowledge of the issues or acquaintance with any party, intervenor or witness shall not constitute good cause for withdrawal.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

**Ph 204.13 Hearing Procedure.**

(a) After calling the hearing to order, the presiding officer shall identify the proceeding for the record by name and docket number, shall briefly state the nature of the proceeding, and shall request those present to identify themselves for the record.

(b) The presiding officer shall afford an opportunity for opening statements or direct testimony by the board representative and the licensee or licensee's representative.

(c) After any opening statements, the board representative shall present witnesses and exhibits, followed by presentation of witnesses and exhibits by the licensee or licensee's representative.

(d) Opportunity shall be afforded to either party to cross-examine each witness of the other party at the conclusion of the witness's direct testimony.

(e) The presiding officer shall if additional information is required pose questions to any witness during or subsequent to direct testimony or cross-examination.

(f) After all testimony and evidence is presented, the presiding officer shall allow closing statements by the board representative and by the licensee or licensee's representative.

(g) After all information has been presented, the presiding officer shall declare the hearing closed.

(h) The presiding officer shall afford intervenors the same opportunities for presenting testimony, evidence, or witnesses, and for conducting cross-examinations and for making closing statements as other parties to the proceeding.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

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Ph 204.14 Burden of Proof.

(a) The party asserting the affirmative of a proposition shall have the burden of proving the truth of that proposition by a preponderance of the evidence.

(b) Without limiting the generality of Ph 204.12 (a), all moving parties and all petitioners shall have the burden to show that their motion or petition should be granted.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.15 Decisions.

(a) If the board finds that the licensee has complied with the statutory requirements and the rules adopted pursuant thereto, the board shall enter a decision favorable to the licensee.

(b) If the board finds that the licensee has not complied with the statutory requirements or any rule adopted pursuant thereto, the board shall enter a decision adverse to the licensee.

(c) The board's decision shall be set forth in writing.

(d) The decision shall include findings of fact and conclusions of law, separately stated.

(e) If any party has submitted proposed findings of fact, the board's decision shall include a ruling on each proposed finding.

(f) The board shall give written notice of decisions to parties within 7 days after the date of decision by first class mail, postage prepaid.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 204.16 Failure to Appear.

(a) Failure of a licensee to appear in person or by representative at the adjudicative proceeding shall constitute a default.

(b) A default for failure to appear shall constitute:

- (1) A waiver of licensee's right to an adjudicative proceeding;
- (2) Admission of the facts alleged; and
- (3) Consent to the board's determination on the matter.



(c) The board shall strike a default for failure to appear based upon a written request and information submitted by the licensee within 7 days after the originally scheduled hearing date which sets forth good cause. Good cause shall include illness, accident, the death of family member, or other circumstances beyond the control of the licensee.

(d) The board shall give written notice to parties of a decision either to grant or deny a request to strike a default for failure to appear within 7 days of the date of decision by first class mail, postage prepaid.

(e) If a request to strike a default for failure to appear is granted, the board shall give notice of a re-scheduled hearing in accordance with Ph 204.04.

Source. #8315-A, eff 3-26-05

Ph 204.17 Informal Settlement.

(a) Any informal settlement of matters by nonadjudicative processes shall be reflected in writing and made part of the record for a particular matter.

Source. #8315-A, eff 3-26-05

PART Ph 205 REHEARINGS AND APPEALS

Ph 205.01 Motion for Rehearing.

(a) A motion for rehearing shall be considered only after a decision or order has been made by the board.

(b) Any party to the proceeding may apply for a rehearing in respect to any matter determined in the action or proceeding, or covered or included in the order.

(c) Motions for rehearing shall be filed with the board within 30 days of the date of the final decision or order.

(d) Motions for rehearing shall set forth fully every ground upon which it is claimed that the decision or order complained of is unlawful or unreasonable, or based upon a mistake of law or fact.

(e) A party may submit a memorandum of law in support of a motion for rehearing.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 205.02 Action on Motion for Rehearing.

(a) Pursuant to RSA 541:5, within 10 days of receiving a motion for rehearing, the board shall render a decision either to grant or deny the motion, or suspend the order or decision complained of pending further consideration.

(b) Pursuant to RSA 541:3, the board shall grant such motion if good reason for the rehearing is provided.

(c) Good reason shall include, but not be limited to, the following:

- (1) New information which was not available at the time of hearing;
- (2) A change in law relied upon by the board in reaching a decision on the hearing, including amendment or repeal of statutes or administrative rules, and changes in common law based upon decisions of the supreme court; or
- (3) Other factors beyond the control of the moving party causing the decision to be unreasonable or unlawful, or to be based upon a mistake of law or fact.

(d) The board shall give written notice of decision on a motion for rehearing to the parties within 7 days after the date of decision by first class mail, postage prepaid.

(e) If a motion for rehearing is granted, the board shall give written notice to the parties at least 30 days prior to the scheduled rehearing date by first class mail, postage prepaid, or by personal service.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 205.03 Burden of Proof. The burden of proof shall be on the moving party to show by preponderance of the evidence that the board's decision was unlawful or unreasonable, or was based upon a mistake of law or fact.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 205.04 Decisions.

(a) The board shall issue a written decision within 20 days of the date of the rehearing which clearly states the reasons for the decision.

(b) The decision shall include information on the rights of appeal to the supreme court pursuant to RSA 541, if the decision is adverse to the party who appeals.

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(c) The board shall keep a final decision in its records for at least 5 years following their dates of issuance, unless the director of the division of records management and archives of the department of state sets a different retention period pursuant to rules adopted under RSA 5:40.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

### **PART Ph 206 DECLARATORY RULINGS**

#### **Ph 206.01 Petitions.**

(a) A person may request a declaratory ruling from the board on matters within its jurisdiction by filing an original and 2 copies of a petition with the board.

(b) All petitions shall contain the following information:

- (1) The name and address of the petitioner;
- (2) The name and address of the petitioner's representative, if any;
- (3) A statement of the issue or question for which the petitioner seeks a declaratory ruling;
- (4) A statement of all relevant and material facts related to the petitioner's request; and
- (5) The identification of any statutes, rules, orders, or other legal authority which support the petitioner's request.

(c) A petition for a declaratory ruling may include the following:

- (1) Legal memoranda, supporting affidavits, tables, exhibits, and other relevant documentation; and
- (2) A statement explaining how the requested ruling would benefit the petitioner or the public at large.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

#### **Ph 206.02 Action on Petition.**

(a) Within 90 days of the receipt of the petition for a declaratory ruling, the board shall:

- (1) Respond to the petitioner in writing, stating the board's declaratory ruling on the issues or questions raised in the petition; and

(2) File the declaratory ruling with the director of legislative services in accordance with RSA 541-A:16, II (b).

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

## PART Ph 207 RULEMAKING PETITIONS

### Ph 207.01 Rulemaking Petitions.

(a) A person may request the adoption, amendment, or repeal of a board rule by filing an original and 2 copies of a rulemaking petition with the board.

(b) A rulemaking petition filed with the board shall include the following:

- (1) The name and address of the petitioner;
- (2) The name and address of the petitioner's representative, if any;
- (3) A statement of the justification for the adoption, amendment, or repeal of a rule;
- (4) Any supporting data, information, exhibits, illustrations, or other documentation;
- (5) The identification of any statutes, rules, orders, or other legal authority which support the petition; and
- (6) A draft of the proposed rule.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

### Ph 207.02 Incomplete Rulemaking Petitions.

(a) The board shall notify the petitioner of deficiencies in the petition within 15 days of the submission of a petition to adopt, amend, or repeal a rule.

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(b) Any corrected petition which is filed with the board shall be deemed to be the first submission of the petition for the purposes of applicable deadlines.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 207.03 Action on Rulemaking Petition.

(a) Within 30 days after the submission of a rulemaking petition, the board shall either grant or deny the petition and:

- (1) Notify the petitioner in writing of a decision to deny the petition with reasons for the denial clearly stated; or
- (2) Notify the petitioner in writing of a decision to grant the petition, and commence rulemaking proceedings by requesting a fiscal impact statement pursuant to RSA 541-A:5 within 120 days of receipt of the petition and continuing the proceeding in accordance with the applicable provisions of RSA 541-A:3.

(b) Any denial shall be based upon a finding by the board that:

- (1) The petition for rule or amendment or repeal of an existing rule would not be consistent with established standards for the practice of pharmacy and the licensees of the board;
- (2) The petition lacks rulemaking authority; or
- (3) The petition is contrary to legislative intent.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

PART Ph 208 RULEMAKING HEARINGS

Ph 208.01 Public Notice of Rulemaking Hearing. The board shall cause to be published in the New Hampshire Rulemaking Register a notice of its intent to conduct a rulemaking hearing pursuant to RSA 541-A:6.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 208.02 Presiding Officer.

(a) The presiding officer shall:

- (1) Maintain order during the rulemaking hearing, and order any person causing disorder or a disruption to the orderly conduct of the hearing to leave the hearing room;
- (2) Recognize speakers who have placed their names on the speakers list;
- (3) Receive all written comment that is submitted during the course of a hearing; and
- (4) Adjourn the hearing.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

Ph 208.03 Order of the Rulemaking Hearing. The hearing shall proceed as follows:

- (a) The presiding officer shall make opening remarks;
- (b) Proponents of the adoption, amendment or repeal of the rule shall be called by the presiding officer to provide comment;
- (c) Opponents of the adoption, amendment or repeal of the rule shall be called by the presiding officer to provide comment;
- (d) After all persons wishing to comment have been heard, the presiding officer shall receive any written comment not previously submitted to the board; and

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(e) After all written comment has been collected, the presiding officer shall make closing remarks and adjourn the hearing.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

### **Ph 208.04 Oral Comment.**

(a) Any proponent of or opponent to the adoption, amendment or repeal of a rule may make oral comment relative to such rule at the rulemaking hearing.

(b) In order to be recognized at the hearing, any person wishing to comment shall sign the speakers list at the hearing and wait to be called by the presiding officer.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

### **Ph 208.05 Written Comment.**

(a) Any proponent or opponent may submit written comment to the board pertaining to the adoption, amendment or repeal of a rule.

(b) All written comment relative to proposed rulemaking shall be submitted to the board in accordance with the notice of rulemaking, which shall set forth a deadline allowing a minimum of 5 days time after adjournment of the rulemaking hearing.

(c) Written comment shall be submitted by filing an original and 2 copies with the board.

Source. #1639, eff 11-1-80; ss by #1909, 1-7-82; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8315-A, eff 3-26-05

## **PART Ph 209 EXPLANATION OF ADOPTED RULES**

Ph 209.01 Requests for Explanation of Adopted Rules. Any interested person may, within 30 days of the final adoption of a rule, request a written explanation of that rule by making a written request to the board including:

(a) The name and address of the individual making the request; or

(b) If the request is that of an organization or other entity, the name and address of such organization or entity and the name and address of the representative authorized by the organization or entity to make the request.

Source. #8315-B, eff 3-26-05, EXPIRED: 3-26-13

New. #12484, eff 2-24-18

Ph 209.02 Contents of Explanation. The board shall, within 90 days of receiving a request in accordance with Ph 209.01, provide a written response which:

- (a) Concisely states the meaning of the rule adopted;
- (b) Concisely states the principal reasons for and against the adoption of the rule in its final form; and
- (c) States, if the board did so, why the board overruled any arguments and considerations presented against the rule.

Source. #8315-B, eff 3-26-05, EXPIRED: 3-26-13

New. #12484, eff 2-24-18

## CHAPTER Ph 300 LICENSING OF PHARMACISTS AND PHARMACIES

### PART Ph 301 LICENSING OF PHARMACISTS BY EXAMINATION

#### Ph 301.01 Application.

(a) Application form Ph A-1, revised September 2015, for licensure to practice the profession of pharmacy in New Hampshire may be obtained from the board or the board website accessible at [www.nh.gov/pharmacy/](http://www.nh.gov/pharmacy/);

(b) Applicants for licensure shall submit a completed form A-1 application for licensure and file it at the office of the board identified in Ph 103.03 along with:

- (1) A copy of the candidate's birth certificate;
- (2) A recent, full face photograph of the candidate;
- (3) An official final transcript sent directly from the college to the board office; and
- (4) The prescribed fee which shall be \$265.

(c) An official final transcript shall be mailed directly from the college to the board before either NAPLEX scores or New Hampshire licensure status is released, or, if a foreign graduate, the foreign graduate shall have completed a transcript verification program as provided by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification.

(d) The photograph required by Ph 301.01 (b)(2) shall be attached to the application form in the presence of a notary public or justice of the peace.



Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a), (d), (e) and subparagraphs (b)(1)-(b)(10) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; (b) intro., subparagraph (b)(11), and paragraph (c) EXPIRED: 2-1-07; paragraphs (a), (d), (e) and subparagraphs (b)(1)-(b)(10) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 301.02 Additional Requirements. In addition to any requirements imposed by statute, all candidates for a license to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

- (a) The candidate shall be not less than 18 years of age;
- (b) The candidate shall be of good professional character, and not have been convicted of any felony, or of a misdemeanor resulting from a violation of any drug and/or pharmacy-related law or rule;
- (c) The candidate shall have graduated with a doctor of pharmacy degree (PharmD) granted by a school of pharmacy, or a college of pharmacy, or a department of a pharmacy of a university;
- (d) To meet the requirements of (c) above, the school, college or department of pharmacy, shall be accredited by the Accreditation Council for Pharmacy Education (ACPE) or the Canadian Council for Accreditation of Pharmacy Programs (CCAPP).
- (e) If a foreign graduate, in lieu of (c) and (d) above, the candidate shall have graduated from a foreign college of pharmacy other than Canada and have obtained full certification from the FPGEC including:
  - (1) Passing the FPGEE with a score of at least 75; and
  - (2) Demonstrating proficiency in english by passing the Test Of English as a Foreign Language Internet Based Test (TOEFL iBT).
- (f) Prior to the examination date, the candidate shall:
  - (1) Have completed an internship in pharmacy which consists of:
    - a. At least 1500 hours, starting no earlier than 4 months prior to the third year of study in a college of pharmacy; and
    - b. Work predominantly related to the practice of pharmacy including, but not limited to:
      - 1. The selling of drugs and medical supplies;
      - 2. Interpreting, compounding, preparing and dispensing prescription orders;
      - 3. Preparing pharmaceutical products; and
      - 4. Keeping records and preparing reports required by federal and state statutes.
  - (2) Have completed the internship record form Ph A-3 revised September 2015 and submitted it to the board.

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(g) The candidate shall complete and pass the examinations described in Ph 301.03.

Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a)-(d) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraphs (e)-(g) EXPIRED: 2-1-07; paragraphs (a)-(d) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 301.03 Required Examinations. The examinations required for pharmacist licensure in New Hampshire shall be the National Association of Boards of Pharmacy Licensure Examination (NAPLEX) and the New Hampshire Multistate Pharmacy Jurisprudence Examination (NH MPJE) administered the National Association of Boards of Pharmacy (NABP).

Source. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99, EXPIRED: 2-1-07

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 301.04 Required Examination Score. To successfully complete the NAPLEX and NH MPJE examinations required by Ph 301.03, the candidate shall, on the initial examination or any subsequent re-examination permitted by Ph 301.05, obtain a score of not less than 75 on each examination.

Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (a) and subparagraphs (b)(1) and (b)(3) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (b) and subparagraphs (b)(2) and (b)(4) EXPIRED: 2-1-07; paragraph (a) and subparagraphs (b)(1) and (b)(3) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (from Ph 301.05)

Ph 301.05 Notice and Election of Re-examination.

(a) Any candidate who fails to obtain the minimum required score on either of the 2 examinations required in Ph 301.03 may elect to retake the examination.

(b) All candidates shall notify the board in writing whether he/she elects to be re-examined. The candidate for re-examination shall register and pay for the re-take examination through the National Association of Boards of Pharmacy online registration website accessible at [www.nabp.net](http://www.nabp.net).

Source. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99, EXPIRED: 2-1-07

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

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New. #11031, eff 1-29-16 (from Ph 301.06)

### Ph 301.06 Issuance or Denial of Original License.

(a) If candidate timely files an application, complete in all respects, successfully completes all examinations required by Ph 301 and demonstrates the complete fulfillment of the requirements of these rules, RSA 318, and RSA 318-B, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for an original license to practice pharmacy in New Hampshire fails to meet the requirements of these rules, or RSA 318, or both, the board shall deliver to the applicant a written denial of the application, specifying in detail the requirement which the candidate failed to meet, and how the candidate is deficient.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (formerly Ph 301.07)

## PART Ph 302 LICENSING OF PHARMACISTS BY RECIPROCITY

### Ph 302.01 Reciprocity.

(a) Instead of retaking the NAPLEX examination required by Ph 301.03, a candidate may transfer the actual score he or she attained on the NAPLEX administered by a state other than New Hampshire, provided that:

- (1) The candidate is still duly licensed and is in good standing in that state; and
- (2) All other New Hampshire pharmacist licensing requirements have been met.

Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; subparagraphs (a)(1)-(a)(3) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (a) intro. EXPIRED: 2-1-07; subparagraphs (a)(1)-(a)(3) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

### Ph 302.02 Application.

(a) The preliminary application for reciprocal licensure may be obtained from a link provided on the NH board of pharmacy website or from the National Association of Boards of Pharmacy, 1600 Feehanville Drive, Mount Prospect, Illinois, 60056, telephone number (847) 391-4406, website [www.nabp.net](http://www.nabp.net). This application shall be filed with the National Association of Boards of Pharmacy.

(b) Following verification of the applicant's credentials by NABP the applicant shall receive an official NABP license transfer application in the mail.

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(c) The candidate shall file a completed NABP license transfer application provided by the National Association of Boards of Pharmacy along with NH form Ph A-1, revised September 2015, application for initial licensure as a pharmacist in NH, and attach the following:

- (1) A copy of the candidate's birth certificate, or if born outside of the United States, a copy of the certificate of naturalization or passport showing date of birth;
- (2) A recent, full-face photograph of the candidate attached to the application;
- (3) An official copy of the candidate's pharmacy college transcript mailed directly from the college to the board, or if a foreign graduate, certification from the FPGEC; and
- (4) The application fee of \$265.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 302.03 Requirements. In addition to any requirements imposed by statute, all candidates for licensure by reciprocity to practice pharmacy in New Hampshire shall demonstrate that they possess the following qualifications:

- (a) The candidate shall be not less than 18 years of age;
- (b) The candidate shall be of good professional character as evidenced by the absence of conviction of any felony or of a misdemeanor resulting from a violation of any drug and/or pharmacy related law or rule;
- (c) The candidate shall possess a professional pharmacy baccalaureate degree or a doctor of pharmacy degree (PharmD) granted by a school of pharmacy, or a college of pharmacy, or a department of pharmacy of a university accredited by the Accreditation Council for Pharmacy Education (ACPE) or the Canadian Council for Accreditation of Pharmacy Programs (CCAPP);
- (d) A candidate who is a foreign pharmacy graduate, other than Canadian, in lieu of (c) above, shall provide written documentation that such candidate has:
  - (1) Obtained full certification from the FPGEC; and
  - (2) Passed NAPLEX;
- (e) The candidate shall be licensed and in good standing in the state from which he or she is seeking licensure transfer; and
- (f) The candidate for a reciprocal license shall complete and pass the NH MPJE examination on the current federal and state laws and rules governing the practice of pharmacy in the state of New Hampshire.

Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99;  
(a) intro. and subparagraphs (a)(1)-(a)(3) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; subparagraphs (a)(4) and

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(a)(5) EXPIRED: 2-1-07; (a) intro. and subparagraphs  
(a)(1)-(a)(3) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (from Ph 302.04)

Ph 302.04 Reciprocity Application Time Limitation. Candidates who fail to complete the MPJE examination, as required by Ph 302.03(f), within one year after the candidate's application is received at the board office shall have their application denied, but fees shall be retained by the board. If a candidate wishes to re-apply for New Hampshire licensure, a new application containing updated information shall be filed with the board.

Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; intro. paragraph and paragraphs (a)-(d) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraphs (e)-(j) EXPIRED: 2-1-07; intro. paragraph and paragraphs (a)-(d) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (from Ph 302.06)

Ph 302.05 NH MPJE Examination Required Scores and Fees.

(a) To successfully complete the examination required by Ph 302.03(f), the candidate shall, in the initial examination or any subsequent re-examination, obtain a score of not less than 75.

(b) The candidate shall pay the current examination fee to, and as assessed by, NABP.

Source. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99, EXPIRED: 2-1-07

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 302.06 NH MPJE Re-Examination Notice and Election.

(a) Any candidate who has failed to attain the minimum score on the NH MPJE examination as required by Ph 302.05, shall notify the board in writing whether he or she elects to be re-examined.

(b) Any candidate for re-examination of the NH MPJE examination shall register and pay for the re-take examination through the National Association of Boards of Pharmacy online registration website accessible at [www.nabp.net](http://www.nabp.net).

Source. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99, EXPIRED: 2-1-07

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 302.07 Reciprocity License Issuance or Denial.

(a) If a candidate timely files an application, complete in all respects and meeting the requirements of Ph 302, and demonstrates the fulfillment of the requirements of these rules and RSA 318 and RSA 318-B, the board shall issue a license to practice pharmacy.

(b) In the event a candidate for a reciprocity license to practice pharmacy in New Hampshire fails to meet the requirements of these rules or RSA 318 and RSA 318-B, or both, the board shall deliver to the candidate a written denial of the application, specifying in detail each requirement which the candidate failed to meet, and how the candidate is deficient.

Source. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99, and by #8572, eff 2-23-06; paragraph (a) EXPIRED: 2-1-07; paragraph (b) EXPIRED: 2-23-14

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (formerly Ph 302.09)

PART Ph 303 PHARMACY PERMIT OPTION

Ph 303.01 Licensing the Entire Store Area.

- (a) The pharmacy shall include the prescription department and all other retail sections of the store.
- (b) The entire pharmacy shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public, according to Ph 702.04.
- (c) The prescription department shall not be closed while the balance of the establishment remains open.
- (d) A licensed pharmacist shall be on duty at all times when the pharmacy is open to the public.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 303.02 Licensing Only the Prescription Department.

(a) The pharmacy shall include only the prescription department where drugs, chemicals, medicines, prescriptions are stored, compounded and dispensed. This area shall not include the other retail sections of the store the principle business of which is not the practice of pharmacy.

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(b) The prescription department described in (a), above, shall be equipped with a functional alarm system to prevent entry when the pharmacy is not open to the public according to Ph 702.04.

(c) The prescription department may be closed while the remainder of the business establishment remains open to the public. During such periods, the pharmacy shall comply with Ph 702.04.

(d) A licensed pharmacist shall be on duty at all times when the prescription department is open to the public and during any absences by the pharmacist, the prescription department shall be secured except as is provided in Ph 704.01(b).

(e) Whenever the prescription department is closed, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in the pharmacy area. Such sign shall be composed of 3" lettering.

(f) Whenever the prescription department is closed, prescriptions may be left via a mail slot which falls directly into the pharmacy area.

(g) The prescription mail slot:

(1) Shall be constructed so as to accept only a written or typed prescription or a notation of the prescription number for refills;

(2) Shall be no larger than 8" X 1" and designed so that prescriptions or notations, once deposited, cannot be retrieved by hand or by mechanical means; and

(3) Shall be constructed so as to deliver these prescriptions or notations directly into the prescription area for access by the pharmacist only so that they are not visible to the general public.

(h) No prescription, new or refill, shall be left with or accepted by pharmacy technicians as defined in RSA 318:1, XI-b or pharmacy interns as provided in RSA 318:42, IX when the prescription department is closed except as is provided in Ph 704.01(c).

(i) No finished prescriptions shall be left outside of the pharmacy area prescription department for pick-up when the prescription department is closed.

(j) No telephone prescriptions, new or refill shall be accepted by pharmacy technicians or pharmacy interns when the prescription department is closed except as is provided in Ph 704.01(c).

(k) All drug order deliveries containing prescription drugs shall be delivered only when the prescription department is open and/or a licensed pharmacist is on the premises in order to secure such drug orders.

(l) A barrier preventing access to the prescription department by the public, shall be erected pursuant to the security requirements of Ph 702.04(c).

(m) The pharmacist-in-charge may designate personnel, in compliance with the provisions of Ph 702.05(b), to have keys, and a list of these individuals shall be communicated to the board of pharmacy in writing whenever changes occur.

(n) All prescription departments licensed under this section shall be so equipped with a physical barrier from floor to ceiling capable of being locked and alarmed, separate from the rest of the store, to be utilized when the prescription department is not opened to the public.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (a)-(c), (e)-(g), (i), and (k)-(n) EXPIRED: 3-26-13; paragraphs (d), (h), and (j) EXPIRED: 2-23-14

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

## PART Ph 304 PHARMACY PERMIT APPLICATION

### Ph 304.01 Obtaining and Filing a Permit Application.

(a) Application Ph B-1 revised September 2015 for a permit to operate a pharmacy in New Hampshire may be obtained from the board or board website, and shall be filed at the board office, identified in Ph 103.03;

(b) Form Ph B-1 shall be used for:

- (1) Applying for a permit to operate a new pharmacy within the State of New Hampshire;
- (2) Changing the location of a currently licensed New Hampshire pharmacy;
- (3) Changing the ownership of a currently licensed New Hampshire pharmacy; and
- (4) Changing the pharmacist-in-charge of a currently licensed New Hampshire pharmacy.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

### Ph 304.02 Application Contents.

(a) The applicant for a permit to operate a pharmacy in New Hampshire, shall complete form Ph B-1 revised September 2015.

(b) The applicant shall also submit scale drawings of the pharmacy, detailing usage of all space.

(c) The applicant shall supplement the application with any certificates, affidavits, plans, documents, or other information sufficient to show full compliance with all of the requirements of Ph 304.



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(d) The applicant shall submit a certificate from the secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

(e) The application shall be filed with the prescribed fee of \$250.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a)-(d) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (e) EXPIRED: 2-1-07; paragraphs (a)-(d) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

### **PART Ph 305 PHARMACY PERMIT PROCEDURE**

#### **Ph 305.01 Pharmacy Permit Conference.**

(a) In addition to all requirements set forth in the statutes and elsewhere in this chapter, each applicant applying for a permit to operate a pharmacy in New Hampshire shall appear before the board for an informal conference to review the responsibilities of the pharmacist-in-charge and permit holder.

(b) If the owner is not the pharmacist-in-charge, then the owner or an officer of the corporation, or the district manager, as well as the anticipated pharmacist-in-charge shall appear before the board.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

#### **Ph 305.02 Site Inspection for Pharmacy Permit.**

(a) Following the applicant's conference, the proposed site shall be inspected by one or more board members or compliance inspectors to determine if the premises are secure and suitable, as set forth in the NH pharmacy application information according to the provisions of Ph 702, for the operation of a pharmacy and that the required professional library material, according to Ph 702.07 (c) & (d), is available.

(b) Within the 60 day period after the issuance of the temporary permit as required by Ph 305.03, an inspector or a board member or both shall inspect the pharmacy. The full operation of the pharmacy shall be examined for compliance with federal and state statutes and rules governing the practice of pharmacy to ensure public protection.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

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New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

**Ph 305.03 Issuance and Denial of Pharmacy Permit.**

(a) Applicants shall file a completed application at least 30 days before consideration will be given for a temporary permit.

(b) Providing that, the premises are suitable, according to Ph 305.02 (a), for the operation of a pharmacy and the applicant has met all other requirements of these rules and RSA 318, the applicant shall be granted a temporary permit which shall expire in 60 days. The temporary permit shall authorize the operation of a pharmacy only in the location and only under the name specified in the permit and shall authorize the pharmacist-in-charge to buy, possess and dispense prescription drugs, chemicals and pharmaceuticals.

(c) After consideration of the application and the report of the primary site inspection, the board shall notify the applicant in writing of all deficiencies in the application which, in the absence of correction, shall result in the denial of the application. The applicant shall, within 20 days of the date of the notice of deficiency, deliver to the board documents evidencing the correction of those deficiencies. In the absence of timely filing of documentation, the application shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

**PART Ph 306 PHARMACY PERMITS - CHANGES IN SUPPORTING DATA**

**Ph 306.01 Pharmacy Ownership Transfer.** A transfer of ownership shall include any of the following:

- (a) The sale of the pharmacy;
- (b) The addition or deletion of one or more partners in a partnership;
- (c) The death of a singular owner; or

(d) In a publicly traded, multi-tiered corporation, a change in the corporate ownership of the majority or controlling interest of the lowest tier of the corporate structure doing business as a pharmacy in the State of New Hampshire.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; intro. paragraph and paragraphs (a)-(c) EXPIRED: 3-26-13; paragraph (d) EXPIRED: 2-23-14

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New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 306.02 Reporting Changes. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall, within 15 days of that person's discovery of a change in any of the data contained in the application for an original or renewal permit, report that change to the board in writing. An original new permit application, form Ph B-1 revised September 2015 shall be completed and filed in addition to the written notice when the name, location, ownership, licensed area or pharmacist in charge of the pharmacy are changed.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 306.03 Change in Pharmacy Name or Location - Prohibited. No person shall operate a pharmacy under a name, or at a location, different from the name and location contained in the permit issued pursuant to Ph 304.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 306.04 Renovations. Plans for any renovation at any time after an original permit is issued shall be filed with the board for review and approval before proceeding with such changes.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 306.05 Special Permit Provisions for Sudden Termination of Pharmacist-In-Charge (PIC). Existing pharmacy permit holders who have a sudden loss of the pharmacist-in-charge (PIC), shall be issued a special pharmacy permit valid for 60 days while a new PIC is identified and appears before the board according to Ph 305.01.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

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New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

**PART Ph 307 RENEWAL AND REPLACEMENT PHARMACY PERMITS**

Ph 307.01 Renewal Permits Required. The person to whom a permit to operate a pharmacy in New Hampshire has been issued shall renew that permit by December 31<sup>st</sup> of each year.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 307.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a permit to operate a pharmacy in New Hampshire may be obtained from, and shall be filed at the board office.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

**Ph 307.03 Renewal Application Contents and When Filed.**

(a) Applications for renewal of a permit to operate a pharmacy in New Hampshire shall consist of the prescribed form Ph B-2 revised September 2015 and the prescribed fee of \$250.

(b) Renewal applications as required pursuant to Ph 307.01 shall be submitted to the board office identified in Ph 103.03 no later than the 15th day of December of each year.

Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (a) EXPIRED: 2-1-07; paragraph (b) EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, , EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 307.04 Renewal Application Deficiencies. The board shall notify the applicant in writing as to how the application for renewal is deficient. The applicant may, within 10 days after the date of the notice of deficiency, correct the deficiency or the renewal shall be denied.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

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New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

**Ph 307.05 Issuance or Denial of Renewal Permit.**

(a) If an applicant shall timely file an application, complete in all respects, and shall demonstrate the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal permit.

(b) An application which continues to fail to meet the requirements of these rules and RSA 318 shall be denied.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

**Ph 307.06 Replacement Permit Application and Contents.**

(a) The holder of a current permit to operate a pharmacy in New Hampshire, whose permit has been lost or destroyed shall apply for a replacement permit within 15 days after the date the licensee discovers, or with reasonable diligence, should have discovered, the loss or destruction of the permit. There shall be no form prescribed for an application for a replacement permit.

(b) The request for a replacement permit shall:

- (1) Be in writing;
- (2) Contain the number of the current permit held by the applicant, if known;
- (3) Be accompanied by the remains, if any, of the permit for which a replacement is sought;
- (4) Be accompanied by the prescribed fee of \$25; and
- (5) Be filed at the board office.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

**PART Ph 308 REVOCATION AND SUSPENSION OF A PHARMACY PERMIT**

**Ph 308.01 Grounds for Revocation or Suspension.** The board may revoke or suspend a permit to operate a pharmacy for grounds which include but are not limited to:

- (a) Misconduct as described in RSA 318:29, II; and

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(b) Violations of the provisions of RSA 318:29, V.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16

Ph 308.02 Effect of Revocation.

(a) The revocation of a pharmacy permit shall permanently withdraw the authority to operate a pharmacy in New Hampshire.

(b) A subsequent permit may be obtained only by:

- (1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacies;
- (2) Paying all penalties assessed in connection with the cause for revocation; and
- (3) By demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (from Ph 308.01)

Ph 308.03 Effect of Suspension.

(a) The suspension of a pharmacy permit shall temporarily withdraw the authority to operate a pharmacy in New Hampshire until the time specified in the order of suspension.

(b) The authority to operate a pharmacy in New Hampshire shall be recovered only by;

- (1) Complying with all of the requirements specified in the order of suspension;
- (2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a pharmacy permit; and
- (3) Paying all penalties assessed in connection with the cause for suspension.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

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New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (from Ph 308.02)

Ph 308.04 Voluntary Surrender When Permitted.

- (a) Any person holding a pharmacy permit may voluntarily return that permit to the board.
- (b) The return of such permit shall be accompanied by the licensee's signed, written statement as to why the permit is being voluntarily returned to the board.
- (c) The voluntary surrender of a permit to operate a pharmacy in New Hampshire shall serve to withdraw the authority for the licensee to operate that pharmacy in New Hampshire.
- (d) Voluntary surrender of a permit to operate a pharmacy in New Hampshire shall not be permitted if there exists, at the time the permit is presented to the board, any cause for involuntary revocation or suspension of the licensee's permit to operate a pharmacy, unless the licensee presenting the permit shall state in writing that the voluntarily surrendered permit is in lieu of proceedings for the involuntary revocation or suspension of the permit to operate a pharmacy in New Hampshire.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (from Ph 308.03)

Ph 308.05 Hearing. Except as authorized by statute or these rules, a permittee to operate a pharmacy in New Hampshire shall not be disciplined except after notice and opportunity for hearing provided by Ph 200.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16 (from Ph 308.04)

**PART Ph 309 STANDARDS OF PRACTICE FOR MANUFACTURERS, WHOLESALERS AND DISTRIBUTORS – Moved to Ph 1000**

Ph 309.01 – Ph 309.14

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10702, INTERIM, eff 10-23-14, EXPIRED: 4-21-15

New. #11031, eff 1-29-16; renumbered by #12007 (see Ph 1000)

## CHAPTER Ph 400 CONTINUED STATUS

### PART Ph 401 RENEWAL AND REPLACEMENT LICENSES

Ph 401.01 Obtaining and Filing Renewal Applications. Application form Ph A-2 for the renewal of a license to practice pharmacy in New Hampshire may be obtained from, and shall be filed at, the board office.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

#### Ph 401.02 Renewal Application Contents and Filing Deadline.

(a) Applications for renewal of a license to practice pharmacy in New Hampshire under RSA 318 shall be completed and filed on a Pharmacist Licensure Renewal Form Ph A-2 (February 2015).

(b) With the exception of authorized immunizing pharmacists per the provisions of Ph 1300, which shall have the combined renewal fee as noted below in (d), the application and the prescribed fee of \$125 shall be filed with the board no later than the 15th day of December each year. Each licensee shall obtain and file his or her application for license renewal prior to this date.

(c) The renewal fee for pharmacists who are authorized immunizing pharmacists shall be \$135, which includes a fee for the immunization endorsement on their pharmacist license.

(d) Per the provisions of RSA 318:29-a, VI(b), \$15 of each pharmacist renewal fee noted in sections (b) and (c) above, shall be used to fund the impaired pharmacist program.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a) and (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #9139-B, eff 4-25-08; paragraphs (a) and (b) EXPIRED: 3-26-13; ss by #10842, eff 6-3-15



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Ph 401.03 Renewal Application Deficiencies. Within 5 days of receipt at the board office, the board shall notify the applicant in writing if the renewal application is deficient. The applicant may then correct the deficiency or file with the board a written request for a hearing before the board.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

### Ph 401.04 Renewal License Issuance and Denial.

(a) If an applicant timely files an application, complete in all respects, and demonstrates the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal license to practice pharmacy.

(b) Applicants shall register with the New Hampshire Prescription Drug Monitoring Program pursuant to the requirements articulated in RSA 318-B:33, II and Ph 1503.01 (a).

(c) An application failing to meet the requirements of these rules or RSA 318, or both, shall, after the notice and opportunity for hearing, be denied.

(d) Applicants who fail to register for the New Hampshire Prescription Drug Monitoring Program pursuant to RSA 318-B:33, II and Ph 1503.01 (a), shall, after the notice and opportunity for hearing, be denied.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

### Ph 401.05 Duplicate/Replacement Original Certificate of Licensure or Renewal License - Issuance.

(a) If seeking a duplicate or replacement for an original certificate of licensure the applicant shall:

- (1) Submit a written request, signed by the pharmacist, to the board for replacement; and
- (2) Provide payment of the prescribed fee which shall be \$50.

(b) If seeking a duplicate or replacement for an annual renewal license the applicant shall:

- (1) Submit a written request, signed by the pharmacist, to the board for a duplicate or replacement; and

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- (2) No fee shall be assessed for a duplicate or replacement renewal license.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 401.06 Reinstatement. A pharmacist whose license to practice pharmacy in this state has been suspended, revoked, voluntarily surrendered or allowed to lapse shall be subject to the following requirements:

- (a) File a reinstatement application with the board which shall include at least the following:
- (1) Name, address and telephone number of the applicant;
  - (2) Date of birth; and
  - (3) Current employment information.
- (b) Pay the reinstatement fee of \$200;
- (c) Submit certificates of attendance/participation in accredited/approved continuing pharmaceutical education courses/programs for a minimum of 15 hours, of which at least 5 hours shall be earned in a live setting. All such continuing education shall have been earned in the period 12 months immediately preceding the date of application for reinstatement;
- (d) Successfully complete the jurisprudence MPJE examination as specified in Ph 302.07(a);
- (e) If the pharmacist has not held a license to practice pharmacy in this state for a period of 2 years or more, the applicant shall provide:
- (1) Notarized affidavit(s) documenting the pharmacist's pharmacy experience during the 2 years immediately preceding the date of his/her application for reinstatement; and
  - (2) Proof of status of licensure in all states that the pharmacist has been licensed in; and

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(f) If the pharmacist has not held a license to practice pharmacy in this state for a period of 5 years or more and has not practiced pharmacy in any other state, the board shall require the completion of a period of pharmacy practice internship prior to reinstatement.

Source. #2442, eff 9-1-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; intro. paragraph and paragraphs (a)-(d) and (f)-(g) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (e) EXPIRED: 2-1-07; intro. paragraph and paragraphs (a)-(d) and (f)-(g) EXPIRED: 3-26-13

New. #10812, eff 4-18-15

### Ph 401.07 Gold Certificates.

(a) The board of pharmacy shall issue a gold certificate to any pharmacist who has been regularly licensed as a pharmacist in New Hampshire for 50 consecutive years.

(b) Gold certificates shall be distinctive in coloration and text from other pharmacist licenses issued by the board, and shall be designed to appropriately recognize each recipient pharmacist for his/her half-century of professional practice.

(c) A gold certificate shall be a one-time issuance of honorary nature and confer no right to practice pharmacy upon the recipient.

(d) The awarding of gold certificates shall be made by the board of pharmacy without charge to the recipient.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

## PART Ph 402 DISCIPLINARY MATTERS

### Ph 402.01 Effect of Revocation.

(a) The revocation of a pharmacist license shall permanently withdraw the authority to practice pharmacy in New Hampshire.

(b) A subsequent license may be obtained only by:

(1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacists;

(2) Paying all penalties assessed in connection with the cause for revocation; and

(3) Demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 402.02 Effect of Suspension.

(a) The suspension of a pharmacist license shall temporarily withdraw the authority to practice pharmacy in New Hampshire until the time specified in the order of suspension.

(b) The authority to practice pharmacy in New Hampshire shall be recovered only by:

- (1) Complying with all of the requirements specified in the order of suspension;
- (2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a license to practice pharmacy in New Hampshire; and
- (3) Paying all penalties assessed in connection with the cause for suspension.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 402.03 Voluntary Surrender of License.

(a) Any person holding a pharmacist license may voluntarily surrender that license by returning it to the board accompanied by a signed letter stating that the pharmacist intends to permanently surrender his or her license.

(b) The surrender shall be effective upon acceptance by the board and shall immediately preclude the pharmacist from practicing pharmacy in New Hampshire.

(c) A voluntary license surrender, standing alone, shall not prevent the pharmacist from subsequently reapplying for a license.

(d) The voluntary surrender of a license shall have no effect upon the board's authority to:

- (1) Investigate violations of the pharmacy laws or the rules of the board by a person licensed at the time the alleged violation occurred; or
- (2) Impose disciplinary sanctions based on past conduct which could affect the ability of the former licensee to reapply for a license at a later date.

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(e) A voluntary license surrender during the pendency of a disciplinary proceeding shall be recorded in the board's files as "surrendered during disciplinary proceeding."

(f) Nothing in this section shall prohibit the board and a licensee from entering into a settlement agreement or a consent decree relative to any alleged violation of the pharmacy laws or the rules of the board.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 402.04 Hearing. Except as authorized by statute or these rules, a licensee shall not be disciplined except after notice and opportunity for hearing.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

### **PART Ph 403 CONTINUING EDUCATION REQUIREMENTS**

#### **Ph 403.01 Definitions.**

(a) "Accredited programs/courses" means continuing education sponsored by providers which are approved by the American Council on Pharmaceutical Education (ACPE) or the Canadian Council on Continuing Education in Pharmacy (CCCEP).

(b) "AMA category I programs" means all programs accepted by the American Medical Association in category I.

(c) "Board approved programs/courses" means continuing education which has been reviewed and recommended by the continuing education advisory council and approved by the board of pharmacy or continuing education programs approved by a Canadian provincial or territorial pharmacy licensing authority.

(d) "Certificate of accredited/approved CEU's" means a document, issued to a particular pharmacist by an accredited or approved provider certifying that the pharmacist has satisfactorily completed a specified number of CEU's. Such certificates include a unique program identification number issued by the accrediting/approving provider.

(e) "Continuing education" means accredited or approved post-licensure pharmacy education designed to maintain professional competence in the practice of pharmacy, improve professional skills, and preserve pharmaceutical standards for the purpose of protecting the health and welfare of the citizens in the state of New Hampshire. Continuing education includes study in one or more of the general areas of the

properties and actions of drugs and dosage forms, etiology, characteristics and therapeutics of the disease state, socio-economic and legal aspects of health care.

(f) “Continuing education advisory council (CEAC)” means a group of individuals appointed by the board of pharmacy to serve in an advisory capacity on continuing education.

(g) “Continuing education unit (CEU)” means 10 contact hours of participation in accredited or board approved continuing education courses/programs.

(h) “In-state approved provider” means an individual, institution, organization, association, corporation or agency located in the state of New Hampshire in no manner affiliated with any manufacturer or distributor of supplies or services used in the practice of pharmacy, who is approved by the board of pharmacy to provide continuing pharmacy education according to Ph 403.12.

Source. #1867, eff 11-22-81; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (c)-(h) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraphs (a) and (b) EXPIRED: 2-1-07; paragraphs (c)-(h) EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.02 Renewal Requirements.

(a) The board of pharmacy shall not issue licensure renewals unless the pharmacist indicates on the renewal application, and under penalty of unsworn falsification, that he/she has completed the minimum required hours of accredited/approved continuing pharmaceutical education courses/programs according to Ph 403.02(d). An incomplete renewal application shall be returned to the applicant.

(b) Continuing education shall be required of all licensed, active or inactive pharmacists who apply for license renewal.

(c) Pharmacists submitting applications for the first annual licensure renewal shall be exempt from the continuing education requirements.

(d) All pharmacists licensed in New Hampshire shall acquire 1.5 CEU's during the 12 months immediately preceding the license renewal date of January 1st. At least 0.5 CEU's shall be earned in a live setting.

(e) Continuing education credits shall not be recognized for any repeat program attended or completed. Repeat programs shall be identified as any program, live or correspondence, which carries the same ACPE, CME or any board of pharmacy program identification number.

(f) The pharmacist shall retain all certificates and/or other documented evidence of participation in an approved/accredited continuing education program/course for a period of at least 3 years. Such documentation shall be made available to the board for random audit and/or verification purposes.

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(g) Not less than 10% of the registrants shall be randomly selected each year by the board for determinations of compliance with Ph 403.02.

Source. #1867, eff 11-22-81: ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a)-(f) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (g) EXPIRED: 2-1-07; paragraphs (a)-(f) EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.03 Excess CEU's. Excess CEU's earned in one licensure period shall not be carried forward into the new licensure period for the purpose of fulfilling that year's continuing education prerequisite for licensure renewal.

Source. #1867, eff 11-22-81: ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.04 CEU's from Other States. The board of pharmacy shall accept comparable continuing education units which have been approved by other boards of pharmacy provided they meet or exceed the requirements as set forth in Ph 403.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.05 Credit for Instructors of Continuing Education.

(a) Any pharmacist, whose primary responsibility is not the education of health professionals, who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy related topics in organized continuing education or in-service programs, shall be granted continuing education credit for such time expended during actual presentation.

(b) Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses or others on pharmacy-related topics outside his/her formal course responsibilities in a learning institution.

(c) Credit for presentation of in-service training programs or other lectures shall be granted only once for any given program or lecture.

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(d) A maximum of 4 hours in this category may be applied toward fulfilling the total continuing education yearly requirements. However, these hours shall not be considered in fulfilling the live requirements as set forth in Ph 403.02(d).

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

**Ph 403.06 Postgraduate Pharmacy Curricula.**

(a) A pharmacist who matriculates in a postgraduate pharmacy curriculum or post graduate pharmacy program shall be awarded CEU's for satisfactory completion of each course within said curriculum or program.

(b) The course work for which CEU credit is provided pursuant to (a) above, shall provide instruction in one or more of the following areas of study:

- (1) Pharmacy;
- (2) Pharmaceutical calculations;
- (3) Pharmaceutical chemistry;
- (4) Pharmacology;
- (5) Therapeutics;
- (6) Pharmacy management;
- (7) Pharmaceutical jurisprudence; or
- (8) Other course work related to the pharmaceutical sciences.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

**Ph 403.07 Audio/Visual Continuing Education.**

(a) Continuing education credit may be claimed for the completion of home study audio and/or video cassette tape programs/courses, provided that such programs require the completion of a written exam by the pharmacist to be scored by the provider of such programs.

(b) Audio/visual continuing education programs, including satellite transmissions, which provide for group discussion and include a facilitator shall, be allowed as live programming.



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(c) Webinars that are ACPE approved and contain an “L” in the program approval number shall be allowed as live programming.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.08 Waiver. The board shall waive some or all of the continuing education requirements, for a period not to exceed one calendar year, for such hardships as illness or incapacity. Written request for waiver shall be submitted to the board for consideration.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.09 Military Personnel. Military personnel or spouses shall not be exempt from the continuing education requirements, because correspondence programs/courses are available, but shall be exempt from the live requirement if assignment is in a foreign country.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.10 Reinstatement. Any pharmacist desiring reinstatement of licensure shall show evidence of completion of at least 1.5 CEU's, according to Ph 403.02(d) and earned in the 12 months immediately preceding the date of application for reinstatement.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.11 Penalty. Any pharmacist 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. Falsification of records shall constitute misconduct.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 403.12 In-State Approved Providers of Continuing Pharmacy Education.

(a) An individual, institution, organization, association, corporation or agency located in the state of New Hampshire desiring to be an in-state provider of continuing pharmacy education shall notify the board in writing subject to the criteria set forth in Ph 403.12 (d)(1) - (10).

(b) Approval of in-state providers shall be valid for a period of 2 years from date of approval after which time re-application shall be necessary.

(c) In-state providers who desire to become approved by the board shall provide their educational qualifications and an example of a program to the CEAC committee for review.

(d) In state providers shall comply with the following:

(1) The provider shall designate a responsible person for the administration of the continuing pharmacy education program and liaison with the CEAC and the board;

(2) Providers shall award continuing pharmacy education credit to successful participants in terms of CEU's;

(3) The provider shall maintain a list of successful participants for each program provided for a period of not less than 3 years;

(4) The list required by (3) above shall be made available to the CEAC and the board on request;

(5) The provider shall award to each successful participant a certificate containing at least the following information:

- a. The name of the provider;
- b. The completion date of the continuing education program;
- c. The name of the participant;
- d. The title of the program;
- e. The number of CEU's the program has been assigned; and
- f. The board of pharmacy program identification number.

(6) All programs shall be referenced as "live" or "correspondence" in nature;

(7) Providers shall present their participants with a statement of goals and objectives prior to each continuing pharmacy education program and involve their participants in identifying their own educational needs;

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(8) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education offerings and the level of fulfillment of the stated objectives with the goal of continual improvements;

(9) Providers shall utilize an evaluation mechanism for the purpose of allowing each participant to assess his/her achievement of personal objectives; and

(10) Providers shall assign an identification number to every program presented according to the numbering system designated by the board of pharmacy.

(e) Continuing education programs presented by in-state approved providers shall not have to be submitted to the CEAC for review and approval by the board.

(f) In-state approved providers of continuing pharmacy education shall publicize programs and/or coursework by referencing endorsement by the board only as follows: "This program is approved by the New Hampshire Board of Pharmacy for \_\_\_\_\_ CEU's of continuing pharmacy education". Programs shall also be referenced as "live" or "correspondence" in nature.

(g) Board approval of in-state provider shall be revoked following notice and opportunity to be heard upon a finding that the provider has engaged in fraud or dishonesty or is no longer in compliance with one or more of the criteria of (d) above.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

**Ph 403.13 Continuing Education Advisory Council Membership.**

(a) The advisory council shall consist of not less than 6, nor more than 10 members, at least one of whom shall be a member of the board.

(b) The term of appointment shall be for 3 years and shall be served until the expiration date or until a successor has been named. Should a vacancy occur, a successor shall be appointed to serve the unexpired term.

(c) The advisory council shall submit all recommendations to the board for its implementation and/or approval.

(d) It shall be the duty of the advisory council to:

(1) Elect from its membership a chairman and a secretary annually;

(2) Recommend to the board the standards and specifications required of programs/courses which might be acceptable for board approval in fulfilling continuing education requirements;

(3) Recommend programs which meet the standards and specifications adopted;

(4) Recommend the number of CEU's granted for the satisfactory completion of approved programs; and

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(5) Provide such other assistance to the board necessary in the implementation and maintenance of the continuing education licensure renewal prerequisite.

(e) The advisory council shall meet a sufficient number of times annually to properly perform its functions.

(f) The advisory council quorum shall be equal to the majority of the council membership.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

**PART Ph 404 STANDARDS FOR COMPOUNDING AND DISPENSING STERILE AND NON-STERILE PHARMACEUTICALS**

**Ph 404.01 Purpose and Scope.**

(a) The purpose of this part is to provide all compounders with guidance on applying good compounding practices for the preparation of non-sterile and sterile compounded formulations for dispensing and/or administration to humans and animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare.

(b) The board shall require all compounders engaging in compounding in all situations to adhere to and comply with the current edition of the United States Pharmacopeia including but not limited to Chapters 795 (USP 795) and 797 (USP 797), following those guidelines that apply to their practice setting. These chapters shall be reviewed in full and followed by compounders prior to non-sterile or sterile pharmaceutical compounding. These regulations shall apply to non-sterile and sterile compounding of medications.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

**Ph 404.02 Definitions.**

(a) “Active pharmaceutical ingredients” means chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

(b) “Added substances” means the ingredients necessary to prepare the drug product but are not intended or expected to cause human pharmacological response if administered alone in the amount or concentration contained in a single doses of the compounded preparation. The term “added substances” includes the terms “inactive ingredients”, “excipients”, and “pharmaceutical ingredients.”

(c) “Ante-area” means:

(1) An ISO Class 8 or better area where personnel perform hand hygiene and garbing procedures, staging of components, order enter, CSP labeling, and other high-particulate-generating activities are performed;

(2) A transition area that:

- a. Provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and
- b. Reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

(d) “Aseptic processing” means a mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package containers, closures or packaging material for medical devices and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.

(e) “Beyond-use date (BUD)” is the date after which a compounded preparation should not to be used; determined from the date the preparation is compounded.

(f) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

(g) “Buffer area” means an area where the primary engineering control (PEC) is physically located.

(h) “Clean room” means a room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(i) “Component” means any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

(j) “Compounder” means a licensed professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.

(k) “Compounding” means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice, and includes the following:

- (1) Preparation of drug dosage forms for both human and animal patients;
- (2) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;
- (3) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients;
- (4) Preparation of drugs or devices for the purposes of, or as an incident to research clinical or academic teaching, or chemical analysis; and

(5) Preparation of drugs and devices on the order of a practitioner, which may be sold to the practitioner for use in his or her office to administer to a specific patient, in limited quantities, but not for resale.

(l) “Compounding Aseptic Containment Isolator (CACI)” means a compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations.

(m) “Compounding Aseptic Isolator (CAI)” means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

(n) “Critical area” means an ISO Class 5 environment.

(o) “Critical site” means a location that includes any component or fluid pathway surfaces such as vial septa, injection ports, beakers or openings such as opened ampules or needle hubs exposed and at risk of direct contact with air including ambient room or HEPA filtered, moisture such as oral and mucosal secretions, or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

(p) “Direct Compounding Area (DCA)” means an area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

(q) “Disinfectant” means an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

(r) “First air” means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(s) “Hazardous drugs” means any drug which in studies of animals or humans have been classified as carcinogenic, toxic to development or reproduction, or toxic to organs.

(t) “Labeling” means a term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term “label” designates that part of the labeling on the immediate container.

(u) “Limited quantities” means a batch with 50 or less dosage units provided to a hospital or practitioner to administer to their own patient.

(v) “Manufacturing” means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices for resale.

(w) “Media-fill test” means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.

(x) “Memorandum of understanding” means a document specific to the preparation(s) provided to a practitioner by a compounder outlining the distinct responsibilities of the compounder and practitioner.

(y) “Multiple-dose container” means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.

(z) “Negative pressure room” means a room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is into the room.

(aa) “Pharmacy bulk package” means a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.

(ab) “Positive pressure room” means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

(ac) “Preparation” means a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug.

(ad) “Primary Engineering Control (PEC)” means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but are not limited to, laminar airflow workbenches (LAFWs), BSCs, CAIs, and CACIs.

(ae) “Product” means a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA.

(af) “Segregated compounding area” means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. This area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

(ag) “Single-dose container” means a single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

(ah) “Sterilization by Filtration” means passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

(ai) “Sterilizing grade membranes” means that membranes that are documented to retain 100% of a culture of 10<sup>7</sup> microorganisms of a strain of *Brevundimonas* (*Pseudomonas*) *diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi or 2.0 (bar). Such filter membranes are nominally at 0.22-um or 0.2-um nominal pore size, depending on the manufacturer’s practice.

(aj) “Terminal Sterilization” means the application of a lethal process, such as steam under pressure or autoclaving, to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10<sup>-6</sup>, or a probability of less than one in one million of a non-sterile unit.

(ak) “Unidirectional flow” means the airflow moving in a single direction in a robust and uniform manner and at a sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

(al) “United States Pharmacopoeia” means a legally recognized compendium of standards for drugs.

(am) “Vehicle” means a component for internal and external use that is used as a carrier for diluent in which liquids, semisolids or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers and proprietary products.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 404.03 Non-Sterile Pharmaceutical Compounding.

(a) Compliance with USP 795 and all applicable USP chapters related to non-sterile compounding shall be followed.

(b) There are 3 general categories of non-sterile compounding described in this section that require different levels of experience, training and physical facilities. The 3 categories shall be:

(1) Simple compounding which includes reconstituting or manipulating a commercial product that might require the addition of one or more ingredients as directed by the manufacturer or preparing a product that has a USP compounding monograph or appears in a peer reviewed article that contains the quantities for all components, procedures and equipment with the exception of pre-measured compounding kits;

(2) Moderate compounding which includes making a preparation that requires complex calculation or procedures to determine quantities of components per preparation or per individualized dosage units, making a preparation for which stability data for that specific formulation is not available and mixing 2 or more manufactured creams when the stability of the mixture is unknown; and

(3) Complex compounding which includes making a preparation that requires specialized training, environment, facilities, equipment, and procedures such as transdermal dosage forms and modified-release preparations.

(c) Responsibilities of the compounder shall include:

(1) Compounding preparations of accepted strength, quality, and purity and in accordance with the prescription or medication order;

(2) Dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with RSA 318:47-a, federal law, and other regulatory agencies where appropriate;

(3) Maintaining proficiency in drug or dietary supplement compounding;

(4) Ensuring the quality of compounded preparation by adhering to the general principles listed in USP 795 and all applicable compounding laws, guidelines and standards including but not limited to:

- a. Training of all the personnel shall be current and documentation of such kept on site;
- b. Compounding ingredients shall be purchased from reliable sources and be properly stored;
- c. Bulk component containers shall be properly labeled and SDS sheets available;
- d. Equipment used shall be clean, properly used and maintained;



- e. Environment shall be suitable to prevent cross contamination including the use of powder containment systems if API's are used or powder is created through manipulation of solid dosage forms or emptying of powder containing vials;
- f. Compounding personnel shall wear appropriate and clean clothing. Protective apparel such as lab coats gowns, gloves, shoes, or masks shall be worn as necessary to protect personnel from chemical exposure and/or contamination;
- g. Only authorized personnel shall be allowed in the compounding area;
- h. Compounding conditions and procedures shall be such to prevent errors;
- i. There shall be assurance that processes are always carried out as intended or specified and are reproducible;
- j. All aspects of compounding shall be properly documented;
- k. Procedures and records exist for investigating and correcting failures or problems in compounding and testing; and
- l. A valid and reproducible recall policy and procedure.

(5) The compounder shall be responsible for ensuring that each individual incidence of the compounding process meets the criteria in USP 795.

(d) The compounding area shall adhere to the general principles listed in USP 795 guidelines including but not limited to:

- (1) Adequate space specifically designated for compounding and storage of equipment and materials;
- (2) Be clean, orderly, and properly maintained;
- (3) Easily accessible hand washing, hot and cold water, soap or detergent, and an air-drier or single-use towels must be present;
- (4) Be located in a separate area from sterile compounding area;
- (5) Purified water shall be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water;
- (6) Disposal of all hazardous drug wastes shall comply with applicable federal and state regulations; and
- (7) All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination including spill clean ups.

(e) All equipment and utensils used in compounding shall comply with the following:

- (1) Be of appropriate design and capacity for the required task;
- (2) Automatic, mechanical, electronic, or other equipment used in compounding shall be routinely inspected, calibrated, or checked according to the manufacturer's recommendations to ensure proper performance; and

(3) Equipment shall be stored to protect it from contamination. It shall be located in an area to facilitate its use, cleaning and maintenance.

(f) Component Selection, Handling and Storage shall be subject to the following requirements:

(1) A United States Pharmacopeia (USP), National Formulary (NF), or Food Chemicals Codex (FCC) substance shall be the recommended source of ingredients for compounding all preparations.

(2) If ingredients are from a non-FDA registered facility the professional judgment of the compounder shall be used in selecting an acceptable and reliable source and shall establish purity and safety including obtaining a certificate of analysis from the manufacturer or qualified third party;

(3) Components for compounding shall be properly labeled with lot numbers and expiration dates. If a component is transferred from the original container to a new container, the new container shall be labeled with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that it is equal to or better than the original container;

(4) For components that do not have expiration dates assigned by the manufacturer or supplier the compounder shall label the container with the date of receipt and assign a conservative expiration date not to exceed 3 years after receipt;

(5) Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that might be responsible for causing variability in the final drug product, including but not limited to, the following:

- a. Capsule weight variation;
- b. Adequacy of mixing to insure uniformity and homogeneity;
- c. Clarity, completeness, or pH of solutions; and
- d. Observation of instability;

(6) When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components;

(7) All components used in compounding shall be stored as directed by the manufacturer, or according to USP or NF requirements, in a clean, dry area under appropriate temperature conditions. All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled; and

(8) Use of pre-measured compounding kits shall adhere to all USP 795 standards, including the level of non-sterile compounding and utilizing a master formulation record and a compounding record.

(g) The following provisions of USP 795 shall be followed when determining stability and beyond use dating:

- (1) Compounders shall consult and apply drug-specific and general stability information and literature when available;
- (2) Compounders shall consider the following when determining BUDs:
  - a. Nature of the drug and degradation mechanism;
  - b. Dosage form and its components;
  - c. Potential for microbial proliferation in the preparation;
  - d. Container when it is packaged;
  - e. Intended duration of therapy; and
  - f. Expected storage conditions;
- (3) When using manufactured solid dosage forms to prepare a solution or aqueous suspension, the compounder shall also consider factors such as hydrolysis, oxidation, and the freeze - thaw property of the final preparation;
- (4) When a manufactured product is used as the source of the active pharmaceutical ingredient for a non-sterile compounded preparation, the product expiration date shall not be used to assign a BUD for the compounded preparation. Instead the compounder shall refer to the manufacturer for stability information and to the literature for applicable information on stability, compatibility, and degradation of ingredients. All data shall be carefully interpreted in relation to the actual compounded formulation;
- (5) Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobials are contraindicated, storage of the preparation at controlled cold temperature shall be necessary to retard microbial growth. Appropriate patient or caregiver instruction regarding storage and handling shall be essential;
- (6) In the absence of reliable stability information or published date the following general guidelines for maximum BUD shall be:
  - a. A maximum of 6 months for non-aqueous formulations;
  - b. A maximum of 14 days under refrigeration for water-containing oral formulations; and
  - c. A maximum of 30 days for water containing topical, dermal and mucosal liquid and semisolid formulations.
- (7) The BUD shall not exceed the expiration date of the API or any other component.
- (h) The compounder shall ensure that the containers and closures used in packaging compounded preparations meet the following USP requirements:
  - (1) The containers and closures shall be made of clean material in order not to alter the quality, strength, or purity of the compounded preparation;
  - (2) Container-drug interaction shall be considered for substances that have sorptive or leaching properties; and

(3) Containers and closures shall be handled and stored in such a way as to prevent contamination.

(i) Compounders shall comply with the following requirements regarding compound documentation;

(1) Documentation, written or electronic, shall be kept for 4 years;

(2) Documentation shall comply with state and federal laws;

(3) Documentation shall not be required when preparing a compounded preparation according to the manufacturer's labeled instructions;

(4) The record may be a copy of the prescription in written or machine-readable form and shall include a master formula record and a compound record;

(5) Information contained in the master formulation record shall include the following:

a. Official or assigned name, strength, and dosage form of the preparation;

b. Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;

c. Description of all ingredients and their quantities;

d. Compatibility and stability information, including references when available;

e. Equipment needed;

f. Mixing instructions;

g. Order of mixing;

h. Mixing temperature or other controls;

i. Duration of mixing;

j. Any other pertinent instruction;

k. Labeling information in addition to legally required information found in RSA 318:47-a including:

1. Name and quantity or concentration of each active ingredient;

2. Assigned BUD;

3. Storage conditions; and

4. Prescription number;

l. Container used in dispensing;

m. Packaging and storage requirements;

n. Description of final preparation; and

o. Quality control procedures and expected results; and

- (6) The compound record shall contain at least the following:
  - a. Official or assigned name, strength, and dosage of the preparation;
  - b. Master formulation record reference for the preparation;
  - c. Names and quantities of all components;
  - d. Sources, lot numbers, and expiration dates of components;
  - e. Total quantity compounded;
  - f. Name of the person who prepared the compound, who performed the quality control procedures, and approved the preparation;
  - g. Date of the preparation;
  - h. Assigned controlled or prescription number;
  - i. Assigned BUD;
  - j. Description of final preparation;
  - k. Results of quality control procedures such as weight range of filled capsules, pH record; and
  - l. Documentation of any QC issues and any ADRs reported by patient or caregiver;
- (j) All significant procedures performed in the compounding area shall be covered by written standard operating procedures (SOPs) including:
  - (1) Facility maintenance, workflow, and cleaning;
  - (2) Equipment use and maintenance;
  - (3) Personnel;
  - (4) Training;
  - (5) Preparation;
  - (6) Packaging;
  - (7) Storage of compounded preparations;
  - (8) Quality assurance;
  - (9) Safety;
  - (10) Uniformity;
  - (11) Continuous quality improvement; and
  - (12) Maintain updated SDS library.
- (k) The compounder shall perform the following to ensure quality control;
  - (1) Review calculation, ingredients, measurements and procedures; and

(2) Observe the finished preparation to ensure that it appears as expected and investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

(l) The compounder shall ensure the following compounding controls are followed:

(1) There are written procedures for the compounding of drug preparations to ensure that the finished preparations have the identity, strength, quality, and purity that they purport to have. These procedures shall be available in either written form or electronically stored;

(2) The written procedures shall be followed in execution of the compounding process;

(3) Check and document each weight and measurement;

(4) Document the identity of the person(s) actually performing the compounding;

(5) Document the name of compounder;

(6) Establish written procedures that will describe quality assurance tests or examinations to be conducted on the compounded preparation to ensure uniformity and integrity;

(7) To monitor the output and to validate the performance of those compounding processes and equipment that could be responsible for causing variability in the final compounded preparation; and

(8) Records shall be maintained with compounding records for 10 years.

(m) At the time of dispensing, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to observe and report to the compounder any changes in the physical characteristics of the compounded preparation. Counseling may be in written, oral, electronic, or other formats. The compounding pharmacist shall investigate any reported problem with a compounded preparation and take corrective action.

(n) It shall be the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. Compounding personnel shall be trained initially and the training shall be documented.

(o) Steps in the training procedure shall include the following:

(1) All employees involved in pharmaceutical compounding shall read and become familiar with USP Chapter 795. They shall also be familiar with other relevant publications including how to read and interpret SDSs;

(2) All employees shall read and become familiar with each of the procedures related to compounding including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage and dispensing;

(3) All personnel who compound hazardous drugs shall be fully trained in the storage, handling and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs;

- (4) All training activities shall be documented. The compounder shall meet with employees to review their work and answer any questions the employee may have concerning compounding procedures;
  - (5) The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee shall then repeat the procedure without any assistance from, but under the supervision of the compounder;
  - (6) When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then shall the employee be permitted to perform the procedure without direct supervision. However the compounder shall be physically present and shall approve all ingredients and their quantities and the final preparation;
  - (7) When the compounder is satisfied with the employee's knowledge and proficiency, the compounder shall sign the documentation records to show that the employee was appropriately trained;
  - (8) The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed; and
  - (9) The compounder shall be solely responsible for the finished preparation.
- (p) The following requirements shall be met when compounding for animal patients:
- (1) Intended use on any animal patient, such as companion, performance or food, shall be determined before compounding for that patient. Because humans can consume animals as food, care shall be taken to prevent drug residue from entering the human food chain;
  - (2) Compounders who compound for animals shall possess knowledge of drug regulation, uses, dosing and disposition in animal patients to properly determine appropriateness of therapy; and
  - (3) The compounding pharmacist shall be knowledgeable about the individual species limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, pharmacists compounding for animals shall use when possible, formulations developed specifically for animal patients. If such formulations are not available, the compounding pharmacist shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. Compounded preparations shall not to be dispensed or sold to veterinary offices for resale.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 404.04 Regulatory Requirements for Sterile Compounding.

- (a) A compounder shall have and maintain a permit issued by the board that allows for the compounding of sterile products as defined by the board.
- (b) When a compounder prepares more than 50 dosage units for non-patient specific preparations the compounder shall be registered as a drug manufacturer or 503B with the FDA.

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(c) Compounders supplying limited quantities, less than 50 dosage units, to providers for administration use shall have an MOU with the provider for each compounded product they supply to the provider. When a compounder provides a practitioner a non-patient specific preparation, the compounder shall provide the practitioner a copy of the test result for each lot provided to the practitioner.

(d) Each batch of a high risk CSP shall be assigned a unique lot number and shall be tested by an independent lab for sterility, potency, and endotoxins. Only a batch that has passed all 3 tests shall be made available to provide to a hospital or practitioner.

(e) A compounder shall not compound a sterile product of an FDA-approved product when the product is commercially available.

(f) When no commercial source of a sterile product exists, such as being listed on the FDA backorder list, the compounder shall only use USP or other USP recognized grades such as BP, JP, EP, bulk ingredients obtained from a good manufacturing practice compliant supplier. The compounder shall obtain and keep on file for at least 3 years a certificate of analysis and potency testing of all bulk ingredients used to compound each and every compounded product made with a bulk, non-sterile ingredient.

(g) A compounder who uses hazardous products shall meet state and federal requirements for handling of hazardous agents.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

### **Ph 404.05 Sterile Quality Requirements.**

(a) Each compounder shall maintain documentation that confirms staff training and competency related to proper garbing and hand hygiene, aseptic technique and related practices, and cleaning and disinfection procedures prior to compounding of any actual sterile product preparation.

(b) Each compounder shall maintain documentation that confirms that the compounder tests aseptic techniques of all staff that compounds sterile products by preparing media fill units per USP standards.

(c) Each compounder shall maintain documentation that confirms all staff that compounds sterile products are pre-qualified using media fills before compounding of actual drug preparations.

(d) When a positive media fill occurs, compounder shall perform a comprehensive investigation to identify root cause, and document the finding.

(e) When a positive media fill occurs, compounder shall institute corrective and preventive action, and document the corrective action.

(f) Each compounder shall verify that all personnel who compound sterile products are complying with gowning, gloving, and glove-tip processes consistent with USP standards by meeting the following requirements:

(1) Three glove fingertip tests shall be performed initially then annually for low and medium risk compounding;

(2) Three glove fingertip tests shall be performed initially then every 6 months for high risk compounding; and



(3) Media fill tests shall be performed every 6 months for high risk compounding.

(g) Each compounder shall perform routine surface microbiological and fungal environmental monitoring to minimize contamination at least every 6 months, or in accordance with facilities policies.

(h) Each compounder shall perform comprehensive investigations of out-of-limit findings, as recommended by USP standards to determine root cause, followed by corrective and preventative actions at least weekly. Each compounder shall maintain all documentation of its findings.

(i) Each compounder shall perform, at least semi-annually, viable particle testing in primary engineering controls, such as laminar flow workbench, biological safety cabinet and room air according to USP standards.

(j) Each compounder shall ensure that all compounded sterile products that require refrigeration are stored in appropriate refrigeration at all times.

(k) When a compounder assigns a BUD for a sterile product that exceeds BUD limits established in USP standards, a compounder shall have laboratory testing results that support extended expiration dating for compounded sterile preparations to any patient or organization that request such documentation.

(l) Each compounder shall perform studies to determine extended expiration dates, using evidence-based and validated stability testing procedures, for compounded sterile preparations for which no extended expiration evidence exists.

(m) Each compounder shall have a policy that requires validation of new or changed facilities, equipment, processes, container types, for sterility, and repeatability.

(n) Each compounder shall have a quality assurance program to promptly address equipment problems.

(o) Each compounder shall have a quality assurance program for compounding that includes at least the following separate, but integrated, components:

- (1) Training;
- (2) Standard operating procedures;
- (3) Documentation;
- (4) Verification;
- (5) Testing;
- (6) Cleaning and disinfecting;
- (7) Containers, packaging and repackaging; and
- (8) Storage.

(p) Personnel involved in the compounding, evaluation, packaging and dispensing of compounded preparations shall be properly trained and evaluated to include:

- (1) Three glove fingertip tests shall be performed initially then annually for low and medium risk compounding; and

(2) Three glove fingertip tests shall be performed initially then every 6 months for high risk compounding.

(q) Personnel shall undergo re-qualification using media fills and glove fingertip tests annually for low and medium risk sterile compounding and every 6 months thereafter for high risk sterile compounding.

(r) Each compounder shall have an action plan and alert limits for environmental monitoring.

(s) Each compounder shall develop and implement methods for improving quality based on analyzed data found in its environmental monitoring.

(t) Each compounder shall evaluate and continuously monitor the methods used for the packaging, handling, and transport of CSPs.

(u) Each compounder shall evaluate and continuously monitor the storage of CSPs to ensure compliance with appropriate storage conditions.

(v) Each compounder shall ensure drug storage refrigerators, freezers and medication storage areas have daily monitoring and documentation of temperatures.

(w) Compounder personnel shall inspect all drug storage areas routinely to ensure drugs are stored separately from food.

(x) Each compounder shall ensure all solutions, medications, equipment, and supplies located in all areas are stored according to the manufacturer or USP requirements and are inspected monthly for proper conditions of light, temperature, moisture, and ventilation.

(y) Each compounder shall ensure all outdated and unused CSPs are segregated in a separate area for return and disposal.

(z) Each compounder shall ensure only pharmacists training in sterile compounding determine whether a CSP not administered as originally intended can be used for an alternate patient or under alternate conditions.

(aa) Each compounder shall have an environmental sampling plan based on the compounding activities performed, locations to be monitored, the device used to monitor, the frequency of collection, and procedures if readings exceed established thresholds.

(ab) The 2 types of monitoring that shall be used are:

(1) Non-viable monitoring which includes particle counts, monitoring pressure or velocity difference between the buffer area, ante area and non-classified area and shall be done at least every 6 months; and

(2) Viable monitoring which detects microbial or fungal contaminants in the compounding area and shall be done using a volumetric collection method.

(ac) Monitoring, sampling, and testing for surface contamination from hazardous drugs is conducted at least every month or earlier in cases of contamination from fluid or solid dosage form spills.

(ad) Compounder shall ensure certification of its PEC complies with the requirements of USP Standards. Certification shall be done by an independent entity certified to perform the test. Each certifying entity shall leave a signed copy of the test with the compounder who shall retain the document for at least 4 years.

(ae) Each compounder shall ensure the PEC is certified every 6 months or sooner if recommended by the manufacturer.

(af) Each compounder shall ensure viable and non-viable airborne sampling occurs minimally every 6 months. Monitoring shall include all areas at risk of contamination including but not limited to inside of PEC, counters, anteroom, areas near doorways, and any pass-through, counters, storage areas, shelves, shipping and receiving areas, and employee work areas.

(ag) Each compounder shall ensure sampling data is base-lined, evaluated and documented on a routine basis as defined by USP standards.

(ah) Each compounder shall have a written plan and schedule for environmental monitoring.

(ai) Each compounder shall have a written environmental plan that adequately evaluates the various controlled air environment areas including the PEC, buffer area, and anteroom.

(aj) Compounder facility personnel, or external personnel, who complete the environmental monitoring shall be appropriately trained and certified by a national certification entity.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 404.06 Compounding Environment.

(a) Each compounder shall ensure there is sufficient space for the type and amount of compounding done.

(b) Each compounder shall ensure there is appropriate space for orderly placement of equipment and materials to prevent mix-ups between ingredients, containers, labels, in-process materials and finished preparations.

(c) Each compounder shall ensure it has procedures to prevent cross-contamination.

(d) Each compounder shall ensure areas used for sterile preparation are separate and distinct from areas used for non-sterile preparation.

(e) Each compounder shall have a well-lighted compounding environment.

(f) Each compounder shall ensure all heating, ventilation and air conditioning systems are controlled to maintain a constant temperature 24 hours per day, 7 days per week.

(g) Each compounder shall maintain a bulk storage area that is adequately arranged and proper temperature and humidity maintained.

(h) Each compounder shall supply hot and cold potable water for hand and equipment washing in the compounding area, and soap or detergent and single-use towels or driers shall be readily available.

(i) Each compounder shall ensure all compounding areas are maintained in a clean and sanitary condition.

(j) When compounder uses hard-wall construction, the finished surface shall provide a non-porous, durable and washable surface.

(k) The compound area shall meet the following requirements:

- (1) All ceilings shall be smooth, impervious, free from cracks and non-shedding, such as plastic covered clean room grade ceiling tiles, and all tiles shall be sealed;
- (2) All floors shall be smooth, impervious, free from cracks and non-shedding, and the floor must be of seamless vinyl;
- (3) All fixtures shall be smooth, impervious, free from cracks and non-shedding. All fixtures shall be mounted to wall in a way that seals any space between wall and fixture;
- (4) All shelving shall be smooth, impervious, free from cracks and non-shedding;
- (5) Counters shall be smooth, impervious, free from cracks and non-shedding;
- (6) All cabinets shall be smooth, impervious, free from cracks and non-shedding;
- (7) Ceiling to wall junctures shall be covered or caulked to avoid cracks;
- (8) Inlaid ceiling panels shall be impervious and hydrophobic;
- (9) Ceiling panels shall be caulked around the perimeter to seal them to frame;
- (10) Floors shall be overlaid with wide sheet vinyl flooring with heat welded seams and coving to the sidewall;
- (11) There shall be no dust-collecting overhangs;
- (12) There shall be no windowsills;
- (13) Exterior lens surface of ceiling light fixtures shall be smooth, mounted flush, and sealed;
- (14) There shall be no sinks in primary and secondary compounding areas;
- (15) There shall be no floor drains in primary and secondary compounding areas;
- (16) Carts shall be made of stainless steel wire or sheet metal with cleanable casters;
- (17) Carts shall be mobile;
- (18) All surfaces shall be designed to provide effective cleaning;
- (19) All surfaces shall be resistant to damage by cleaning agents;
- (20) There shall be no cardboard containers in buffer area at any time;
- (21) There shall be no computers, printers, radios and refrigerators in the buffer area at any time;
- (22) The bulk storage area shall be maintained in a clean and sanitary condition;
- (23) Trash shall be disposed of in a safe, sanitary and timely manner; and
- (24) All components, containers and equipment shall be stored off the floor in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area.

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(l) Each compounder shall ensure equipment is of appropriate design and size for the compounding that is performed.

(m) Each compounder shall ensure that all equipment is of appropriate design such that the surface that contact pharmaceutical components, in-process materials or finished preparations is not reactive, additive or adsorptive.

(n) Each compounder shall ensure that all equipment is thoroughly cleaned immediately after use to avoid cross-contamination.

(o) Each compounder shall ensure all equipment is stored to prevent it from contamination and is located to facilitate its use, maintenance, and cleaning.

(p) Each compounder shall ensure all equipment used for allergenic ingredients is appropriately handled, cleaned and stored immediately after use.

(q) Each compounder shall ensure all work surfaces are cleaned of loose materials and residue from spills before compounding.

(r) Each compounder shall ensure all floors in the buffer area and ante area are mopped daily with a cleaning and disinfecting agent at a time when no aseptic compounding is in progress.

(s) Each compounder shall approve all cleansing and sanitizing agents considering compatibilities, effectiveness, and presence of inappropriate or toxic residues.

(t) Each compounder shall ensure the following requirements are met:

(1) Mops, wipes, sponges, and other cleaning materials shall be non-shedding and dedicated for use only in the sterile compounding area;

(2) Cleaning tools shall be replaced as soon as they are identified as unsuitable for use;

(3) All cleaning materials shall be disposable and discarded after one use;

(4) All trash shall be collected in suitable plastic bags and removed on a daily basis with minimal agitation;

(5) Workspaces shall be cleaned and sanitized daily including all buffer room carts, equipment, workbenches, work surfaces, and floors, and document the activity;

(6) Storage shelving in buffer and ante areas shall be emptied of all supplies, cleaned, and sanitized at planned intervals at least monthly;

(7) Walls and ceilings in buffer and ante areas shall be cleaned at least monthly; and

(8) All equipment shall be clean, properly maintained, validated and documented at appropriate intervals as defined by USP Standards.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 404.07 Engineering Controls.

- (a) Each compounder shall ensure the PEC, LAFW and BSCs provide ISO Class 5 air quality;
- (b) Each compounder shall ensure the buffer room maintains a minimum of an ISO Class 7 air quality;
- (c) Each compounder shall ensure the buffer room is designed to reduce the risk of contaminants being blown into the primary compounding area, or PCA. To be considered a clean room, buffer area must meet specific air quality, HEPA filtration, air changes per hour, and room pressure differentiation criteria to provide at least ISO Class 7 air quality.
- (d) Each compounder shall ensure that within the buffer area, the PEC should be kept away from excess traffic, doors, air vents, or anything that could introduce contaminants into the workbench.
- (e) Each compounder shall ensure that the anteroom is separate from buffer area.
- (f) Each compounder shall ensure that the anteroom provides ISO Class 8 air quality, or ISO Class 7 air quality, depending on the connecting buffer area.
- (g) Each compounder shall ensure the anteroom area should store an adequate amount of gowning supplies but should not be part of high traffic area or corridor.
- (h) Each compounder shall ensure the anteroom is used to un-carton and sanitize all supplies to be taken into buffer area.
- (i) Each compounder shall ensure the anteroom contains:
  - (1) Hand sanitizing equipment;
  - (2) Proper gowning equipment and space to accommodate gowning activities;
  - (3) Faucet handles that shall be designed to be hands-free; and
  - (4) That the buffer area can be accessed without the use of hands.
- (j) Each compounder that only compounds low and/or medium risk preparations, the ante room may be in the same area as the buffer room, separated by a line of demarcation. However, a separate ante room shall be the preferred method.
- (k) Each compounder that compounds high risk preparations, the buffer room and the ante room shall be 2 separate rooms.
- (l) Each compounder shall ensure all supplies brought into the buffer area are non-permeable, non-shedding, and resistant to disinfectants.
- (m) Each compounder shall ensure all materials exposed to patient care areas are kept out of the buffer area.
- (n) Each compounder shall ensure the PECs are cleaned and disinfected at the beginning of each shift, before each batch, at least every 30 minutes during compounding, when surfaces are visibly soiled, and when surface contamination is known or even suspected.
- (o) Each compounder shall ensure all interior working surfaces are cleaned and disinfected of LAFW from top to bottom, back to front, away from the HEPA filter. Cleaning shall be performed with purified water, and disinfecting with sterile 70% isopropyl alcohol or similar antimicrobial, residue-free sanitizing agent.

(p) Each compounder shall ensure nothing shall be permitted to come in contact with the HEPA filter. This includes cleaning solutions, aspirate from syringes, or glass from ampules, which shall not be broken towards the filter.

(q) Each compounder shall ensure air exchange with the surrounding environment shall not occur unless the air is first passed through a microbial retentive filter such as a HEPA system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed building ventilation.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

New. #10812, eff 4-18-15

Ph 404.08 Compounding Procedures.

(a) Each compounder shall ensure that all personnel adhere to the following when they are in the LAFW or buffer areas:

- (1) No smoking, food, drink, or chewing gum shall be allowed in the buffer area at any time;
- (2) No jewelry shall be worn on the hands or wrists and there shall be no visible piercings;
- (3) No make-up shall be worn in the buffer area as it can shed particles;
- (4) Before putting on gloves, the nails shall be cleaned, and the hands, wrists, and forearms shall be washed thoroughly for at least 30 seconds with warm water and antimicrobial skin cleanser;
- (5) Personnel shall appropriately utilize gowns, masks, gloves, hair covers, and shoe covers;
- (6) No paper, pens, labels, or trays shall be placed in the workbench; and
- (7) No objects that shed particles shall be brought into the buffer area such as cardboard cartons, paper towels, and cotton items.

(b) Each compounder shall ensure when cleaning and disinfecting the interior work surfaces of the LAFW it is done from top to bottom, back to front, away for the HEPA filter.

(c) Each compounder shall ensure personnel check the quality, purity, amount, and identity of all ingredients.

(d) Each compounder shall ensure all personnel use the correct compounding procedures when compounding sterile products, and periodically disinfect gloves with sterile 70% isopropyl alcohol and allow them to dry thoroughly before continuing.

(e) Each compounder shall ensure that open and partially used containers are properly labeled and stored.

(f) Each compounder shall ensure the following:

- (1) CSP has an appropriate BUD that is identified on all product labels;

- (2) When the BUD exceeds USP standards, it is based on scientific criteria;
- (3) Packaging is appropriate for sterility and stability;
- (4) Product labels are appropriate and complete for safe use; and
- (5) Products are visually inspected for physical integrity during and after compounding, and a final check of the CSP is performed.

(g) Each compounder shall ensure any deficiencies in compounding procedures can be rapidly identified and corrected.

(h) Each compounder shall ensure that finished compounded products are maintained in a separate area away from the active compounding area, and that no more than 2 entries into any one sterile container or sterile administration device.

(i) Each compounder shall ensure all compounding activity only involves closed or sealed packaging systems.

(j) In the absence of stability and sterility testing of any CSP the compounder shall use BUD based on USP standards as defined for the following CSPs:

- (1) Low risk compounded product storage shall not exceed 48 hours at room temperature, 14 days at cold temperature or 45 days in a frozen state if the stability of the product allows;
- (2) Medium risk compounded product storage shall not exceed 30 hours at controlled room temperature, 9 days at cold temperature or 45 days in a frozen state;
- (3) High risk compounded product storage shall not exceed 24 hours at room temperature, 3 days at cold temperature or 45 days in a frozen state.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 404.09 Records Management.

(a) Compounder shall maintain the following records related to compounding of sterile products for at least 4 years:

- (1) PEC certification records;
- (2) GAP analyses; and
- (3) Detailed formulation record of each sterile compounded preparation that includes:
  - a. Name of preparation, strength and dosage form;
  - b. All ingredients and their quantities;
  - c. Equipment used for the preparation;
  - d. Add mixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors;



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- e. Assigned beyond-use date;
- f. Container used;
- g. Storage requirements; and
- h. Quality control procedures.

(b) Each compounder shall have procedures developed for the facility, equipment, personnel, preparation, packaging and storage of compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding.

(c) Each compounder shall have a procedure for recalls. The recall file shall be maintained with information concerning any applicable recalled products affecting the pharmacy.

(d) Each compounder shall perform and maintain a quality control history and quality assurance trend reports on a quarterly basis and upon request.

(e) Each compounder shall maintain documentation that confirms that sterile media used is certified by the manufacturer to be sterile and guaranteed to promote growth.

(f) Each compounder shall maintain detailed reports on the incidence of positive media test results and the follow-up retests after corrective action is completed.

(g) Each compounder shall provide a guaranteed shelf life upon delivery. This date shall be based on USP Standards, or based on established scientific criteria.

(h) Each compounder shall document processes and procedures including shipping validation studies to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle.

(i) Each compounder shall ensure that all personnel annually receive live training and visual process validation including written documentation of both processes.

(j) Each compounder shall maintain documentation that it's cleaning methods and agents are effective in preventing contamination of the sterile preparations area.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

### PART Ph 405 STANDARDS OF PRACTICE FOR NUCLEAR/RADIOLOGIC PHARMACY

Ph 405.01 Purpose. The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the state board of pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

#### Ph 405.02 Definitions.

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(a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(b) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services.

(c) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(d) "Quality assurance procedures" means all activities necessary to guarantee the integrity of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by the department of health and human services, bureau of radiological health.

(e) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(f) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. The term includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(g) "Radiopharmaceutical service" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

### **Ph 405.03 General Requirements for Pharmacies Providing Radiopharmaceutical Services.**

(a) A permit to operate a pharmacy which provides radiopharmaceutical services shall only be issued to a person who is, or who employs, a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The nuclear pharmacist who licenses the pharmacy shall hold a current license issued by the board, and be either certified as a nuclear pharmacist by the board of pharmaceutical specialties or satisfy each of the following requirements:

(1) Meets minimal standards of training for status as authorized user of radioactive material, as specified by the department of health and human services, bureau of radiological health;

(2) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy, or other training program recognized by the department of health and human services, bureau of radiological health;

(3) The 200 hours of instruction referenced in (2) above shall be apportioned as follows:

- a. Radiation physics and instrumentation, 85 hours;
- b. Radiation protection, 45 hours;
- c. Mathematics pertaining to the use and measurement of radioactivity, 20 hours;
- d. Radiation biology, 20 hours; and
- e. Radiopharmaceutical chemistry, 30 hours;

(4) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

- a. Procuring radioactive materials;
- b. Compounding radiopharmaceuticals;
- c. Performing routine quality control procedures;
- d. Dispensing radiopharmaceuticals;
- e. Distributing radiopharmaceuticals;
- f. Implementing basic radiation protection procedures; and
- g. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and

(5) Has submitted an affidavit of experience and training to the board.

(c) The permit to operate a nuclear pharmacy shall be effective only so long as the pharmacy also holds a current license issued by the department of health and human services, bureau of radiological health. Copies of the bureau of radiological health inspection reports shall be available at the pharmacy for board inspection.

(d) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and meeting minimal space requirements established for all pharmacies in the state.

(e) All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

- (1) Radiopharmaceutical preparation/dispensing area;
- (2) Radioactive material shipping/receiving area;
- (3) Radioactive material storage area; and
- (4) Radioactive waste decay area.

(f) The application for a permit to operate a nuclear pharmacy shall be the same as in Ph 304.01 and Ph 304.02.

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(g) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and shall be totally enclosed and lockable.

(h) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with the board and the department of health and human services, bureau of radiological health statutes and rules.

(i) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the department of health and human services, bureau of radiological health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(j) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(k) The writing or record required by (i) above shall contain at least the following:

- (1) The name of the institution and prescriber, or prescribers' agent;
- (2) The date of dispensing and the calibration time of the radiopharmaceutical;
- (3) The name of the procedure;
- (4) The name of the radiopharmaceutical;
- (5) The dose or quantity of the radiopharmaceutical;
- (6) The serial number assigned to the order for the radiopharmaceutical;
- (7) Any specific instructions;
- (8) The initials of the person who received the order; and
- (9) The initials of the person who dispensed the order.

(l) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall be obtained and recorded prior to dispensing.

(m) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

- (1) The name and address of the pharmacy;
- (2) The name of the prescriber;
- (3) The date of dispensing;
- (4) The serial number assigned to the order for the radiopharmaceutical;
- (5) The standard radiation symbol;
- (6) The words "Caution Radioactive Material";
- (7) The name of the procedure;
- (8) The radionuclide and chemical form;

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(9) The amount of radioactivity and the calibration date and time;

(10) If a liquid, the volume;

(11) If a solid, the number of items or weight;

(12) If a gas, the number of ampules or vials;

(13) Molybdenum 99 content to USP limits; and

(14) The name of the patient or the words "Physician's Use Only" in the absence of a patient name.

(n) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(o) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name of the pharmacy;

(2) The standard radiation symbol;

(3) The words "Caution Radioactive Material";

(4) The identity of the radionuclide;

(5) The chemical form;

(6) The name of the procedure; and

(7) Serial number of the radiopharmaceutical.

(p) When a radiopharmaceutical is dispensed under the authority of an investigational new drug application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, and a letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(q) Each nuclear pharmacy shall have a current copy of the United States Pharmacopeia/National Formulary (USP/NF), USP-DI, and a current copy of state and federal rules and regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10812, eff 4-18-15

Ph 405.04 Minimum Equipment. The pharmacy shall have at least the following equipment:

(a) A radionuclide dose calibrator;

(b) A refrigerator;

(c) A single or multiple channel scintillation counter with well-type NaI (Tl) or Ge (Li) detector;

- (d) A radiochemical fume hood and filter system with air sampling equipment;
- (e) An area survey meter;
- (f) At least 2 Geiger Mueller survey meters including one high-range meter;
- (g) A microscope and hemacytometer;
- (h) A laminar air flow hood and appropriate supplies to ensure sterile practices for parenteral solutions;
- (i) Syringe and vial radiation shields;
- (j) A lead-shielded drawing station;
- (k) Decontamination supplies;
- (l) Supplies to perform quality assurance testing;
- (m) Lead transport shields for syringes and vials; and
- (n) United States Department of Transportation approved USA Type A - 7A transport containers and other labels and supplies for shipping radioactive materials.

[Source.](#) #6181-B, eff 2-5-96, EXPIRED: 2-5-04

[New.](#) #8316, eff 3-26-05, EXPIRED: 3-26-13

[New.](#) #10812, eff 4-18-15

## CHAPTER Ph 500 ETHICAL STANDARDS

### PART Ph 501 CODE OF ETHICS

#### Ph 501.01 Standards of Conduct.

- (a) The ethical standards set forth in this part shall bind all licensees, and violation of any such standard shall be a basis for the imposition of disciplinary sanctions.
- (b) A licensed pharmacist shall:
  - (1) Hold the health and safety of patients to be of first consideration and render to each patient the full measure of his/her ability as an essential health practitioner;
  - (2) Never condone the dispensing, promoting or distributing of drugs or medical devices, or assist therein, which are not of good quality, which do not meet standards required by law or which lack therapeutic value for the patient;
  - (3) Always strive to perfect and enlarge his/her professional knowledge;
  - (4) Utilize and make available his/her knowledge as might be required in accordance with his/her best professional judgment;
  - (5) Observe the law, uphold the dignity and honor of the profession, and accept its ethical principles;

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- (6) Not engage in any activity that will bring discredit to the profession and shall expose, without fear or favor, illegal or unethical conduct in the profession;
- (7) Seek at all times only fair and reasonable remuneration for services rendered;
- (8) Never agree to or participate in transactions with practitioners of other health professions or any other person under which fees are divided or which might cause financial or other exploitation in connection with the rendering of their professional services;
- (9) Respect the confidential and personal nature of professional records, except in emergency situations where the best interest of the patient requires or the law demands, and shall not disclose such information to anyone without patient authorization;
- (10) Not agree to practice under terms or conditions which tend to interfere with or impair the proper exercise of professional judgment and skill, which could cause a deterioration of the quality of his/her service or which require him/her to consent to unethical conduct;
- (11) Refrain from advertising professional services in a manner which is misleading to the public or which conveys by implication that the services of fellow pharmacists are unethical or inferior;
- (12) Maintain a sanitary and orderly prescription department which is fully equipped and stocked to meet the needs of the community; and
- (13) Fulfill all professional obligations conscientiously and with due respect for the physical and well-being of the community, and, uphold at all times the standards of the profession of pharmacy.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10455, eff 11-1-13

**CHAPTER Ph 600 LIMITED RETAIL DRUG DISTRIBUTOR**

Statutory Authority: RSA 318:51-b

**PART Ph 601 LICENSING OF LIMITED RETAIL DRUG DISTRIBUTORS**

**Ph 601.01 License Required.**

(a) No person shall act as a limited retail drug distributor, as defined in RSA 318:1,VII-a, without first obtaining a license to do so from the board according to RSA 318:51-b.

(b) No license shall be issued or renewed for a limited retail drug distributor unless the same shall be operated in a manner prescribed by RSA 318:51-b and according to Ph 600.

(c) Separate licenses shall be required for each site owned and operated by the limited retail drug distributor.

(d) The board shall provide, on an annual basis, a license renewal application to all licensed limited retail drug distributors.

(e) The prescribed fee for annual and renewal licenses for limited retail drug distributors shall be:

- (1) For clinics under contract with the department of health and human services (DHHS), \$150;
- (2) For methadone maintenance/detoxification treatment centers, \$250; and
- (3) For medical gas suppliers, \$150.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #8572, eff 2-23-06; amd by #9139-B, eff 4-25-08; paragraphs (a)-(d) EXPIRED: 2-23-14; paragraph (e) EXPIRED: 4-25-16

New. #12335, eff 7-22-17

Ph 601.02 Obtaining and Filing a License Application.

(a) Applications for licensure of limited retail drug distributors may be obtained from and filed at the board office, identified in Ph 103.03.

Source. #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #12335, eff 7-22-17

Ph 601.03 Application Contents.

(a) The applicant for licensure shall complete and submit a “Limited Retail Drug Distributor of Medical Gases and/or Medical Devices” form, form MM-1, revised June 2017.

(b) The applicant shall also submit the following:

- (1) A scaled drawing of the facility;
- (2) A copy of the state license from the state licensing agency where the facility is located, if such facility is outside New Hampshire, or an explanation detailing why the applicant does not have such a license; and
- (3) A copy of the facility’s most recent inspection report completed by the state licensing board or agency where the facility is domiciled, if it is located outside New Hampshire, or an explanation detailing why the applicant does not have such an inspection report.

(c) The applicant shall supplement the application specified in (a) and (b) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements of Ph 600.

(d) If the applicant is a corporation, or the limited retail drug distributor will be operated under a corporate name, a certificate from the NH secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name shall be included with the application.

(e) If the applicant proposes to hold, store, or dispense controlled substances as a methadone maintenance/detoxification facility, the application shall be supplemented with the following information:



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- (1) A brief description of the security system;
- (2) A list of all persons with access to the controlled substances;
- (3) The applicant shall supplement the application specified in (a) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements for operation of a drug abuse treatment facility, as outlined in He-A 304; and
- (4) If the application is for a methadone maintenance/detoxification facility, the applicant shall submit the current registration number issued by the federal drug enforcement administration (DEA).

(f) The applicant shall sign, indicate his or her title, and date the application under the following affirmation:

“I affirm that I am the person authorized to sign this application for licensure and declare under penalties of unsworn falsification under RSA 641:3 that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire board of pharmacy and to the laws and rules of this state.”

(g) The board shall issue a license pursuant to this section if the applicant:

- (1) Files a complete application that meets the requirements of these rules and RSA 318; and
- (2) Is of good moral character, or, if the applicant is an association or corporation, that the managing officers are of good moral character, as evidenced by the absence, within the last 5 years, of conviction of any felony, or of a misdemeanor resulting from a violation of any drug related law of the United States or of any state.

Source. #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #12335, eff 7-22-17

Ph 601.04 Consultant Pharmacist. All applicants licensed under the provisions of RSA 318:51-b shall have a written contract with a pharmacist, licensed in NH, to serve as a consultant on all matters relating to procurement, storage and dispensing of prescription drugs as defined in RSA 318:1, XVII.

Source. #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #12335, eff 7-22-17

Ph 601.05 Changes in Supporting Information. The applicant shall notify the board, immediately, of any changes of information from that which was submitted on the original application pursuant to Ph 601.03. Failure to report changes shall result in the imposition of a \$25 administrative fine. No license shall be issued until all fees and fines are paid in full.

Source. #8572, eff 2-23-06; ss by #9139-B, eff 4-25-08, EXPIRED: 4-25-16

New. #12335, eff 7-22-17

Ph 601.06 Renewal Applications.

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- (a) The license period shall be from July 1 thru June 30 of the following year.
- (b) Applications for renewal of a license to operate as a limited retail drug distributor shall consist of prescribed fee as indicated in Ph 601.01(e) and the following appropriate application form:
  - (1) For medical gas suppliers, Form MM-2A, “Renewal Application for Limited Retail Drug Distributor of Medical Gases and/or Medical Devices for Sale Direct to Patient/Consumer Pursuant to a Prescription,” revised June 2017;
  - (2) For clinics under contract with DHHS, Form MM-2B, “Limited Retail Drug Distributor Public Health Clinic”, revised June 2017; or
  - (3) For methadone maintenance/detoxification facilities, Form MM-2C, “Limited Retail Drug Distributor Methadone Maintenance/Detoxification Facility”, revised June 2017.
- (c) Medical gas supplier and methadone maintenance/detoxification renewal applicants shall submit the following additional information with their renewal applications:
  - (1) For medical gas suppliers:
    - a. A copy of the current state license from the applicant’s home state licensing authority if outside New Hampshire, or an explanation as to why the renewal applicant does not have such a license; and
    - b. A copy of the most recent inspection report from the applicant’s home state licensing authority if outside New Hampshire, or an explanation as to why the renewal applicant does not have such an inspection report; and
  - (2) For methadone maintenance/detoxification facilities:
    - a. A copy of the clinic’s current NH DHHS certified drug treatment provider certificate; and
    - b. A copy of the clinic’s current DEA registration.
- (d) Renewal applications shall include a dated signature and title under the following affirmations:
  - (1) For medical gas suppliers:

“I affirm that I am the person authorized to sign this application for licensure on behalf of the company/licensee and affirm that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State.”
  - (2) For clinics under contract with DHHS:

“I declare under penalties of unsworn falsification under RSA 641:3 that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the permit herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State.”; and
  - (3) For methadone maintenance/detoxification facilities:

“I declare under penalties of unsworn falsification under RSA 641:3 that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the permit herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State. To the best of my knowledge, myself nor any of the employees listed on this application, have been arrested, investigated for, charged with, convicted of, sentenced, entered a plea of non contendere, or entered into any other legal agreements for any criminal offense in any state, territory or possession of the United States or by the federal government.”

(e) The board shall renew a license pursuant to this section if the applicant:

- (1) Files a complete application that meets the requirements of these rules and RSA 318; and
- (2) Is of good moral character, or, if the applicant is an association or corporation, that the managing officers are of good moral character, as evidenced by the absence, within the last 5 years, of conviction of any felony, or of a misdemeanor resulting from a violation of any drug related law of the United States or of any state.

[Source.](#) #8572, eff 2-23-06, EXPIRED: 2-23-14

[New.](#) #12335, eff 7-22-17

Ph 601.07 Temperature. The temperature in any area wherein drugs are compounded shall, at all times, be in compliance with the standards established by the United States Pharmacopoeia as defined in Ph 701.02(s).

[Source.](#) #8572, eff 2-23-06, EXPIRED: 2-23-14

[New.](#) #12335, eff 7-22-17

Ph 601.08 Quarantine. Any drug, which is adulterated as defined in Ph 701.02(a) or misbranded as defined in Ph 701.02(j), shall be removed from the routine stock and held in a specifically designated secure area of the facility pending proper and safe disposition.

[Source.](#) #8572, eff 2-23-06, EXPIRED: 2-23-14

[New.](#) #12335, eff 7-22-17

Ph 601.09 Space. Drugs shall be housed in a well-lighted and ventilated room or department with clean and sanitary surroundings.

[Source.](#) #8572, eff 2-23-06, EXPIRED: 2-23-14

[New.](#) #12335, eff 7-22-17

Ph 601.10 Security.

(a) That portion of the facility where drugs are stored, compounded or dispensed, shall be lockable so as to prevent entry into that area by any person or persons without the knowledge of the authorized individuals on duty, or when the facility is not open.

(b) If the facility contains controlled substances, it shall be equipped with an alarm system as referenced in Ph 1002.03.

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(c) Methadone maintenance/detoxification facilities shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting to illuminate the outside perimeter of the premises.

(d) All controlled substances shall be stored pursuant to the security provisions outlined in 21 CFR 1301.72(a).

(e) For those facilities which are open to the public 24 or more hours per week, the consultant pharmacist shall visit, at least monthly, all areas of the facility where drugs are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any drugs not conforming to these standards shall be removed from stock. For facilities which are open to the public less than 24 hours per week, such visits shall be conducted on a quarterly basis.

(f) The consultant pharmacist shall create a written record of each monthly and/or quarterly inspection, specified in (e), which shall be maintained on site and available to the board upon request.

(g) The pharmacist shall ensure that the areas specified in (e) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(h) The consultant pharmacist shall develop a distribution system that prevents the illegal diversion of drugs. Where applicable, the inventory of all schedule II controlled substances and other controlled drugs stored in any area of the facility, shall be checked by 2 persons at least every 24 hours and accountability records shall be completed by the nursing or medical staff and maintained on-site for inspection by the consultant pharmacist.

(i) Notwithstanding (h) above, in situations at the methadone maintenance/detoxification facilities that result in only one staff member being present, the inventory shall be counted, signed, dated and shall be “cosigned” immediately upon the presence of a second staff member. However, at no time shall there lapse more than 72 hours before this inventory verification by a second party.

Source. #8572, eff 2-23-06; amd by #9139-B, eff 4-25-08; paragraphs (a)-(g) EXPIRED: 2-23-14; paragraph (h) EXPIRED: 4-25-16

New. #12335, eff 7-22-17

Ph 601.11 Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, physician, advanced registered nurse practitioner, physician assistant, or registered nurse as identified in RSA 318:42, VII (a), in compliance with state and federal pharmacy-related laws and rules.

(b) In the case of methadone maintenance/detoxification facilities and according to the provisions of RSA 318:42 the dispensing of narcotics is extended to employees of the clinic, authorized in writing according to the provisions of 21 CFR 1301.74(i) of the federal law.

Source. #8572, eff 2-23-06; amd by #9139-B, eff 4-25-08; paragraphs (c) and (d) EXPIRED: 2-23-14 paragraphs (a)& (b) EXPIRED: 4-25-16

New. #12335, eff 7-22-17

Ph 601.12 Deliveries.

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(a) All drug order deliveries containing prescription drugs shall be delivered only when a licensed practitioner is on the premises in order to secure such drug orders.

(b) In the case of methadone maintenance/detoxification facilities, drug deliveries may be accepted only by the licensed practitioner or other individuals identified according to the requirements of 21 CFR 1301.74(h).

Source. #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #12335, eff 7-22-17

Ph 601.13 Access to Drug Supply.

(a) Only the pharmacist, physician, advanced registered nurse practitioner, physician assistant or registered nurse, as identified in RSA 318:42 shall have access to the drug supply.

(b) In the case of methadone maintenance/detoxification facilities, access to the drug storage area may also be extended to licensed practical nurses provided such authorization is granted, in writing, according to the provisions of 21 CFR 1301.72(d) of the federal law.

(c) Methadone maintenance/detoxification facilities shall supply the board with a list of all individuals that have been granted access to the drug supply, and, should this list change, the board shall be notified, in writing, within 72 hours of such changes.

Source. #8572, eff 2-23-06; ss by #9139-B, eff 4-25-08  
EXPIRED: 4-25-16

New. #12335, eff 7-22-17

Ph 601.14 Dispensing Records.

(a) A readily retrievable record, completed by the nursing or medical staff, shall be made of all administration or dispensing of prescription drugs from the facility.

(b) The record, as specified in (a) above, shall be separate from the patient's medical record and include:

- (1) Name and address of the patient;
- (2) Date of administration or dispensing;
- (3) Name, strength and quantity of drug(s) administered or dispensed;
- (4) Identity of the prescriber; and
- (5) Signature of the person administering or dispensing.

(c) Methadone maintenance/detoxification facilities shall maintain a dispensing log, completed by the nursing or medical staff, containing the following information:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;
- (4) Date administered;

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- (5) Patient identification number;
- (6) Amount consumed;
- (7) Amount and dosage form taken home; and
- (8) Dispenser's signature.

(d) Records of administrations and dispensing as specified in (b) and (c) above shall be maintained for a period of 4 years. Such records shall be open to inspection by the pharmacy board and its agents during regular business hours.

Source. #8572, eff 2-23-06; amd by #9139-B, eff 4-25-08; paragraphs (a)-(c)(4), (c)(6)-(7), & (d) EXPIRED: 2-23-14 paragraph (c) intro. & (c)(5) EXPIRED: 4-25-16

New. #12335, eff 7-22-17

Ph 601.15 Prescription Labels.

(a) Whenever an authorized practitioner dispenses a controlled drug, as defined in RSA 318-B:1-a and b, or a non-controlled prescription drug, as defined in RSA 318:1, XVII, he/she shall affix to the container in which such drug is dispensed, a label showing at least:

- (1) Name and address of the facility;
- (2) Name of the patient;
- (3) Date dispensed;
- (4) Name, strength and quantity of drug dispensed;
- (5) Directions for use;
- (6) Name of the prescribing practitioner;
- (7) Name or initials of the dispensing practitioner; and
- (8) All pertinent auxiliary labels.

Source. #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #12335, eff 7-22-17

Ph 601.16 Labeling Exemption. The labeling requirements, as specified in Ph 601.15, shall be exempted when medication is being administered for immediate consumption, such as in a methadone maintenance/detoxification facility.

Source. #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #12335, eff 7-22-17

Ph 601.17 Violations. Any person who distributes legend drugs according to RSA 318:51-b and the provisions of Ph 600, shall be subject to disciplinary action as provided in RSA 318:29.

Source. #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #12335, eff 7-22-17

PART Ph 602 MEDICAL GASES

Ph 602.01 Annual Registration Required. Pursuant to Ph 601.06, every person, or corporate entity that is not a licensed pharmacy, engaged in supplying medical gases to the consuming public, or to a patient or a patient's agent, in the state of New Hampshire, shall renew annually with the board as a limited retail drug distributor.

Source. #12335, eff 7-22-17

Ph 602.02 Medical Gas Supplier Requirements.

(a) The limited retail drug distributor license shall be posted in a conspicuous place in the wholesaler's place of business for which it is issued.

(b) A medical gas supplier shall not:

- (1) Supply prescription medications, except medical gases, without appropriate licensure as a limited retail drug distributor;
- (2) Manufacture or distribute medical gases without appropriate licensure as a limited retail drug distributor; or
- (3) Instruct patients regarding clinical use of equipment, or provide any monitoring, assessment, or other evaluation of therapeutic effects without appropriate licensure as a respiratory care practitioner.

(c) A medical gas supplier shall supply medical gas only pursuant to prescription order by an authorized prescriber.

(d) A medical gas supplier shall label each medical gas container with the name, address, and telephone number of the supplier.

(e) A medical gas supplier shall establish and implement written procedures for maintaining records pertaining to the acquisition and supply of, and complaints related to, medical gases.

(f) Records shall be retained for at least 3 years after supply to a patient or one year after the expiration date of the medical gas, whichever is longer.

(g) Medical gases and equipment shall be secure from unauthorized entry and have a system to detect or deter entry after hours and provide protection against theft.

(h) The facility shall be maintained in a clean and orderly condition, and only service animals shall be allowed.

(i) A policy and procedure shall be in place for:

- (1) Recalls;
- (2) Emergencies;
- (3) Shipping and receiving;
- (4) Returned goods; and

(5) Outdates.

(j) Records shall be readily available for review by the board or its inspector during regular business hours.

Source. #12335, eff 7-22-17

## CHAPTER Ph 700 STANDARDS OF PRACTICE

### PART Ph 701 REFERENCES AND DEFINITIONS

Ph 701.01 Applicability. The provisions of this chapter shall apply to, and impose duties upon, all pharmacists, pharmacies, manufacturers, wholesalers and distributors holding licenses issued by the board.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 701.02 Definitions. Except where the context makes another meaning manifest, the following words mean:

(a) "Adulterated drug" means any drug:

- (1) That is contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals;
- (2) Which has been manufactured, composed, prepared, stored, or dispensed in such a manner which may cause it to be contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals; and
- (3) Which can be defined as an adulterated drug under the provisions of RSA 146:4 or federal law.

(b) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician" or "Rx only".

(c) "Distributor" means a person or persons who supplies or facilitates the supply of prescription drugs or devices to someone other than the patient, including, but not limited to, manufacturers, repackagers, brokers and wholesale drug distributors.

(d) "Drug outlet" means all pharmacies, limited retail drug distributors, durable medical equipment providers, dispensing practitioners, hospitals, drug abuse treatment centers, retail stores, penal institutions, infirmaries, clinics and federal or state facilities that are engaged in delivery or distribution of drugs.

(e) "Drug room" or "medication room" means that room or area in an institution used to store prescription drugs.



(f) "Electronic prescription" means transmission of information in electronic form, modem to modem, by way of electronic equipment.

(g) "Facsimile prescription" means the transmission of the exact visual image of a document by way of electronic equipment.

(h) "Institution" means a health care facility which provides inpatient care and includes:

- (1) Hospitals;
- (2) Nursing homes;
- (3) Extended care facilities;
- (4) Residential care facilities;
- (5) Infirmaries;
- (6) Correctional facilities; and
- (7) Clinics.

(i) "Institutional pharmacy" means an area in an institution where drugs are stored, manufactured, compounded, dispensed, or issued to other areas or departments of the institution.

(j) "Misbranded drug" means a drug:

- (1) Whose label misrepresents the contents or is misleading;
- (2) If dispensed by prescription, a drug whose label does not comply with the provisions of RSA 318 or RSA 318-B; and
- (3) Which can be defined as a misbranded drug under the provisions of RSA 146 or federal law.

(k) "NH Pharmacy Law Book" means a publication of the board which contains RSA 318, RSA 318-B and Ph 100 through Ph 1700 and any future chapters.

(l) "Prescriber" means a practitioner, duly authorized by statute, who issues a drug order or prescription.

(m) "Principal" means an officer, director, or primary stockholder of a business entity or corporation.

(n) "Professional corporation" as used in these rules means a corporation organized under RSA 294-A for the purpose of providing professional services in the field of medicine, dentistry, veterinary, podiatry, or any other profession in which individual practitioners can lawfully possess, dispense, or distribute prescription drugs.

(o) "Signature" means:

- (1) The handwritten name of an individual affixed by the hand of that individual to a document;
- (2) An electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign a document or record; or
- (3) An electronic signature.

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(p) "Traditional physician-pharmacist-patient relationship" means a situation whereby the pharmacist knows either the physician, the patient, or both, and/or can readily and easily check on factors concerning the prescription.

(q) "Unit-dose" means a single-unit container that is designed to hold a quantity of drug product intended for administration as a single dose and labeled with the identity, quantity and/or strength, name of the manufacturer, lot number and expiration date of the drug product.

(r) "Unprofessional conduct" means conduct and practices which are hostile to the protection of public health, safety and welfare and includes:

- (1) Knowingly engaging in any activity which violates state and federal statutes, regulations and rules governing the practice of pharmacy;
- (2) Knowingly dispensing an outdated product;
- (3) Knowingly charging for more dosage units than are actually dispensed;
- (4) Knowingly altering prescriptions or other records which the law requires the pharmacy or pharmacist to maintain;
- (5) Knowingly dispensing medication without proper authorization or prescription;
- (6) Defrauding any persons or government agency receiving pharmacy services; or
- (7) Placing a signature on any affidavit pertaining to any phase of the practice of pharmacy which the pharmacist knows to contain false information.

(s) "USP" means the United States Pharmacopeia, published by and issued under the authority of the Pharmacopeial Convention, which provides recognized standards and specifications for all drug entities in the U.S.

(t) "Wholesale drug distribution" means distribution of prescription drugs other than to the patient, including, but not limited to distribution by manufacturers, repackers, own label distributors, jobbers, and wholesale drug distributors.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; amd by #7535, eff 8-1-01; paragraph (a) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (b), (d)-(m), and (p)-(s) EXPIRED: 2-1-07; paragraph (o) EXPIRED: 8-1-09; paragraph (a) EXPIRED: 3-26-13; paragraphs (c) and (n) EXPIRED: 2-23-14

New. #10903, eff 8-5-15

Ph 701.03 References. Persons subject to these rules shall comply with the following regulations and statutes as cited:

- (a) RSA 146, Purity and Branding of Foods and Drugs;
- (b) RSA 318, Pharmacists and Pharmacies;

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- (c) RSA 318-B, the New Hampshire Controlled Drug Act;
- (d) 21 USC Sections 300 through 369, the Federal Food, Drug, and Cosmetic Act;
- (e) 21 CFR 1300 to end; and
- (f) The United States Pharmacopeia.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**PART Ph 702 PHARMACY FACILITIES AND EQUIPMENT**

**Ph 702.01 Area, Space and Fixtures.**

(a) Pharmaceuticals, library and equipment shall be housed in a well-lit and ventilated room or department with clean and sanitary surroundings devoted primarily to the preparation and dispensing of prescriptions. This portion of a pharmacy shall have an area of not less than 200 square feet. No area shall be included in the calculation of the minimum area required by this section unless that area is used exclusively for the storage, manufacture, preparation and dispensing of drugs.

(b) The space primarily devoted to the preparation of prescriptions shall be equipped with:

- (1) Necessary counters and storage cabinets;
- (2) A sink with hot and cold running water with plumbing that meets all applicable state and local building codes ; and
- (3) Temperature controlled storage equipment used exclusively for drugs.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (a)-(b)(2) and (c) EXPIRED: 3-26-13; paragraph (b)(3) EXPIRED: 2-23-14

New. #10903, eff 8-5-15

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Ph 702.02 Temperature. The temperature in any area wherein drugs are stored, manufactured, prepared or dispensed, shall be monitored and at all times be in compliance with the standards established by the manufacturer.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 702.03 Quarantine. Any drug which is expired, adulterated or misbranded shall be removed from routine stock and held in a specifically designated area of the pharmacy pending proper and safe disposition.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 702.04 Security.

(a) That portion of a pharmacy wherein drugs are stored, manufactured, prepared or dispensed, shall, when the pharmacy is open, be so designed and constructed as to prevent entry into that area by any person or persons without the knowledge of the pharmacist then on duty, or when the pharmacy is not open to the public, by the activation of an alarm.

(b) The pharmacy shall be equipped with an alarm system which, when activated, shall emit a signal which is:

- (1) Audible to the average person situated outside the building in which the pharmacy is located, at least 100 feet from any point of that building, or the public highway closest to that building, whichever is greater; or
- (2) Observable by a law enforcement or security officer situated in a station of the law enforcement organization having jurisdiction over the area in which the pharmacy is located, an office of a security organization serving the area in which the pharmacy is located or an alarm monitoring company.

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(c) In order to be adequately designed and constructed, within the meaning of this section, a pharmacy shall be equipped with a door or doors capable of being locked.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 702.05 Limitations on Access.

(a) Except as provided in Ph 704.01(b), no pharmacy shall be open unless a pharmacist is on duty. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the licensed pharmacy area shall be barred by locked doors.

(b) The keys to the locked doors of a pharmacy shall be possessed only by:

- (1) The pharmacist-in-charge;
- (2) Pharmacists in the employ of the pharmacy;
- (3) A non-pharmacist owner or owners of the pharmacy; or
- (4) Store management and security personnel when secured in a locked safe in the building and kept separate from the alarm code needed to access the secured area.

(c) A non-pharmacist owner or owners may be on the premises of a pharmacy which he or she owns in the absence of a pharmacist employed by that pharmacy, provided that the pharmacy is not open and no drugs are prepared, dispensed or sold.

(a) Except as provided in Ph 704.01(b), no pharmacy shall be open unless a pharmacist is on duty in the pharmacy. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the pharmacy shall be barred by locked doors.

(b) The keys to the locked doors of a pharmacy shall be possessed only by:

- (1) The pharmacist-in-charge;
- (2) Pharmacists in the employ of the pharmacy;
- (3) A non-pharmacist owner or owners of the pharmacy;
- (4) Qualified security personnel as shall be designated by the pharmacist-in-charge and a list of such personnel shall be filed with the board by the pharmacist-in-charge; or
- (5) If an institutional pharmacy, administrators of the institution and those nurses designated to enter the pharmacy to obtain medications in emergency situations.

(c) A non-pharmacist owner or owners may be on the premises of a pharmacy which he or she owns in the absence of a pharmacist employed by that pharmacy, provided that the pharmacy is not open and no drugs are compounded, dispensed or sold.

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(d) The pharmacy permit shall be issued to the pharmacy in the name of the pharmacist-in-charge, who shall have sole control and responsibility for the operation of the pharmacy in accordance with all laws and rules pertaining to the practice of pharmacy in this state and always in the best interest of public health and safety.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a)-(c) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; para. (d) EXPIRED: 2-1-07; ss by #10456, eff 11-1-13; ss by #10903, eff 8-5-15

Ph 702.06 Minimum Drug Standards. Registrants shall comply with the minimum drug standards set forth in the latest edition of the United States Pharmacopeia (USP).

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 702.07 Minimum Standard of Technical Equipment and Stock.

(a) Permit holders shall provide that every pharmacy shall have contained therein, at all times, the following:

- (1) Prescription labels showing the name, address, telephone number and DEA number of the pharmacy;
- (2) All equipment, supplies and drugs that are relevant to the practice and meet all state and federal standards;
- (3) An assortment of auxiliary labels or the software to produce them;
- (4) A current reference library, or the ability to access references on line, as determined by the pharmacist-in-charge to meet the needs of the practice, and specialties, of that pharmacy and the patients it serves; and
- (5) A current copy, with supplements, or the ability to access on line within the licensed area the New Hampshire Pharmacy Law Book.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99, EXPIRED: 2-1-07

New. #10102, eff 3-30-12; ss by #10903, eff 8-5-15

PART Ph 703 RECORDS AND REPORTS

Ph 703.01 Recordkeeping Requirements.

(a) The requirements of Ph 703 shall be in addition to all record keeping and reporting requirements contained in all federal and state rules and regulations.

(b) Hard copies of prescription records and reports shall not be required to be maintained if they can be reproduced on demand with the exception of Schedule II – V controlled substance prescriptions not presented in electronic format.

(c) Hardcopy prescriptions for Schedule II –V controlled substances shall be kept on file for 4 years.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 703.02 Prepackaging of Drugs.

(a) Drugs shall be prepackaged in quantities suitable for internal distribution only by a pharmacist or by supportive personnel under the direct supervision of a pharmacist.

(b) The label of a prepackaged unit shall indicate the:

- (1) Brand name and strength of the drug, or if no brand name, the generic name, strength, and name of the manufacturer or distributor;
- (2) Assigned in-house, quality control lot number;
- (3) Expiration date; and
- (4) Quantity of the drug, if the quantity is greater than one.

(c) The pharmacist who prepackages or supervises prepackaging shall maintain a written or electronic record that contains at least the following information:

- (1) Name of the drug, strength, and dosage form;
- (2) Assigned in-house, quality control lot number;
- (3) Manufacturer or distributor;
- (4) Manufacturer's lot number;
- (5) Expiration date;
- (6) Quantity per prepackaged unit;
- (7) Number of prepackaged units;
- (8) Date packaged;

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(9) Identifier of the prepacker; and

(10) Signature of the responsible pharmacist.

(d) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15 (from Ph 703.03)

**Ph 703.03 Controlled Drug Losses.**

(a) The pharmacist-in-charge or pharmacist on duty shall report to the board in writing, any theft or significant loss of controlled substances within one business day. The pharmacist-in-charge shall complete a New Hampshire Drug Loss Form (revised 5/2015) or DEA 106 Form and mail or fax to the board as soon as the investigation into the loss is complete or within 30 days of the discovery of the loss.

(b) All instances of diversion shall be reported.

(c) A pharmacy shall keep a perpetual inventory for all Schedule II drugs and actual counts shall be verified monthly. The inventory reports shall be maintained for a minimum of 2 years.

(d) A pharmacy shall consider a controlled drug loss to be significant when:

(1) The percentage of dosage units of a specific drug exceeds 2% of monthly dispensing volume; or

(2) Fifteen or more dosage units are not accounted for.

(e) The written report referenced in (a) shall contain at least the following:

(1) Date of discovery;

(2) The identity of the person making the discovery;

(3) The name and location of the pharmacy from which the drug is missing;

(4) Name, strength, dosage form, NDC and quantity of the missing drug(s); and

(5) The cause of the controlled drug loss as determined by the investigation.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15 (from Ph 703.04)



Ph 703.04 Automated Data Processing Systems. All pharmacies shall have an automated data processing system to be used for the storage of original, faxed or written prescriptions and the retrieval of refill information for all prescription orders including, but not limited to, controlled substances in schedules II, III, IV, and V, as defined in 21 CFR 1308.11-1308.15 subject to the following conditions:

(a) The system shall provide security against improper manipulation or alteration of stored records. Individual access codes shall be unique to each licensed location and shall not be available to any other location;

(b) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have access to the complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall assure continuity in the maintenance of records for the protection of public health;

(c) Any computerized system shall provide on-line retrieval, via electronic display or hard-copy printout, of all prescription records processed at that licensed location;

(d) The information required by (c) above shall include:

- (1) The original prescription number;
- (2) The date of issuance of the original prescription order by the practitioner;
- (3) The full name and address of the patient;
- (4) The name, address, and DEA registration number of the practitioner, when applicable;
- (5) The name, strength, dosage form, quantity prescribed, and quantity dispensed if different from the quantity prescribed, and the total number of refills authorized by the prescribing practitioner, if any; and
- (6) The date each fill is dispensed.

(e) Any computerized system shall also provide on-line retrieval, via electronic display or hard-copy printout, of the current refill history of all prescription orders including controlled substances in schedules III, IV, and V;

(f) This refill history shall include:

- (1) The name of the drug;
- (2) The date of refill;
- (3) The quantity dispensed;
- (4) The identification code, or name or initials of the dispensing pharmacist for each refill; and
- (5) The total number of refills dispensed to date for that prescription order;

(g) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order, including refill orders for a schedule III, IV, or V controlled substances is correct shall be provided by:

- (1) A hard-copy printout of each day's controlled substance prescription order refill data which shall be verified, dated, and signed by each pharmacist who refilled such prescription orders; or

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(2) In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown;

(h) The hard-copy printout or log book referenced in (g) above shall be kept at the pharmacy, in a separate file, for a period of 4 years from the dispensing date;

(i) The computerized system shall have the capability of producing a printout of all refill data and shall include:

- (1) A refill-by-refill audit trail for any specified strength and dosage form of any controlled substance;
- (2) Name of the prescribing practitioner;
- (3) Name and address of the patient;
- (4) Quantity dispensed on each refill;
- (5) Date of the dispensing for each refill;
- (6) Name or identification code of the dispensing pharmacist; and
- (7) The number of the original prescription order;

(j) In any computerized system employed by a user pharmacy, the central recordkeeping location shall be capable of sending the printout to the pharmacy within 48 hours;

(k) Each pharmacy using an automated data processing system shall maintain on file a hard copy of all controlled substance prescriptions in schedules II, III, IV and V, excluding electronic, preserving all information contained on the original written or oral prescription. Any computer generated material shall be affixed to the rear of the prescription, leaving the face of the prescription intact; and

(l) Computer-produced prescription container labels shall comply with RSA 318:47-a, RSA 318:47-b and RSA 318-B:13, II.

Source. #2118, eff 8-12-82: ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15 (from Ph 703.05)

Ph 703.05 Federal DEA #222 Order Forms. All used DEA #222 order forms or any successor forms shall be maintained on the premises to which the forms and the corresponding DEA permit number were issued. In the case of on-line ordering of CII drugs, all records of such shall be maintained on said premises and be readily retrievable. Such records shall meet the requirements of federal laws and regulations and shall be maintained for a period of not less than 2 years.

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Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99, EXPIRED: 2-1-07

New. #10066, eff 12-28-11; ss by #10903, eff 8-5-15 (from Ph 703.06)

Ph 703.06 Inspection Report. The current compliance inspection report of the licensed location, conducted by the board, shall be kept on file in the prescription department.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15 (from Ph 703.07)

**PART Ph 704 DISPENSING OF DRUGS AND DEVICES**

**Ph 704.01 Presence of Pharmacists.**

(a) No pharmacist shall work more than 8 hours without a rest break of 30 minutes. Breaks shall be scheduled as close as possible to the same time each day so that patients may become familiar with the approximate break times.

(b) Whenever the prescription department is staffed by a single pharmacist, the pharmacist may take a rest break for a period of 30 minutes without closing the pharmacy and removing support personnel from the pharmacy, provided that the pharmacist reasonably believes that the security of the prescription drugs will be maintained in the pharmacist's absence.

(c) Pharmacy technicians, NH certified pharmacy technicians and pharmacy interns may remain in the pharmacy if the pharmacist on duty reasonably believes that the security of the prescription drugs will be maintained in his or her absence and in accordance with the following:

- (1) Rest breaks shall be scheduled as close as possible to the same time each day in order for the patients to become familiar with the approximate times of breaks;
- (2) The pharmacist shall remain on the premises, within the building, during the rest break and be available for emergencies. Emergencies shall be defined by the pharmacist;
- (3) Whenever the pharmacist temporarily leaves the prescription department for a rest break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in full view of patients approaching the prescription department service area. The signage shall also indicate the time when the pharmacist is to return;
- (4) Only pharmacy technicians or pharmacy interns authorized by the pharmacist on duty may remain in the pharmacy while the pharmacist is on break;
- (5) During such times that the pharmacist is temporarily absent from the pharmacy, only pharmacy technicians or pharmacy interns duly authorized by the pharmacist on duty may

continue to perform non-discretionary duties as delineated by the pharmacist. However, all duties performed by the technicians or interns shall be reviewed by the pharmacist upon his or her return from break;

(6) When a pharmacist is not in the pharmacy, there shall be no dispensing or sale of new prescriptions that the pharmacist has checked and are waiting to be picked up nor shall counseling be provided by the pharmacy technician or pharmacy intern;

(7) New, written prescriptions, presented in person by the patient or his agent, may be accepted by the pharmacy technician or pharmacy intern and the processing of that prescription, up to the final check, may occur during the absence of the pharmacist. However, no new prescriptions may be dispensed or sold until the final check is completed by the pharmacist on his or her return;

(8) New prescriptions conveyed by telephone shall be accepted by a NH certified pharmacy technician or pharmacy intern or when authorized by the pharmacist or the caller shall be instructed to call back or a telephone number obtained for the pharmacist to call upon his or her return;

(9) During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or his agent. If the patient has no questions, the sale may proceed as normal with the patient signing a statement indicating the refusal of counseling by the pharmacist. If the patient desires counseling, he or she shall be asked to wait for the pharmacist to return from break or, alternatively, asked to leave a telephone number for the pharmacist to call later that day; and

(10) Telephone refill orders as well as refill requests presented, in person, by the patient or his agent, may be accepted by the pharmacy technician or intern and such refill orders may be processed by the technician or intern up to the final check. However, no such refill orders shall be dispensed or sold until the final check is completed by the pharmacist on his or her return from break.

(d) A pharmacist who takes a rest break in compliance with this section shall continue to be responsible for the operation and security of the pharmacy department. Therefore, if in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy. All pharmacy technicians, NH certified pharmacy technicians, and pharmacy interns shall leave the pharmacy during his or her absence. A sign informing the public of the pharmacist's return shall be conspicuously posted.

(e) Pharmacists shall follow company protocols in leaving the pharmacy department unattended for any reason, such as but not limited to counselling patients, giving immunizations, or rest room breaks.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; ss by #6933, eff 2-1-99; ss by #8572, eff 2-23-06; ss by #10459, eff 11-1-13; ss by #10903, eff 8-5-15; ss by #11189, eff 9-23-16

Ph 704.02 Pre-signed Prescription Blanks. No person shall possess, and no pharmacy shall have within it, any document signed by a prescriber which, if completed, would be usable as a prescription.

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Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 704.03 Transmission of Prescription Drug Order by Prescriber.

(a) A prescription drug order may be transmitted to a pharmacy by an authorized prescriber or his designated agent in writing, orally, by facsimile or electronically.

(b) A facsimile or electronically transmitted prescription drug or device order shall:

(1) Be sent to the pharmacy of the patient's choice;

(2) For a non-controlled substance prescription drug or device order, include:

- a. The name of the patient;
- b. The name, strength, and quantity of the drug prescribed;
- c. Any directions specified by the prescribing practitioner;
- d. The name and address of the prescribing practitioner which shall be printed or typewritten;
- e. The prescribing practitioner's phone number for verbal confirmation; and
- f. The date the prescription was ordered;

(3) For a schedule III through V controlled substance prescription drug order, as defined in RSA 318-B:1-b and transmitted by facsimile or as an electronic prescription, shall include:

- a. The name and address of the patient;
- b. The name, strength, and quantity of the drug prescribed;
- c. Any directions specified by the prescribing practitioner;
- d. The full name of the prescribing practitioner which shall be printed, rubber stamped, or typewritten above or below his or her handwritten signature;
- e. The address of the prescribing practitioner;
- f. The federal drug enforcement administration (DEA) number assigned to the prescribing practitioner; and
- g. The date the prescription was ordered;

(4) A facsimile prescription for a schedule II controlled substance shall not be accepted as an original written prescription except in circumstances when:

- a. A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, to be compounded for the direct administration to a patient in a private residence, long-term care facility, or hospice setting, by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be electronically transmitted, by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I;
  - b. A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a resident of a long-term care facility may be electronically transmitted by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I; and
  - c. A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a patient enrolled in a hospice care program, may be electronically transmitted by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The practitioner or the practitioner's designated agent shall note on the prescription that the patient is a hospice patient. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I;
- (5) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the electronically transmitted prescription drug order which shall be consistent with existing federal or state laws and rules;
- (6) For controlled substances in schedules II, III, IV or V, as defined in RSA 318-B:1-b, a pharmacy may receive an electronically transmitted drug order from the prescriber for filling provided that it is transmitted in accordance with federal law with an electronic signature meeting security requirements required by the Drug Enforcement Agency (DEA) for electronic prescriptions; and
- (7) The devices used for the receipt of facsimile or electronically transmitted prescription drug orders shall be located in the prescription department of the pharmacy in order to protect patient confidentiality and to assure security.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06; ss by #10224, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 704.04 Transfer of Prescriptions. Original prescription drug order information for drugs may be transferred between pharmacies for the purpose of refill dispensing subject to the following:

- (a) The transfer of controlled drug prescriptions shall be communicated between 2 licensed pharmacists;

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(b) The transfer of non-controlled prescriptions shall be communicated between 2 licensed pharmacists, NH certified pharmacy technicians or pharmacy interns; and

(c) The transferring pharmacist, NH certified pharmacy technician or pharmacy intern shall notate in the computer record the following:

(1) That a copy has been issued, the date of transfer, and the name of the pharmacist transferring the prescription; and

(2) The name, address, phone number and DEA number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.

(d) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.

(e) The pharmacist receiving the transferred prescription information shall:

(1) Include the word "transfer" on the face of the transferred prescription; and

(2) Provide all information required to be on the prescription including the:

a. Patient's name and address;

b. Doctor's name and address;

c. Date of issuance of the original prescription and date of transfer;

d. Number of valid refills remaining and date of last refill;

e. Pharmacy name, address, and original prescription number from which the prescription information was transferred;

f. Full name of the transferor pharmacist, NH certified pharmacy technician or pharmacy intern; and

g. DEA registration number of the transferor pharmacy for controlled substances.

(f) The pharmacist shall maintain both the original and transferred prescription as if they were original prescriptions.

(g) A transferred prescription may be refilled, without limitation, up to the number of remaining refills, as originally authorized, or up to one year from the date of original issue, whichever shall occur first.

(h) The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV or V shall conform to the requirements of 21 CFR 1306.26 and shall be permissible between pharmacies on a one-time basis and shall not be further transferred.

(i) For non-controlled drugs, 2 or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common electronic file shall not be required to physically transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file, except that any such common file shall contain complete and adequate records of such prescription and the date and location of each refill dispensed and provisions shall be made to assure that the number of authorized refills shall not be exceeded.

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(j) New or on-hold prescription orders for prescription orders other than control substances may be transferred to another pharmacy provided that a copy of the original prescription or electronic transmission is provided to the pharmacy accepting the transfer.

(k) New or on-hold prescription orders for controlled substances shall not be transferred to another pharmacy.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; ss by #10458, eff 11-1-13; ss by #10903, eff 8-5-15

Ph 704.05 Schedule V Controlled Substances. All cough syrups containing codeine shall not be dispensed without a prescription.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 704.06 Drug Product Selection.

(a) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug product prescribed by its trade or brand name may select a therapeutically equivalent drug product with the same established name, active ingredient, strength, quantity and dosage form as the drug product identified in the prescription.

(b) Therapeutically equivalent drugs shall include only those drug products listed in "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations" Published by the United States Department of Health and Human Services, according to RSA 146-B:2, I, or any written notification or confirmation from the federal Food and Drug Administration (FDA) that a drug product is a therapeutically equivalent drug product.

(c) The pharmacist shall not select an equivalent drug product:

- (1) If the prescriber handwrites "medically necessary" on the written prescription;
- (2) If when ordering a prescription orally, the prescriber specifies that the prescribed drug is medically necessary; or
- (3) If the prescription is electronically transmitted, the prescriber includes a statement on the face of the prescription indicating medically necessary.

(d) The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.



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(e) Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established generic name and the name of the manufacturer, packer or distributor, using abbreviations such as the National Drug Code (NDC) number if necessary. In the interest of public health and safety, the pharmacist may, when dispensing a generic drug, include the brand name on the prescription label following the generic name. The brand name, however, shall be preceded or followed with the word "sub", indicating substituted for, or "I.C.", indicating interchanged for or "generic for".

(f) The pharmacy file copy or computer record of every dispensing of a prescription shall include the trade or brand name, the name of the manufacturer, and the packer or distributor of the drug product dispensed.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (a), (d), (e), & (g) EXPIRED: 3-26-13; paragraphs (b), (c), and (f) EXPIRED: 2-23-14

New. #10903, eff 8-5-15

### Ph 704.07 Return of Drugs and Devices.

(a) Except as provided in Ph 704.07(b), no drug, prescription, device, sickroom supply or item of personal hygiene which has left control of the pharmacist or pharmacy and is returned to the pharmacy shall be resold or re-dispensed after such item has been taken from the premises by the patient or the patient's representative, subject to the pharmacist's professional judgement.

(b) Exceptions to Ph 704.07 (a) shall include:

- (1) Orthopedic appliances;
- (2) Crutches;
- (3) Canes;
- (4) Wheelchairs;
- (5) Hospital beds;
- (6) Bed rails;
- (7) Trapezes;
- (8) Other durable equipment that can be properly sanitized; and
- (9) Medications dispensed in unit-dose packaging to institutionalized patients.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

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New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (a) EXPIRED: 2-1-07; paragraph (b) EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 704.08 Prescription Pick-up and Delivery.**

(a) No person licensed under the provisions of RSA 318, shall enter into or participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any store, shop or location not licensed as a pharmacy.

(b) This section shall not prohibit a licensee from picking up prescriptions or delivering prescribed medications at the residence of the patient, or directly to the patient at his/her workplace, or at the institution in which the patient is confined, by means of an employee or by use of a common carrier.

(c) In situations where it is in the best interest of the patient due to behavioral health issues or homelessness a licensee may deliver the prescriptions to an authorized party for distribution to the patient.

(d) Drugs with special handling or storage requirements that will be administered by the practitioner may be delivered directly to the practitioner's office such as radio pharmaceuticals or frozen Immunizations.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 704.09 Dispensing Adulterated or Misbranded Drugs.** A pharmacist shall not dispense or sell to the public any drug which is adulterated or misbranded. After notice and opportunity for a hearing, a pharmacist who is found by the board to have knowingly dispensed or otherwise sold for consumption an adulterated or misbranded drug, shall be subject to disciplinary action according to RSA 318:29.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 704.10 Out-of-State Prescriptions.** Prescriptions written by physicians in a state other than New Hampshire may be dispensed to a patient only when the traditional physician-pharmacist-patient relationship exists.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 704.11 Pharmacist-in-Charge/Corporate Entity Requirements/Duties.

(a) Pharmacists looking to serve as a Pharmacist-in-Charge (PIC) shall:

- (1) Have worked as a pharmacist for a minimum of 2 years post-graduation;
- (2) Complete and pass with a minimum of 80% an exam designed by the board to assess the knowledge of the candidate in regard to their responsibilities as PIC; and
- (3) Work a minimum of 20 hours per week at the location where he/she serves as PIC except when absent due to scheduled vacation or other authorized leave.

(b) Pharmacist in charge duties shall include:

- (1) Responsibility for the control of all drugs issued or dispensed in the pharmacy where he/she practices;
- (2) Ensuring written policies and procedures for the procurement, storage, compounding and dispensing of drugs are in place;
- (3) Ensuring that all staff pharmacists are familiar with and in compliance with the established policies and procedures;
- (4) Establishing and supervising the recordkeeping system for the purchase, sale, possession, storage, and repackaging of drugs;
- (5) Maintaining the security of the prescription department and its contents;
- (6) Determining who will have keys and access to the pharmacy with the exception of security personnel;
- (7) Establishing quality assurance guidelines to ensure the medication dispensed is in conformance with the prescription received;
- (8) Prohibiting the presence of adulterated or misbranded drugs in the pharmacy;
- (9) Ensuring compliance with the provisions of RSA 318 and RSA 318-B and any other state or federal pharmacy-related laws or rules;
- (10) Supervising personnel in the prescription department; and
- (11) Ensuring all personnel involved in the preparation and dispensing of prescriptions are properly licensed or registered with the board.

(c) Pharmacists may serve as a pharmacist-in-charge for a maximum of 2 pharmacies, providing that one of these pharmacies shall be in an institution requiring the services of a pharmacist only on a part-time basis.

(d) The corporate entity or permit holder shall be responsible for the following:

- (1) Written policies and procedures for the procurement, storage, compounding and dispensing of drugs;
- (2) Ensuring that all staff pharmacists are familiar with and in compliance with the established policies and procedures;
- (3) Determining which security personnel will have keys and access to the pharmacy and inform the pharmacist in charge;
- (4) Establishing procedures and policies to ensure the security of the pharmacy department when a pharmacist is working alone and needs to leave the licensed area for counseling, immunizations, lunch or rest room breaks;
- (5) Providing online access to the New Hampshire law book, medical reference material and other state and local sites for reference by their pharmacists;
- (6) Assuming all the responsibilities of the pharmacist in charge in an interim period when the pharmacist in charge has been vacated unexpectedly; and
- (7) Supplying adequate staffing to assist the board of pharmacy during scheduled routine inspections to assist with the retrieval of records when hard copy records are not maintained

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10457, eff 11-1-13; ss by #10903, eff 8-5-15

Ph 704.12 Termination of Pharmacist-in-Charge Notice. Whenever a pharmacist-in-charge shall cease performing that function, that pharmacist-in-charge shall notify the board in writing of the date upon which the cessation of that function is effective. That pharmacist-in-charge shall remain responsible for compliance, in the pharmacy in which he or she was the pharmacist-in-charge, with all pharmacy related statutes and rules until the effective date of termination.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 704.13 Termination of Pharmacist-in-Charge - Inventory. Whenever a pharmacist-in-charge shall cease performing that function in a pharmacy, the new pharmacist-in-charge shall, within 3 days, cause to be completed a written inventory of all controlled substances located in that pharmacy. The record of that inventory shall be retained in the pharmacy for a minimum of 2 years.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 704.14 Prescription Refill Limitations.

(a) Prescriptions bearing "PRN", "Ad lib", or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and in no instance shall such prescription be refilled beyond one year from the date of issue. If additional medication is needed thereafter, the original prescription shall be voided and a new prescription obtained.

(b) No prescription containing either specific or "PRN" refill authorization shall be refilled when the pharmacist has knowledge that the prescribing practitioner ceases to practice due to:

- (1) License suspension or revocation;
- (2) No longer maintaining a valid license;
- (3) Prescribing limitations placed on a practitioner's license by any state or federal licensing agency which impact on certain previously refillable prescriptions; or
- (4) Death.

(c) Notwithstanding (a) and (b) above, the pharmacist may dispense an additional refill supply according to the provisions of Ph 704.15.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a) and (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (c) EXPIRED: 2-1-07; paragraphs (a) and (b) EXPIRED: 3-26-13

New. #10685, EMERGENCY, eff 10-6-14, EXPIRED: 4-6-15

New. #10903, eff 8-5-15

Ph 704.15 Prescription Refill - Interim Supply. A pharmacist may refill a prescription drug order, including controlled substances listed in Schedules III, IV and V, without the authorization of the prescribing practitioner, provided that:

(a) A failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) The pharmacist is unable to contact the practitioner due to:

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- (1) A natural or man-made disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or
- (2) The practitioner's office being closed without a practitioner on call;
- (c) The quantity of prescription drug dispensed does not exceed a 30 day supply for maintenance medications;
- (d) The pharmacist informs the patient or the patient's agent at the time of dispensing that the interim supply shall be final and that authorization by the practitioner shall be required for future refills;
- (e) The pharmacist shall inform the prescribing practitioner of the limited emergency supply, provided to the patient, at the earliest reasonable time; and
- (f) The pharmacist exercises professional judgement in refilling the prescription drug order.

Source. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a), (b), (d), and (e) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; intro. paragraph and (c) EXPIRED: 2-1-07; paragraphs (a), (b), (d), and (e) EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 704.16 Acts Prohibited. Splitting fees, making rebates, or sharing money received for pharmaceutical services, or the donation of and/or the use of equipment with other health practitioners or with health institutions providing patient care shall be deemed by the board to be contrary to the best interests of the patient, and shall therefore be prohibited.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**PART Ph 705 STORAGE OF DRUGS**

Ph 705.01 Prescription Drugs. All prescription drugs shall be stored in an area which is under the immediate control of a pharmacist and not accessible to unauthorized persons.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-15-15 (from Ph 705.02)

Ph 705.02 Emergency Drug Kits for Long Term Care Facilities/Specialized Care Facilities.

(a) "Emergency drug kit" means a select supply of drugs and/or biologicals located at the licensed institution for the immediate administration to patients/residents upon the order of a practitioner as set forth in rules adopted under RSA 151.

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(b) “Automated electronic emergency drug kit” means an automated medication storage system for the immediate administration to patients/residents upon the order of a practitioner as set forth in rules adopted under RSA 151.

(c) “Automated medication dispensing system” means a computerized drug storage device or cabinet designed for use in long term care facilities and other health care institutions.

(d) The placement of controlled substances in emergency drug kits in non-federally registered long term care facilities/specialized care facilities shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:

(1) Controlled substances shall be stored in the emergency drug kit as deemed necessary and jointly approved by the pharmacist in charge and the consultant pharmacist, medical director and the director of nursing services;

(2) The source from which controlled substances for emergency drug kits are obtained shall be a DEA registered hospital, clinic, pharmacy or practitioner;

(3) Controlled substances in emergency drug kits shall be limited to a maximum of 16 separate drug entities with not more than 8 single use containers of each drug entity;

(4) The emergency drug kit containing controlled substances shall be closed with a tamper proof seal and kept in a locked medication room, cart or closet;

(5) Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist or practitioner shall have access to controlled substances stored in an emergency drug kit;

(6) Controlled substances in emergency drug kits shall be administered to patients only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21;

(7) A usage record shall be contained in the emergency drug kit for each separate drug included which shall be completed by the nursing staff when using any controlled substance or substances from the kit;

(8) The pharmacist shall receive and file for 2 years a copy of all completed usage records;

(9) When the emergency drug kit is opened:

a. The pharmacist shall be notified by the facility within 24 hours; and

b. Shift counts shall be done by the nursing staff on all controlled substances until resealed by the consultant pharmacist;

(10) Shift counts of the controlled substances contained in the emergency kit shall not be required when the kit is sealed;

(11) The pharmacist shall check the controlled substances in the emergency drug kit at least monthly and so document inside the kit; and

(12) The placement of controlled substances in emergency drug kits shall be only upon the written authorization of the board of pharmacy.

(e) Automated electronic emergency drug kits shall meet the following conditions:

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- (1) Real time electronic communication to the provider pharmacy;
- (2) For access, employ at least but not limited to:
  - a. Bio-Identification; and
  - b. Unique individualized password protections assigned by the provider pharmacy;
- (3) Automatically generate notice to the provider pharmacy whenever the kit is accessed and provide at least the following information:
  - a. Name of individual accessing the kit;
  - b. Date and time the kit was accessed;
  - c. Name, strength and quantity of drug removed; and
  - d. Name of patient for whom the drug was administered; and
- (4) Upon restocking the automated electronic emergency drug kit the following conditions shall be met:
  - a. The filling/restocking of an automated electronic emergency drug kit shall be performed by a licensed pharmacist, physician, physician assistant, advanced practice nurse, registered nurse and registered pharmacy technician.
- (5) “Automated medication dispensing system” means a computerized drug storage device or cabinet designed for use in long term care facilities and other health care institutions. An automated medication dispensing system may be used as an electronic emergency drug kit provided the system performs operations or activities relative to the storage, packaging, dispensing and distribution of medications, and which tracks and maintains a record of transaction information;
- (6) Automated emergency drug kits shall be allowed as set forth in rules adopted under RSA 151;
- (7) Non-controlled legend drugs may be stored in the emergency drug kit in quantities deemed necessary and jointly approved by the pharmacist in charge of the provider pharmacy, consultant pharmacist, medical director and the director of nursing services; and
- (8) The placement of controlled substances in automated electronic emergency drug kits in non-federally registered long term care facilities and other health care institutions shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:
  - a. Controlled substances shall be selected and stored in the automated electronic emergency drug kits in quantities deemed necessary and jointly approved by the pharmacist in charge and the consultant pharmacist, medical director and the director of nursing services;
  - b. Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist, registered pharmacy technician or practitioner shall have access to controlled substances stored in an automated electronic emergency drug kit;
  - c. Controlled substances in automated electronic emergency drug kits shall be administered to patients only by authorized personnel and only as expressly authorized



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by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21; and

d. When an automated electronic emergency drug kit is utilized, notification of usage shall be reported in accordance with Ph705.02 (e) (3).

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-15-15 (formerly Ph 705.03)

**PART Ph 706 PHARMACEUTICAL CARE STANDARDS**

**Ph 706.01 Patient Records.**

(a) A patient record system shall be maintained by all pharmacies for patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing.

(b) The pharmacist or supportive personnel shall make a reasonable effort to obtain, record, and maintain the following information:

- (1) The full name of the patient for whom the drug is intended;
- (2) The address and telephone number of the patient;
- (3) The patient's age or date of birth;
- (4) The patient's gender;
- (5) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the 12 months immediately preceding the most recent entry showing:
  - a. The name of the drug or device;
  - b. The prescription number;
  - c. The name and strength of the drug;
  - d. The quantity and date received; and
  - e. The name of the prescriber; and
- (6) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) The pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent, and record, any known:

- (1) Allergies;

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- (2) Drug reactions;
- (3) Idiosyncrasies; and
- (4) Usage of other drugs, including over-the-counter drugs, or medical devices currently being used by the patient.

(d) A patient record shall be maintained for a period of not less than 12 months from the date of the last entry in the profile record. This record shall be a hard copy or a computerized form.

Source. #5552 INTERIM eff 1-8-93, EXPIRES 5-8-93;  
ss by #5622, eff 5-8-93; ss by #6181-B, eff 2-5-96,  
EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 706.02 Prospective Drug Review.**

(a) A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of identifying:

- (1) Over-utilization or under-utilization;
- (2) Therapeutic duplication;
- (3) Drug-disease contraindication;
- (4) Drug-drug interactions;
- (5) Incorrect drug dosage or duration of drug treatment;
- (6) Drug-allergy interactions; and
- (7) Clinical abuse or misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which might include consultation with the prescriber.

Source. #5552 INTERIM eff 1-8-93, EXPIRES 5-8-93;  
ss by #5622, eff 5-8-93; ss by #6181-B, eff 2-5-96,  
EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 706.03 Patient Counseling.**

(a) Pharmacists shall be required to make a reasonable attempt to counsel the patient or patient's caregiver in person or by telephone when dispensing the first fill of a new prescription in the following situations:

- (1) Prescriptions for patients under the age of 13;
- (2) Concentrated medications;

- (3) Anticoagulant/antiplatelet medications;
- (4) Endocrine medications; and
- (5) Anti-infective medications.

(b) Pharmacists, pharmacy interns or New Hampshire certified technicians shall document that counselling was given.

(c) In situations where there is no direct contact with the patient or caregiver including but not limited to nursing homes, assisted living or prisons, supplemental printed information shall be provided.

(d) Upon receipt or delivery of a new prescription, where mandatory counseling is not required, and following a review of the patient's record, a pharmacist or his/her designee, shall orally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient.

(e) Patient counseling shall:

- (1) Be by the pharmacist or pharmacy intern and in person, whenever practicable, or by telephone; and
- (2) Include appropriate elements of patient counseling, such as the following:
  - a. The name and description of the drug;
  - b. The dosage form, dose, route of administration, and duration of drug therapy;
  - c. Intended use of the drug and expected action;
  - d. Special directions and precautions for preparation, administration, and use by the patient;
  - e. Common side or adverse effects or interactions and therapeutic contraindications that might be encountered, including their avoidance, and the action required if they occur;
  - f. Techniques for self-monitoring drug therapy;
  - g. Proper storage;
  - h. Prescription refill information;
  - i. Action to be taken in the event of a missed dose; and
  - j. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(f) Alternative forms of patient information may be used to supplement patient counseling. Examples shall include written information leaflets, pictogram labels, or video programs.

(g) Patient counseling, as described above shall not be required for inpatients of penal institutions or inpatients of a hospital or long term care facility where other licensed health care professionals are authorized to administer the drugs and drug therapy reviews are conducted on a routine basis.

(h) A pharmacist shall not be required to counsel a patient or agent when the patient or agent refuses such consultation. However, failure to document the patient's refusal of counseling shall imply that counseling was provided.

Source. #5552 INTERIM eff 1-8-93, EXPIRES 5-8-93; ss by #5622, eff 5-8-93; ss by #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

## PART Ph 707 DISPOSAL AND DESTRUCTION OF CONTROLLED DRUGS

Ph 707.01 Controlled Drug Destruction. Any person authorized to possess controlled drugs and desiring to dispose of such drugs may request destruction of the drugs by the board or request an authorization from the board to destroy such drugs.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06, EXPIRED: 2-23-14

New. #10903, eff 8-5-15

### Ph 707.02 Request for Destruction.

(a) A request to destroy controlled drugs shall be in writing and signed by a duly authorized person as defined in (b) below. The itemized written request shall be conveyed to the board office and the destruction process shall not proceed until the authorization is received by the person who made the request.

(b) Personnel authorized to sign a request for controlled drug destruction shall include:

- (1) Pharmacist-in-charge, as defined in RSA 318:1, X, practitioners or their designated agents;
- (2) Administrators of health care institutions or their designated agent or agents;
- (3) Agents of the superior court;
- (4) County attorneys;
- (5) Director, New Hampshire state police;
- (6) Chiefs of local police departments; and
- (7) Director, New Hampshire division of public health services or his/her designated agent(s).

(c) The written request shall not be required when a consultant pharmacist, acting as an agent of the pharmacy board, destroys controlled drugs in a licensed long-term care or specialized care facility.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (a), paragraph (b) intro., subparagraphs (b)(2)-(b)(7), and paragraph (c) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (b)(2)-(b)(6) EXPIRED: 3-26-13; paragraphs (a), (b) intro., (b)(1), (b)(7), and (c) EXPIRED: 2-23-14

New. #10903, eff 8-5-15

**Ph 707.03 Board Authorized Controlled Drug Destruction.**

(a) A consultant pharmacist to a nursing home, group home or assisted living facility shall be designated an agent of the pharmacy board for the sole purpose of destroying controlled drugs at the licensed home or homes for which he or she serves as consultant by filing a written request at the board office, identified in Ph 103.03. The written request shall be on the facility's letterhead, shall identify the pharmacist as the home's consultant pharmacist, and shall be signed by both the administrator of the facility and the consultant pharmacist.

(b) Once authorization is obtained:

(1) A record of the controlled drugs destroyed shall be made on form # Ph 558 (revised 7/2015) obtained at the board office, identified in Ph 103.03; and

(2) Copies of form # Ph 558 (revised 7/2015) shall be distributed as follows:

- a. The original shall be sent to the board office;
- b. A copy shall be maintained on the premises where the destruction occurred for a period of 4 years; and
- c. A copy shall be retained by the consultant pharmacist/agent making the destruction.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (c) and (d) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraph (a) EXPIRED: 2-1-07; paragraph (b)-(f) EXPIRED: 2-23-14

New. #10903, eff 8-5-15

**Ph 707.04 Controlled Drug Destruction by the Board of Pharmacy.**

(a) The destruction of controlled drugs by the board shall occur on the premises of the practitioner, institution or agency requesting the destruction. Destruction shall be carried out by any person so designated as the authorized agent of the board provided that such agent as well as the person requesting destruction or his or her designee are present during the entire destruction process.

(b) The practitioner or person requesting destruction or their designee shall also be present and shall witness destruction of the controlled drugs.

(c) Witnesses may include:

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- (1) The practitioner or practitioner's agent, including a pharmacist;
- (2) The administrator or assistant administrator; and
- (3) The director of nursing, nursing supervisor or charge nurse.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83;; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 707.05 Record of Controlled Drug Destruction.**

(a) A record of the drugs destroyed shall be made on federal form DEA-41, "Registrant's Inventory of Drugs Surrendered" in accordance with 21 CFR 1307.21, 22. This form may be obtained from the board office, identified in Ph 103.03, or from an office of the Drug Enforcement Administration.

(b) The data recorded on form DEA-41 shall include at least the:

- (1) Name, strength, and quantity of the drugs destroyed;
- (2) Date, time and place of destruction;
- (3) Manner of destruction; and
- (4) Signature and title of persons destroying and witnessing destruction of the controlled drugs.

(c) Copies of the form designated in Ph 707.05(a) shall be distributed as follows:

- (1) The original shall be maintained at the board office, identified in Ph 103.03; and
- (2) A copy shall be retained on the premises of the practitioner, agency, court, or person requesting the destruction.

(d) A copy of the record of those drugs destroyed shall be maintained on the premises where the destruction occurred for a period of 4 years.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a), (b), and (d) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraph (c) EXPIRED: 2-1-07; paragraphs (a), (b), and (d) EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 707.06 Exemption.** Nothing contained in part Ph 707 shall require the board to destroy any drug if the board determines that to do so would impair law enforcement efforts or the health or safety of any person.

Source. #1639, eff 11-1-80; ss by #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**PART Ph 708 TERMINATION OF A PHARMACY OPERATION**

**Ph 708.01 Notification of Closing.**

(a) Written notification to the board shall be filed at least 15 days prior to the date of the anticipated closing. This notice shall indicate the date of closing and the planned disposition of legend drugs including controlled substances and all records thereof.

(b) Written notification to DEA shall be filed at least 15 days prior to the date of the anticipated closing. Compliance with DEA instructions relative to closing procedures shall be required.

(c) At least 5 days prior to the anticipated closing a notice shall be conspicuously posted at the pharmacy indicating the date of closing and the future location of the prescription files. This notice shall be posted for a period of at least 30 days unless removed by the landlord or a new tenant.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**Ph 708.02 Disposition of Drugs/Records.**

(a) Security of the pharmacy shall be maintained while there is a supply of legend drugs including controlled substances on the pharmacy premises. Stable, unopened containers of legend drugs including controlled drugs may be returned by the pharmacy to the wholesaler/manufacturer.

(b) At the time of closing, the remaining supply of controlled substances may be sold or given to another pharmacy provided that:

(1) The transfer of schedule II substances shall comply with 21 CFR 1307.14 and 21 CFR 1305.06 by means of a properly executed federal DEA #222 Form;

(2) The transfer of schedules III, IV, and V are made by invoice with copies to each party and the board; and

(3) Prescription files, executed DEA #222 forms, biennial DEA inventories, applicable invoices, the balance of stock of all controlled substances, and the final printouts required by Ph 703.05(r)(2), shall be transferred as a package.

(c) At the time of closing, in addition to the electronic file transfer of the prescription records the closing pharmacy shall:

(1) Provide an up-to-date hard-copy printout of all non-controlled drug prescriptions stored in the automated system and a printout of all controlled drug prescriptions for the current 2 year period as part of the final records of that pharmacy;

(2) In lieu of such printout, an electronic back-up of the prescription records for the last 2 year may be provided on electronic media; and

(3) In the event that the pharmacy files are not sold to another pharmacy, the closing pharmacy shall make provision for these records to be available to any nearby pharmacy.

(d) If, in the interest of public health and safety, the board determines that after closure of the pharmacy a lack in the security, according to Ph 702.04, of the prescription drugs including controlled substances exists, the licensee shall immediately surrender to the board all prescription drugs including controlled substances and forms and invoices thereof. The drugs so held shall be inventoried, packaged, sealed and stored at the expense of the licensee in a place determined by the board to be appropriately secure. The licensee shall have 60 days after the effective date of the closing to make arrangements for the lawful sale or other disposition of these drugs. Lawful sale and/or disposition of these drugs shall be to a duly licensed person authorized to possess and store prescription drugs including controlled substances. Failing compliance within this 60-day period, such drugs shall then be surrendered to the board for destruction.

(e) Before disposing of any merchandise in the pharmacy, the owner and pharmacist-in-charge shall submit the licensed premises to an inspection by a representative of the board to certify that all prescription drugs including controlled substances have been secured.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a), (b), (c) intro., (c)(1)-(2), and (e) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; paragraphs (c)(3) and (d) EXPIRED: 2-1-07; paragraphs (a), (b), (c) intro., (c)(1)-(2), and (e) EXPIRED: 3-26-13

New. #10903, eff 8-5-15

Ph 708.03 Final Written Report. No later than 20 days after a pharmacy closing, the licensee shall:

(a) Return the pharmacy permit to the board;

(b) Notify the board that all signs and symbols indicating the presence of a pharmacy have been removed;

(c) Notify the board that all labels and blank prescriptions have been destroyed;

(d) Notify the board that the DEA license and all blank DEA #222 forms have been returned to the regional director of the DEA;

(e) File with the board, a copy of the dated inventory of all controlled substances transferred including the name and address of the person(s) to whom these drugs and applicable records were transferred; and



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(f) In the case of an involuntary closing, file with the board the final disposition of the drugs as soon as possible after the transfer is made.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

**PART Ph 709 INSTITUTIONAL PRACTICES**

**Ph 709.01 Definitions.**

(a) “Automated medication supply system” means an electronically controlled system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(b) “Electronic identifier”, for purposes of paragraph (a) above, means a unique security code or other identifier which specifically identifies the person entering information into a data processing system.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

**Ph 709.02 Licensing and Practice Standards.**

(a) A pharmacy permit shall be required for each institution with an on-premise pharmacy. Such permit shall be issued to a pharmacist-in-charge, who shall be licensed in the state of New Hampshire. When an institution procures prescription drugs for its patients only on individual prescriptions for specific patients from an off-premise licensed pharmacy, the institution shall not be required to obtain a pharmacy permit.

(b) If an institution does not have a pharmacy on its premises, it may enter into an agreement with a pharmacy licensed to provide such services. Such agreement shall be in writing and shall state the policy and procedures as required by Ph 709. A copy of the agreement shall be made available by the consultant pharmacist to the board upon request. The consultant pharmacist shall be responsible for the maintenance of all records and the compliance with state and federal laws and rules governing the practice of pharmacy.

(c) An institutional license shall permit the pharmacy to dispense medications to in-patients of the institution, staff or employees of the institution, interim supplies of medication to outpatients in emergency situations and home infusion therapy to contractual patients not requiring hospitalization. If a pharmacist is on the premises, outpatient prescription services may be provided by the pharmacy, on a one-time, no-refill basis, to an ambulatory care patient and any patient who is being discharged with medications related to the patient's hospitalization. Labeling for all outpatient prescriptions shall be according to RSA 318:47-a and RSA 318-B: 11.

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(d) Members of the board and/or their agents shall inspect the pharmacy, drug room/medication room and all areas or departments of the facility where drugs are stored, manufactured, compounded, dispensed or distributed to ensure:

- (1) That adequate drug security and storage requirements are met;
- (2) That proper records are maintained; and
- (3) That the facility is in compliance with all local, state and federal drug and pharmacy laws and rules.

(e) Those facilities obtaining prescription drugs only on individual prescriptions for specific patients from an off-premise licensed pharmacy shall not be exempt from inspection.

(f) Each institution shall have a pharmacy and therapeutics committee or a comparable committee of its medical staff. This committee shall be composed of representatives of the medical staff and the pharmacist-in-charge, or a licensed staff pharmacist designated by the pharmacist-in-charge, and representatives of the administrative and nursing departments. The pharmacy representative shall be a voting member of the committee and the committee shall meet at least twice a year. The major functions of this committee shall be to establish the written policies and procedures governing the practice of pharmacy, use of drugs, drug specifications and drug distribution.

(g) An institutional pharmacy may dispense a generic or therapeutic equivalent that has been approved by the pharmacy and therapeutics committee or its equivalent only to in-patients of the institution, staff or employees of the institution and their dependents, or interim supplies of medication to outpatients in emergency situations.

(h) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit shall be held accountable, along with the pharmacist-in-charge, regarding compliance to federal, state, and local laws related to the practice of pharmacy. Both individuals shall be held accountable regarding compliance as required by the New Hampshire board of pharmacy or other governmental agency regarding the practice of pharmacy.

(i) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit, and the pharmacist-in-charge, shall comply with federal, state and local laws related to the practice of pharmacy.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a), (b), (d), (e), and (f) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (c) & (h) EXPIRED: 2-1-07; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.03 Environment.

- (a) The institutional pharmacy shall be enclosed, lockable and alarmed.
- (b) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing and sterile preparation of drugs prepared in the pharmacy.
- (c) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean.

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- (d) A sink with hot and cold running water shall be available to all pharmacy personnel.
- (e) The institutional pharmacy shall have locked storage for schedule II controlled substances and other controlled drugs requiring additional security.
- (f) The institutional pharmacy shall have designated areas for the storage of flammable and caustic materials. Such areas shall meet the requirements set by local and state fire laws.
- (g) The institutional pharmacy shall have a designated area for the preparation of sterile products.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15; ss by #10903, eff 8-5-15

**Ph 709.04 Drug Security.**

- (a) Drugs stored in any area or department of the facility shall be plainly labeled and kept in a specifically designated, well-illuminated cabinet, closet or storage area and shall be accessible only to authorized personnel.
- (b) When controlled drugs are stored in authorized areas other than in the pharmacy, special locked storage for all controlled substances requiring additional security shall be used.
- (c) When using an automated medication supply system, the pharmacist-in-charge or designee shall have the responsibility for developing a secure system to assign, discontinue or change personnel access codes.
- (d) A pharmacist or registered pharmacy technician under the direction of a pharmacist shall visit and create a retrievable record, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.
- (e) A retrievable record of each monthly inspection specified in (d) above shall be maintained in the pharmacy for at least 2 years and shall be available to the board upon request.
- (f) The pharmacist-in-charge shall ensure that the areas specified in (d) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.
- (g) The pharmacist-in-charge shall develop a distribution system which shall prevent the illicit diversion of drugs.
- (h) Discrepancies shall be reported to the pharmacy within 24 hours and resolved within 72 hours. Missing or unaccounted controlled drugs shall be reported to the NH board and Drug Enforcement Agency (DEA) as specified by 21 CFR § 1301.76-b.
- (i) When an emergency drug kit other than regulated by Ph 705.03, containing controlled substances is opened, shift counts shall be done by the nursing staff on all controlled substances until resealed by a pharmacist.

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Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

### **Ph 709.05 Dispensing Practices.**

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, or prescriber in compliance with local, state and federal pharmacy-related laws and rules. Upon the written order of a prescriber a nurse may leave a properly labeled container of any non-controlled drug at the patient's bedside. A licensed nurse shall not dispense or compound drugs except as permitted by RSA 318:42.

(b) The pharmacy shall dispense medications pursuant of an order from a prescriber. Drugs shall be provided to patients in institutions only on the order of a practitioner legally authorized to write prescriptions. No change in the order for drugs shall be made without the approval of a practitioner qualified to write prescriptions.

(c) Each order pursuant to (b) above shall include at least the:

- (1) Patient's name and location;
- (2) Date of the order;
- (3) Name and dosage of the drug;
- (4) Directions; and
- (5) Signature of the prescriber or licensed health care professional receiving the order.

(d) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, and which are consistent with state and federal pharmacy laws and rules.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

### **Ph 709.06 Access to the Pharmacy.**

(a) Only a pharmacist shall open and close the pharmacy. The pharmacist-in-charge of each institutional pharmacy shall establish written policies identifying specific situations when pharmacy technicians may be present in the pharmacy in the absence of a licensed pharmacist.

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(b) In the absence of a pharmacist and in accordance with RSA 318:38, I licensed nurses, designated for this purpose by the pharmacist-in-charge, may obtain from the pharmacy or night cabinet such drugs as needed in an emergency when these drugs are not available in floor stock supplies.

(c) The authorized nurse may enter the pharmacy area and remove the following:

- (1) A drug in its original container or a drug prepackaged for use within the facility subject to these rules; or
- (2) An emergency supply of a drug from the original container to be administered to a specific patient.

(d) The authorized nurse shall leave a copy of the physician's order in the pharmacy or night cabinet and on a suitable form record the following:

- (1) Name and strength of the drug taken;
- (2) Dosage form taken;
- (3) Quantity taken;
- (4) Time and date of withdrawal;
- (5) Patient name and/or location, where applicable and; and
- (6) Nurse's signature.

(e) The nurse shall leave with the record the bulk container from which the medication was taken or a representative sample of the unit-dose medication.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

**Ph 709.07 Drug Control in Ambulatory Patient Treatment Areas.**

(a) In the ambulatory patient treatment areas, a medical practitioner may dispense drugs for the immediate needs of the patient, not in excess of a 72-hour supply, except that, for Schedule II controlled substances, a maximum of 48-hour supply shall be allowed, if permitted by the institution. The drug container shall be properly labeled.

(b) If a licensed pharmacist is on the premises, that pharmacist may fill one time, full amount, non-refillable prescriptions for patients for medications related to the ambulatory patient treatment visit.

(c) A readily retrievable record shall be made of all administrations and dispensing of controlled drugs in the ambulatory patient area.

(d) This record shall include:

- (1) Name and address of the patient;

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- (2) Name of the medical practitioner;
- (3) Name, strength and quantity of the drug(s);
- (4) Date of administration or dispensing; and
- (5) Signature or electronic identifier, as defined in Ph 709.01(b), of the agent removing the drug(s) from the inventory.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paras. (a) & (c) EXPIRED: 2-1-07; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.08 Investigational Drugs. Investigational drugs for research shall be used only under the supervision of the principal investigator and shall be approved by an appropriate medical staff committee. Such drugs shall be controlled by the pharmacy and shall be properly labeled. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06 ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.09 Purchase of Drugs.

(a) The pharmacist-in-charge, with the consent of the institution's pharmacy and therapeutics committee or comparable committee of its medical staff shall be responsible for the quality of all drugs, biologicals and pharmaceutical chemicals.

(b) Purchasing of drugs, pharmaceuticals, biologicals, intravenous and irrigation fluids shall be subject to approval of the pharmacist-in-charge with the consent of the institution's pharmacy and therapeutic committee or comparable committee of its medical staff.

(c) Radiopharmaceuticals, blood products, radiopaque media and medical devices may be exempted from the approval and/or control of the pharmacist-in-charge by the institution's pharmacy and therapeutics committee.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

PART Ph 710 ADMINISTRATIVE FINES

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Ph 710.01 Liability for Administrative Fines. Persons subject to the disciplinary authority of the board and other persons subject to administrative fines or penalties under RSA 318:29, IV shall, at the discretion of the board, after notice and an opportunity to be heard, be assessed fines and/or penalties as authorized under RSA 318:29, IV.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13; ss by #10903, eff 8-5-15

Ph 710.02 Severity of Fine.

(a) The decision to impose a fine and the amount of such fine shall depend on:

- (1) The severity of harm to the public posed by the violation(s);
- (2) The number of concurrent and/or repeated violations; and
- (3) The frequency of violations committed by the particular licensee, permit holder, or other person.

(b) When no violation of the same type has occurred within the 5 years preceding the board's notice to the respondent, the fine assessed shall not exceed \$1,000 per violation upon the licensee and/or \$2,000 per violation upon the permit holder.

(c) When a single disciplinary infraction of the same type has occurred within the 5 years preceding the board's notice to the licensee, the fine assessed shall not exceed \$2,000 per violation upon the licensee and/or \$3,000 per violation upon the permit holder.

(d) When more than one disciplinary infraction of the same type has occurred within the 5 years preceding the board's notice to the licensee, the fine assessed shall not exceed \$3,000 per violation upon the licensee and/or \$5,000 per violation upon the permit holder.

(e) In the case of continuing violations, a separate fine shall be assessed for each day the violation continues, but the total amount of the fine and the licensee's promptness and cooperativeness in ceasing the prohibited conduct in question shall be considered in assessing the daily fines.

(f) In all cases, the board shall consider:

- (1) The nature of the offense;
- (2) The purpose of the rule or statute violated;
- (3) The licensee's state of mind at the time the offense occurred;
- (4) The potential harm to the public health;
- (5) The deterrent effect upon other practitioners;
- (6) The licensee's willingness to cooperate with the board;
- (7) The cost to the board of any formal disciplinary hearings which were necessary;

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- (8) The licensee's acknowledgment of his or her wrongdoing; and
- (9) The nature of any other disciplinary sanctions imposed as a result of the offense in question.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13

New. #10903, eff 8-5-15

### CHAPTER Ph 800 PHARMACY TECHNICIANS

Statutory Authority: RSA 318:5-a, X, XI

#### PART Ph 801 PURPOSE AND SCOPE

Ph 801.01 Purpose and Scope. The provisions of this chapter shall apply to, and impose duties upon, all pharmacy technicians holding registrations or certifications issued by the board.

Source. #7535, eff 7-25-01, EXPIRED: 7-25-09

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18

#### PART Ph 802 DEFINITIONS

Ph 802.01 Definitions. Except where the context makes another meaning manifest, the following definitions shall apply:

(a) “Registered pharmacy technician” means a person who is registered with the board, employed by a pharmacy, and who can assist in performing, under the supervision of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties, subject to such restrictions as the board has specified; and

(b) “Certified pharmacy technician” means a pharmacy technician who has become and who maintains national certification by taking and passing an exam recognized by the board for the purpose of certifying technicians and who has been certified by the board.

Source. #7535, eff 7-25-01, EXPIRED: 7-25-09

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18

#### PART Ph 803 REQUIREMENTS FOR REGISTERED PHARMACY TECHNICIANS

Ph 803.01 Registered Pharmacy Technician Qualifications.

(a) An applicant for a registered pharmacy technician shall:

- (1) Be at least 16 years of age;
- (2) Have a high school or equivalent diploma, or be working to achieve a high school or equivalent diploma;
- (3) Not have been convicted of a drug or pharmacy-related felony or misdemeanor or admitted to sufficient facts to warrant such a finding; and



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(4) Register with the board within 15 days of start date of employment as a pharmacy technician, and post such registration in the pharmacy within 30 days.

(b) No person shall perform the functions or duties of a pharmacy technician unless such person is registered by the board.

Source. #7535, eff 7-25-01; and by #8572, eff 2-23-06; paras (a) & (b) EXPIRED: 7-25-09; paras. (c) and (d) EXPIRED: 2-23-14

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18 (formerly Ph 807.02)

Ph 803.02 Application Procedures for Registered Pharmacy Technicians.

(a) Registered pharmacy technician applicants shall complete and submit an “Initial Application for Pharmacy Technician Registration” form (PT-1), or electronic equivalent, for registration to the board that contains the following:

- (1) Legal name, residence address, mailing address, home or cell phone number, personal e-mail address, and social security number of the applicant;
- (2) Date and place of birth and gender of the applicant;
- (3) Name of current employer and the mailing address, phone number, and e-mail address of employment site;
- (4) Name of supervisor and pharmacy phone number;
- (5) An indication as to whether or not the applicant has been convicted of a drug or pharmacy-related felony or misdemeanor or admitted to sufficient facts to warrant such a finding, and if yes, an explanation, an explanation of the circumstances surrounding such a finding or conviction;
- (6) An indication as to whether the applicant has ever voluntarily surrendered for disciplinary reasons a license, registration, or certification to practice as a pharmacy technician in any jurisdiction and, if so, an explanation of such surrender;
- (7) An indication as to whether the applicant has any felony convictions and, if so, an explanation of such convictions; and
- (8) Applicant's signature and date.

(b) The prescribed fee shall be \$100, and shall be submitted with the completed application form.

(c) The “Initial Application for Pharmacy Technician Registration” form PT-1 for registration of pharmacy technicians in New Hampshire may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

Source. #12671, eff 11-17-18

PART Ph 804 REGISTERED PHARMACY TECHNICIAN RENEWALS

Ph 804.01 Renewal Requirements for Registered Pharmacy Technicians.

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- (a) All pharmacy technician registrations shall expire biennially on March 31.
- (b) Applications for the renewal of a registration for a pharmacy technician may be obtained from, and shall be filed at the office of the board, identified in Ph 103.03.
- (c) A pharmacy technician applying for renewal shall do so online at <https://nhlicenses.nh.gov/eGov/Login.aspx> by providing the following information:
  - (1) Legal name, residence address, mailing address, personal e-mail address, and a mobile or home telephone number;
  - (2) License number and work email address of the pharmacist-in-charge;
  - (3) Name and phone number of current employer and address of employment site;
  - (4) Record of convictions of violations of federal, state or local drug or pharmacy related laws or regulations; and
  - (5) Applicant's signature and date.
- (d) The application and the prescribed fee of \$100 shall be filed with the board no later than March 15.

Source. #7535, eff 7-25-01, EXPIRED: 7-25-09

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18  
(formerly Ph 806.01)

**PART Ph 805 ONGOING REQUIREMENTS FOR REGISTERED PHARMACY TECHNICIANS**

**Ph 805.01 Change in Registration Information for Registered Pharmacy Technicians.**

- (a) The person to whom a pharmacy technician registration has been issued shall, within 15 days of a change of address or location of employment, notify the board of such changes.
- (b) The notice shall contain:
  - (1) Legal name of registrant;
  - (2) Address, phone number, and personal email address of the registrant, including old and new, if applicable;
  - (3) Registrant's registration number;
  - (4) Name of the pharmacy where employed including former and current, if applicable; and
  - (6) All new violations of law, convictions, fines, disciplines or any registration, certification, or license revocations for violation of pharmacy-related drug laws or regulations in this or any other state.
- (c) Failure to comply with Ph 805.01 shall constitute misconduct under RSA 318.

Source. #7535, eff 7-25-01, EXPIRED: 7-25-09

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18

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Ph 805.02 Penalty. Any registered pharmacy technician 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.

Source. #12671, eff 11-7-18 (formerly Ph 806.05)

### **PART Ph 806 REVOCATION, DENIAL, AND REINSTATEMENT OF REGISTERED PHARMACY TECHNICIANS**

#### **Ph 806.01 Effect of Revocation and Denial for Registered Pharmacy Technicians.**

(a) The board shall refuse to issue a registration or, after notice and hearing, shall revoke a registration whenever the board finds by the preponderance of the evidence any of the following:

- (1) That the applicant, or registrant, has violated any of the provisions of RSA 318, RSA 318-B, or the board's administrative rules;
- (2) That the applicant has been convicted of a felony or a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule or regulation;
- (3) That the applicant has attempted to obtain a pharmacy technician registration by fraudulent means;
- (4) That the applicant is unable to engage in the performance of pharmacy technician functions with reasonable skill and safety by reason of illness, inebriation, misuse of drugs, narcotics, alcohol, chemicals or any other substance, or as a result of any mental or physical condition;
- (5) That another state has suspended, revoked, or placed on probation the applicant's license, permit, or registration to practice as a pharmacy technician;
- (6) That the applicant refused to appear before the board after having been ordered to do so in writing; or
- (7) That the applicant made any fraudulent or untrue statement to the board.

(b) The pharmacist on duty shall notify the board, in writing, within one calendar day after becoming aware that a pharmacy technician has adulterated, abused, stolen or diverted drugs.

(c) The board shall reinstate a revoked technician's previous permit after review, provided that the reason for revocation no longer exists or it is determined that there is no longer a threat to public safety.

Source. #7535, eff 7-25-01, EXPIRED: 7-25-09

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18

Ph 806.02 Reinstatement of a Registered Pharmacy Technician. Registered pharmacy technicians who either voluntarily or accidentally allow their registration to lapse as of March 31 of the renewal year shall complete the following procedures to reinstate their registration:

(a) Complete a reinstatement application found on the board's website at <https://www.oplc.nh.gov/pharmacy/documents/technician-reinstatement.pdf> (revised April 2018);

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

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

(d) Submit a signed and dated statement as to why the applicant did not renew his or her pharmacy technician registration prior to expiration and whether or not the applicant has practiced as a pharmacy technician since his or her registration has lapsed.

Source. #7535, eff 7-25-01, EXPIRED: 7-25-09

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18

**PART Ph 807 REGISTERED PHARMACY TECHNICIANS – STANDARDS OF PRACTICE**

**Ph 807.01 Determination of a Registered Pharmacy Technician's Duties.**

(a) A pharmacy technician shall only perform such tasks and duties which are prescribed by the permit holder or pharmacist-in-charge based upon the needs of the pharmacy.

(b) A pharmacy technician's duties may be further limited by the pharmacist on duty or the supervising pharmacist.

(c) Any training given under the direction of a pharmacist shall be documented by the pharmacist-in-charge and be retrievable upon inspection.

Source. #7535, eff 7-25-01; amd by #8572, eff 2-23-06; para (d) EXPIRED: 7-25-09; paras. (a)-(c) and (e) EXPIRED: 2-23-14

New. #10720, eff 11-22-14; ss by #12671, eff 11-17-18

**Ph 807.02 Registered Pharmacy Technician Duties.** A registered pharmacy technician's duties, upon showing the requisite skill and receiving the appropriate training, shall be:

(a) Non-discretionary functions within the pharmacy concerning cashier, stocking, delivery, and other non-clinical functions necessary for pharmacy operation under the supervision of a licensed pharmacist or certified pharmacy technician;

(b) The counting, weighing, measuring, pouring, and reconstitution of non-parenteral prescription medication or stock legend drugs and controlled substances;

(c) Performing stocking or replenishment of automated dispensing machine, other automated dispensing equipment or other stock locations. Products shall be verified by a pharmacist or certified pharmacy technician. Bar-coding, radio frequency identification, or another form of electronic verification shall be used at the time of stocking or replenishment, or a licensed health professional shall check the medication before administration; and

(d) If in training to become a certified technician, the duties of a certified pharmacy technician under the direct supervision of a pharmacist or certified pharmacy technician.

Source. #10720, eff 11-22-14; ss by #12671, eff 11-17-

18

**PART Ph 808 REQUIREMENTS FOR CERTIFIED PHARMACY TECHNICIANS**

**Ph 808.01 Certified Pharmacy Technician Qualifications.**

(a) An applicant for a certified pharmacy technician shall:

- (1) Be at least 18 years of age;
  - (2) Have a high school or equivalent diploma;
  - (3) Obtain and maintain national certification from a nationally recognized certifying organization, such as the Pharmacy Technician Certification Board (PTCB) or the National Healthcare Association (NHA);
  - (4) Not have been convicted of a drug or pharmacy-related felony or misdemeanor or admitted to sufficient facts to warrant such a finding; and
  - (5) Seek certification from the board within 15 days of the start date of employment as a certified pharmacy technician, and post such certification in the pharmacy within 30 days.
- (b) A registered pharmacy technician seeking certified status shall obtain and maintain certification from a nationally recognized certifying organization, such as the PTCB or the NHA, within one year of entering into a certified pharmacy program.
- (c) A certified pharmacy technician with duties involving sterile and non-sterile compounding, shall complete a American Society of Hospital Pharmacies (ASHP), PTCB, or other nationally recognized training program before participating in those duties.
- (d) Pharmacy technician applicants with previous out of state experience shall meet the requirements set by the board in this section before obtaining certification status.
- (e) No person shall perform the functions or duties of a certified pharmacy technician unless such person is certified by the board.

[Source.](#) #12671, eff 11-17-18

Ph 808.02 Application Procedures for Certified Pharmacy Technicians.

- (a) Pharmacy technician applicants shall complete and submit an application form “Initial Application for Pharmacy Technician Registration” form PT-1, or electronic equivalent, for certification by the board that contains the following:
- (1) Legal name, residence address, mailing address, home telephone number, personal e-mail address, and social security number of the applicant;
  - (2) Date and place of birth, and gender of the applicant;
  - (3) Name of current employer and the mailing address, and phone number of employment site;
  - (4) Name of supervisor and pharmacy phone number;
  - (5) An indication as to whether or not the applicant has been convicted of a drug or pharmacy-related felony or admitted to sufficient facts to warrant such a finding, and if yes, an explanation of the circumstances surrounding such a finding or conviction;
  - (6) An indication as to whether the application has any other felony convictions and, if so, an explanation of such convictions; and
  - (7) Applicant's signature and date.
- (b) The prescribed fee shall be \$100, and shall be submitted with the completed application form.

(c) “The Initial Application for Pharmacy Technician Registration” form for pharmacy technicians in New Hampshire may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

[Source.](#) #12671, eff 11-17-18

#### PART Ph 809 CERTIFIED PHARMACY TECHNICIAN RENEWALS

##### Ph 809.01 Renewal Requirements for Certified Pharmacy Technicians.

(a) All certified pharmacy technician certifications shall expire biennially on March 31.

(b) Applications for the renewal of a certification for a pharmacy technician may be obtained from, and shall be filed at the office of the board, identified in Ph 103.03.

(c) A pharmacy technician applying for renewal shall do so online at <https://nhlicenses.nh.gov/eGov/Login.aspx> by providing the following information about him or herself:

- (1) Legal name, residence address, mailing address, personal e-mail address, and a mobile or home telephone number;
  - (2) License number and work email address of the pharmacist-in-charge;
  - (3) Name and phone number of current employer and address of employment site;
  - (4) Record of convictions of violations of federal, state or local drug or pharmacy related laws or regulations;
  - (5) Report or copies of continuing education;
  - (6) Certification status; and
  - (7) Applicant’s signature and date.
- (d) The application and the prescribed fee of \$100 shall be filed with the board no later than March 15.

[Source.](#) #12671, eff 11-17-18

#### PART Ph 810 ONGOING REQUIREMENTS FOR CERTIFIED PHARMACY TECHNICIANS

##### Ph 810.01 Changes in Certification Information for Certified Pharmacy Technicians.

(a) The person to whom a pharmacy technician certification has been issued shall, within 15 days of a change of address or location of employment, notify the board of such changes.

(b) The notice shall contain:

- (1) Legal name of certified pharmacy technician;
- (2) Address, phone number, and personal email address of the certified pharmacy technician, including old and new, if applicable;
- (3) Certified pharmacy technician’s New Hampshire permit number;

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(4) Name of the pharmacy where employed including former and current, if applicable;

(5) Certification status; and

(6) All new violations of law, convictions, fines, disciplines or any registration, certification, or license revocations for violation of pharmacy-related drug laws or regulations in this or any other state.

(c) Failure to comply with Ph 810.01 shall constitute misconduct under RSA 318.

[Source.](#) #12671, eff 11-17-18

**Ph 810.02 Continuing Education Requirements for Certified Pharmacy Technicians.**

(a) Certified pharmacy technicians shall maintain their nationally certified status and stay up to date with all continuing education requirements such certification demands.

(b) A certified pharmacy technician shall retain all certificates and/or other documented evidence of participation in an approved/accredited continuing education program/course for a period of 3 years. Such documentation shall be made available to the board for random audit or verification.

(c) Certified pharmacy technicians with duties involving sterile and non-sterile compounding shall complete a minimum of 0.4 CEU's in the area of compounding.

(d) Not less than 10% of certified pharmacy technicians shall be randomly selected each year by the board for determinations of compliance.

[Source.](#) #12671, eff 11-17-18 (formerly Ph 806.04)

**Ph 810.03 Excess Continuing Education Requirements for Certified Pharmacy Technicians.** Excess continuing education units earned in one licensure period shall not be carried forward into the new licensure period for the purpose of fulfilling that year's continuing education prerequisite for licensure renewal.

[Source.](#) #12671, eff 11-17-18

**Ph 810.04 Penalty.** Any certified pharmacy technician 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.

[Source.](#) #12671, eff 11-17-18 (formerly Ph 806.05)

**PART Ph 811 REVOCATION, DENIAL, AND REINSTATEMENT OF CERTIFIED PHARMACY TECHNICIANS**

**Ph 811.01 Effect of Revocation and Denial for a Certified Pharmacy Technician.**

(a) The board shall refuse to issue a certification or, after notice and hearing, shall revoke a certification whenever the board finds, by the preponderance of the evidence, any of the following:

(1) That the applicant, or certified pharmacy technician, has violated any of the provisions of RSA 318, RSA 318-B, or the board's administrative rules;

(2) That the applicant has been convicted of a felony or a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule or regulation;

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(3) That the applicant has attempted to obtain certified pharmacy technician status by fraudulent means;

(4) That the applicant is unable to engage in the performance of certified pharmacy technician functions with reasonable skill and safety by reason of illness, inebriation, misuse of drugs, narcotics, alcohol, chemicals or any other substance, or as a result of any mental or physical condition;

(5) That another state has suspended, revoked, or placed on probation the applicant's license, permit, certification, or registration to practice as a pharmacy technician;

(6) That the applicant refused to appear before the board after having been ordered to do so in writing; or

(7) That the applicant made any fraudulent or untrue statement to the board.

(b) The pharmacist-in-charge shall notify the board, in writing, within one calendar day after becoming aware that a pharmacy technician has adulterated, abused, stolen or diverted drugs.

(c) The board shall issue a new certification after review, provided that the reason for revocation no longer exists or it is determined that there is no longer a threat to public safety.

[Source.](#) #12671, eff 11-17-18

Ph 811.02 Reinstatement of a Pharmacy Technician Certification. Certified pharmacy technicians who either voluntarily or accidentally allow their certification to lapse as of March 31 of the renewal year shall complete the following procedures to reinstate their certification:

(a) Complete a reinstatement application found on the board's website at <https://www.oplc.nh.gov/pharmacy/documents/technician-reinstatement.pdf> (revised April 2018);

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

(c) Submit any required documentation as outlined on the form;

(d) Submit a signed and dated statement as to why the applicant did not renew his or her pharmacy technician certification prior to expiration and whether or not the applicant has practiced as a pharmacy technician since his or her certification has lapsed.

(e) Submit a current national certification certificate; and

(f) Submit proof of continuing education as defined in Ph 805.02 completed within the immediately preceding 24 months.

[Source.](#) #12671, eff 11-17-18

### **PART Ph 812 CERTIFIED PHARMACY TECHNICIANS – STANDARDS OF PRACTICE**

#### **Ph 812.01 Determination of a Certified Pharmacy Technician's Duties.**

(a) Any certified pharmacy technician who does not maintain national certification shall notify the board and the pharmacist-in-charge immediately of the lapse of certification. Those whose certification has lapsed shall be permitted to perform the duties of a registered pharmacy technician, but shall no longer perform the additional duties of a certified pharmacy technician.



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(b) A certified pharmacy technician shall only perform such tasks and duties which are prescribed by the permit holder or pharmacist-in-charge based upon the needs of the pharmacy.

(c) A certified pharmacy technician's duties may be further limited by the pharmacist on duty or the supervising pharmacist.

(d) Any training given under the direction of a pharmacist shall be documented by the pharmacist-in-charge and be retrievable upon inspection.

[Source.](#) #12671, eff 11-17-18

### Ph 812.02 Certified Pharmacy Technicians Duties.

(a) A certified pharmacy technician's duties shall include:

- (1) Any duties performed by registered pharmacy technicians under Ph 807.02;
- (2) Accepting a new oral telephone order;
- (3) Accepting an oral refill authorization from a provider;
- (4) Communicating a prescription transfer for a non-control medication to or from another pharmacy that does not maintain a common database;
- (5) Communicating orally or in writing, any medical, therapeutic, clinical, or drug information, or any information recorded on a patient profile that does not require professional judgment;
- (6) Performing the data entry of a prescription or medication order into the computer without supervision;
- (7) The task of reducing to writing a prescription left on a recording or message line;
- (8) Preparing or compounding sterile and non-sterile compounds;
- (9) Verifying stock replenishment medications against the stocking/replenishment system, report or label prior to the stocking/replenishment of the automated dispensing machine, other automated dispensing equipment, or other stock location provided that bar-coding, radio frequency identification or another form of electronic verification is used at the time of stocking/replenishment, or a licensed health professional checks the medication before administration to the patient;
- (10) Clarification of an original prescription or drug order with a practitioner or authorized agent of the practitioner; and
- (11) Preparation, verification, and sealing of an emergency kit.

[Source.](#) #12671, eff 11-17-18 (formerly Ph 807.03)

## CHAPTER Ph 900 MAIL-ORDER PHARMACY

Statutory Authority: RSA 318:37, II

### PART Ph 901 PURPOSE AND SCOPE

Ph 901.01 Scope. The provisions of this chapter shall apply to, and impose duties upon, all mail-order pharmacies holding registrations issued by the board.

Source. #7474, eff 4-5-01; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

**PART Ph 902 DEFINITIONS**

Ph 902.01 “Mail-order pharmacy” means “mail-order pharmacy” as defined in RSA 31 8:1, VII-b, namely, “a pharmacy that is located in a state of the United States, other than this state, whose primary business is to dispense a prescription drug or device under a prescription drug order and to deliver the drug or device to a patient, including a patient in this state, by the United States mail, a common carrier, or a delivery service. Mail-order pharmacies include, but are not limited to, pharmacies that do business via the Internet or other electronic media.”

Source. #7474, eff 4-5-01; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

**PART Ph 903 REGISTRATION**

**Ph 903.01 Application.**

(a) No person shall conduct or operate a mail-order pharmacy located outside of this state by delivering in any manner prescription drugs or prescription devices into this state unless such pharmacy is registered in New Hampshire and a permit has been issued by the New Hampshire board of pharmacy.

(b) Application form MO-1, “Registration of Mail-order Pharmacy,” may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(c) Applicants for registration as a mail-order pharmacy shall submit a completed MO-1 that contains the following information:

- (1) Name, address, telephone number and Internet address, if applicable, of the pharmacy;
  - (2) The names, addresses and titles of all principal corporate officers, if incorporated and if unincorporated, partners or owners of the pharmacy;
  - (3) If a corporation, a certificate of incorporation from the state in which incorporated;
  - (4) If a limited liability company, partnership or sole proprietorship, a tax ID number;
  - (5) The name and home-state pharmacist license number of the pharmacist-in-charge of the location listed in number (1) above;
  - (6) A copy of the pharmacy’s current license, permit, or registration certificate used by the regulatory or licensing agency of the state in which the pharmacy is located, as well as a copy of the current DEA registration, if applicable;
  - (7) A copy of the most recent inspection report conducted by the state in which the pharmacy is located;
  - (8) A list of any and all Internet websites from which the mail-order pharmacy solicits business; and
  - (9) Signature of the pharmacist-in-charge and date.
- (f) As attachments to the completed MO-1, the applicant shall provide the following:
- (1) One of the following:

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- a. Verified Internet Pharmacy Practice Sites™ accreditation from the National Association of Boards of Pharmacy®; or
- b. The following materials:
  - 1. At least 2 photographs of the actual existing exterior, including the pharmacy signage, of the building in which the pharmacy will be or is currently located;
  - 2. At least 2 photographs of the prescription department as viewed by an approaching patron;
  - 3. At least 4 photographs of the prescription department as viewed from the interior, showing the prescription compounding area, refrigerator, water facilities and pharmaceutical inventory storage area; and
  - 4. Scaled drawings of the pharmacy and drug storage area.
- (2) A prescription label, containing the name, address and phone number of the pharmacy, that would be used on finished prescription products mailed to NH residents;
- (3) A sample copy of a printed patient medication profile that shall include the following information:
  - a. Name and address of the patient;
  - b. Name, address and DEA registration number of the prescriber;
  - c. Name, strength and quantity of drug dispensed;
  - d. Assigned prescription number;
  - e. Date of original filling; and
  - f. Date of refill(s); and
- (4) Copies of the following documents:
  - a. A copy of an inspection report, created within the last 12 to 18 months, which documents compliance with the State of New Hampshire board of pharmacy rules regarding sterile compounding of injectable drugs and non-sterile compounding in compliance with the United States Pharmacopeia Chapter 797 and Chapter 795 pursuant to RSA 318:14-a performed by:
    - 1. Your home state's board of pharmacy;
    - 2. Other responsible state or national regulatory agency; or
    - 3. New Hampshire board of pharmacy approved third party entity.
  - b. A signed attestation by the pharmacist-in-charge stating there is a policy and procedures manual available showing compliance with USP 795 and 797; and
  - c. A hood certification inspection report completed under dynamic conditions, not at rest, within the last 6 months; and
- (5) The prescribed fee which shall be \$1,000.

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(g) Failure to comply with any of the provisions of Ph 903 shall result in denial of a permit.

(h) Any person or pharmacy whose pharmacy business fits the definition of a mail-order pharmacy and delivers prescription drugs or prescription devices to New Hampshire residents from more than one out-of-state pharmacy shall register each such pharmacy separately.

Source. #7474, eff 4-5-01; amd by #9139-B, eff 4-25-08; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

### **PART Ph 904 REGISTRATIONS – CHANGES IN SUPPORTING DATA**

#### **Ph 904.01 Reporting Changes.**

(a) The mail-order pharmacy to which a registration has been issued shall within 30-days of any change of information supplied in the original application, notify the board.

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

- (1) Current New Hampshire registration number of the pharmacy;
- (2) Name of the pharmacy, old and new, if applicable;
- (3) Address of the pharmacy, old and new, if applicable;
- (4) Name of the pharmacist-in-charge, old and new, if applicable; and
- (5) Name(s), addresses and titles, of new corporate officers, or partners, or owners.

(c) A new registration shall be required for a change of ownership of an established pharmacy to a successor business entity which results in a change in the controlling interest in the pharmacy.

Source. #7474, eff 4-5-01; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

### **PART Ph 905 REVOCATION AND DENIAL**

#### **Ph 905.01 Effect of Revocation and Denial.**

(a) The board shall refuse to issue a registration or shall revoke a registration whenever the board determines that a mail-order pharmacy, its pharmacist-in-charge, 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 registration;
- (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 318:37, II, the provisions of Ph 900, or both;
- (5) Based on an investigation of a complaint resulting from the dispensing of prescription drugs or prescription devices 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 mail-order pharmacy shall notify the board within 15 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 registration 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 registration 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.

[Source.](#) #7474, eff 4-5-01; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

## **PART Ph 906 RENEWAL OF REGISTRATIONS**

Ph 906.01 Renewal Registrations Required. All mail-order pharmacy registrations shall expire annually on December 31.

[Source.](#) #7474, eff 4-5-01; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

Ph 906.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a registration for a mail-order pharmacy may be obtained from, and shall be filed at the office of the board, identified in Ph 103.03 or online.

[Source.](#) #7474, eff 4-5-01; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

Ph 906.03 Renewal Application Contents and When Filed. Renewal applications shall be filed with the board in accordance with the following:

(a) Applications for renewal of a registration for a mail-order pharmacy shall be made on form MO-2 "Application for Renewal of Registration for Mail-order Pharmacy";

(b) Each applicant shall provide the following documents via fax, mail, or scanned and emailed to the board, or in the case of items (6) and (7) directly on the renewal form, in order for the renewal application to be processed by December 31<sup>st</sup>:

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- (1) A copy of an inspection report, created within the last 12 to 18 months, which documents compliance with the State of New Hampshire board of pharmacy rules regarding sterile compounding of injectable drugs and non-sterile compounding in compliance with the United States Pharmacopoeia Chapter 797 and Chapter 795 pursuant to RSA 318:14-a, I performed by;
  - a. Your home state's board of pharmacy;
  - b. Other responsible state or national regulatory agency; or
  - c. New Hampshire board of pharmacy approved third party entity;
- (2) A signed attestation by the pharmacist-in-charge stating there is a policy and procedures manual available showing compliance with USP 795 and 797;
- (3) A hood certification inspection report completed under dynamic conditions, not at rest, within the last 6 months;
- (4) Copy of the pharmacy's current home state pharmacy license/permit;
- (5) Copy of the pharmacy's current federal DEA permit if shipping controlled substances;
- (6) Name, address, telephone number and Internet address, if applicable, of the pharmacy;
- (7) The names, corporate or business addresses and titles, of all principal corporate officers, if incorporated, or all partners or owners of the pharmacy if not incorporated;
- (8) The application and the prescribed fee of \$1,000; and
- (9) Signature of the pharmacist-in-charge and date.

Source. #7474, eff 4-5-01; amd by 9139-B, eff 4-25-08; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

Ph 906.04 Failure to Comply. Failure to comply with any of the provisions of Ph 906 shall result in non-renewal of the pharmacy permit.

Source. #10663, eff 9-3-14

**PART Ph 907 CONDITIONS OF REGISTRATION**

Ph 907.01 Compliance. As conditions of registration, the mail-order pharmacy shall:

- (a) Maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident;
- (b) Maintain in readily retrievable form, records of legend drugs, devices, or both dispensed to New Hampshire patients;
- (c) Supply upon request, any and all information needed by the board to carry out its responsibilities under the statutes and rules pertaining to mail-order pharmacies;
- (d) Provide for a toll-free telephone communication consultation between New Hampshire patients and a pharmacist at the mail-order pharmacy who has access to the patient's records, and ensure that such toll-free telephone number(s) shall be placed upon the label affixed to each prescription container;
- (e) Provide to the board, upon request, a copy of the policies and procedures governing:

- (1) Normal delivery protocols and times;
  - (2) Any special packaging or procedures used in delivering temperature-sensitive drug products;
  - (3) The procedure to be followed if the patient's medication is not available at the mail-order pharmacy, or if delivery will be delayed beyond the normal delivery time;
  - (4) The procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the mail-order pharmacy at the earliest possible time, such as courier delivery, or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time; and
  - (5) The procedure to be followed when the mail-order pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available;
- (f) All finished prescription products shipped to New Hampshire residents shall be shipped in tamper-evident envelopes or boxes;
- (g) A mail-order pharmacy shall not dispense or sell to the public, any drug which is adulterated or misbranded;
- (h) A mail-order pharmacy shall supply, upon request from the board, a statement of origin of any specific drug dispensed to a New Hampshire resident; and
- (i) Any mail-order pharmacy shipping finished prescription products into the State of New Hampshire shall use the address, but without the name of the pharmacy, on file with the New Hampshire board of pharmacy as the return address on the labels of any package shipped into the State of New Hampshire. The return address shall be placed on the package in a clear and prominent manner.

[Source.](#) #7474, eff 4-5-01; ss by #9341, eff 12-4-08; ss by #10663, eff 9-3-14

## 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 board pursuant to 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 the rules adopted by the board of pharmacy 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 he is acting in the usual course of his business or employment.

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(c) Licensed manufacturers and wholesale distributors of prescription drugs and devices shall annually complete and submit a board provided Renewal Application, revised 09/16.

(d) The prescribed fee for original and annual renewal licenses for manufacturers and wholesale distributors of prescription drugs and devices shall be \$250.

(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.

12-06 [Source.](#) #8447, INTERIM, eff 10-14-05, EXPIRED: 4-

[New.](#) #8708, eff 8-23-06, EXPIRED: 8-23-14

[New.](#) #12007, eff 10-22-16 (formerly Ph 309.01)

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.

12-06 [Source.](#) #8447, INTERIM, eff 10-14-05, EXPIRED: 4-

[New.](#) #8708, eff 8-23-06, EXPIRED: 8-23-14

[New.](#) #12007, eff 10-22-16 (formerly Ph 309.02)

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 scaled floor plan of the proposed facility.

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



12-06

[Source.](#) #8447, INTERIM, eff 10-14-05, EXPIRED: 4-

[New.](#) #8708, eff 8-23-06, EXPIRED: 8-23-14

[New.](#) #12007, eff 10-22-16 (formerly Ph 309.03)

## PART Ph 1002 OPERATIONS

### 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.

[Source.](#) #12007, eff 10-22-16 (formerly Ph 309.04)

### 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.

[Source.](#) #12007, eff 10-22-16 (formerly Ph 309.05)

### 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.

[Source.](#) #12007, eff 10-22-16 (formerly Ph 309.06)

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.

[Source.](#) #12007, eff 10-22-16 (formerly Ph 309.07)

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.

[Source.](#) #12007, eff 10-22-16 (formerly Ph 309.08)

Ph 1002.06 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; 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.

[Source.](#) #12007, eff 10-22-16 (formerly Ph 309.09)

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Ph 1002.07 Returned Goods. A wholesale operation shall maintain a procedure for the proper handling and disposal of returned goods.

Source. #12007, eff 10-22-16 (formerly Ph 309.10)

Ph 1002.08 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.

Source. #12007, eff 10-22-16 (formerly Ph 309.11)

Ph 1002.09 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.

Source. #12007, eff 10-22-16 (formerly Ph 309.12)

Ph 1002.10 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.

Source. #12007, eff 10-22-16 (formerly Ph 309.13)

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.

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(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.

[Source.](#) #12007, eff 10-22-16 (formerly Ph 309.14)

Ph 1002.12 Reporting Changes.

(a) It shall be the responsibility of the manufacturer/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 30<sup>th</sup>. 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.

(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.

[Source.](#) #12007, eff 10-22-16

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.

[Source.](#) #12007, eff 10-22-16

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:

(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;

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- (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.

[Source.](#) #12007, eff 10-22-16

### 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.

[Source.](#) #12007, eff 10-22-16

## CHAPTER Ph 1100 COLLABORATIVE PHARMACY PRACTICE

### PART Ph 1101 PURPOSE

Ph 1101.01 Purpose. The purpose of this chapter is to implement and regulate collaborative pharmacy practice as a means to make the provision of certain aspects of health care more efficient, less costly, and provided in a more timely manner.

[Source.](#) #9381, eff 1-31-09, EXPIRED: 1-31-17

[New.](#) #12464, eff 1-23-18

### PART Ph 1102 DEFINITIONS

Ph 1102.01 “Attending practitioner” means “attending practitioner” as defined in RSA 318:1, XXV, namely, “the physician or advanced practice registered nurse who has the primary responsibility for the treatment and care of the patient” and as outlined in the collaborative agreement.

[Source.](#) #9381, eff 1-31-09, EXPIRED: 1-31-17

[New.](#) #12464, eff 1-23-18

Ph 1102.02 “Collaborative pharmacy practice” means “collaborative pharmacy practice” as defined in RSA 318:1, XXVI, namely, “the practice of pharmacy whereby one or more pharmacists jointly agree, on a voluntary basis, to work in conjunction with one or more attending practitioners under written protocol whereby the collaborating pharmacist or pharmacists may perform medication therapy management authorized by the attending practitioner or practitioners under certain specified conditions and limitations.”

[Source.](#) #9381, eff 1-31-09, EXPIRED: 1-31-17

[New.](#) #12464, eff 1-23-18

Ph 1102.03 “Collaborative pharmacy practice agreement” means “collaborative pharmacy practice agreement” as defined in RSA 318:1, XXVII, namely, “a written and signed specific agreement between a pharmacist, an attending practitioner, and the patient or patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of medication

therapy management for the patient.” The term includes each protocol developed pursuant to RSA 318:16-a, II(a).

Source. #9381, eff 1-31-09, EXPIRED: 1-31-17

New. #12464, eff 1-23-18

Ph 1102.04 “Board” means “board” as defined in RSAA 318:1, III.

Source. #9381, eff 1-31-09, EXPIRED: 1-31-17

New. #12464, eff 1-23-18

## **PART Ph 1103 COLLABORATIVE PHARMACIST QUALIFICATIONS AND APPLICATION**

### **Ph 1103.01 Qualifications.**

(a) A pharmacist who seeks to engage in collaborative practice shall:

- (1) Hold an unrestricted and current license to practice as a pharmacist in New Hampshire;
- (2) Have at least \$1,000,000.00 of professional liability insurance that covers services performed under a signed, written collaborative agreement;
- (3) Have the knowledge to properly perform the duties in the collaborative agreement; and
- (4) Depending on the complexity of services to be provided by the pharmacist the board shall require additional education credits to meet the needs of the collaborative practice agreement.

Source. #9381, eff 1-31-09, EXPIRED: 1-31-17

New. #12464, eff 1-23-18

Ph 1103.02 Attending Practitioner Qualifications. Pharmacists shall not enter into a collaborative agreement with any other practitioner unless that practitioner:

- (a) Holds an active, unrestricted license to practice in the state of New Hampshire;
- (b) Has prescriptive authority granted by a New Hampshire licensing board; and
- (c) Authorizes the pharmacist to perform only those services that fall within that practitioner’s scope of practice.

Source. #9381, eff 1-31-09, EXPIRED: 1-31-17

New. #12464, eff 1-23-18

## **PART Ph 1104 APPLICATION AND SUPPORTING DOCUMENTATION**

### **Ph 1104.01 Application.**

(a) A pharmacist who seeks to engage in collaborative practice shall submit:

- (1) A completed and signed “Collaborative Practice Application”, effective December 2017 and available on the board’s website;

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(2) A certificate of insurance from the pharmacist's professional liability carrier indicating that the pharmacist maintains insurance coverage that complies with RSA 318:16-a, I(b), and covers the duties and responsibilities within the collaborative agreement; and

(3) A copy of the collaborative agreement, as well as detailed information on the quality assurance program required by RSA 318:16-a, IV (c).

(b) A pharmacist who seeks to engage in the administration of vaccines shall hold current basic or higher certification in cardiopulmonary resuscitation (CPR) from the American Heart Association, the American Red Cross, or from another organization or entity that is nationally recognized as an issuer of such certifications.

(c) After receipt of a "Collaborative Pharmacy Practice Application" the board's staff shall review it for any apparent errors or omissions and inform the applicant in writing if any are found. If informed of errors or omissions, the pharmacist shall correct the error or provide the missing application materials within 30 days of such notification being sent.

(d) Pharmacists engaged in collaborative practice shall provide written or electronic notification to the board of any change to the original application or supporting documentation within 15 days of such change taking effect.

[Source.](#) #9381, eff 1-31-09, EXPIRED: 1-31-17

[New.](#) #12464, eff 1-23-18 (from Ph 1103.02)

### **PART Ph 1105 COLLABORATIVE PRACTICE AGREEMENTS AND INFORMED CONSENT**

#### **Ph 1105.01 Collaborative Practice Agreements.**

(a) Collaborative practice agreements shall describe in detail services that a pharmacist may perform for a patient that provides informed consent, including but not limited to:

- (1) Specific drugs to be managed by the pharmacist;
- (2) Terms and conditions under which a drug therapy may be implemented, modified, or discontinued;
- (3) Conditions and events upon which the pharmacist is required to notify the collaborating practitioner, and the manner and time frame in which such notification shall occur;
- (4) The laboratory tests that may be ordered to manage a medication therapy;
- (5) Activities which may be performed by the pharmacist in conjunction with a written protocol;
- (6) A statement of the expected amount of dedicated time that a pharmacist will use exclusively to perform duties in the collaborative agreement;
- (7) Documentation of the care delivered and, if applicable, methods of communication of essential information the patient's other health care providers;
- (8) Education and training designed to enhance patient understanding and the appropriate use of his or her medication;
- (9) The beginning and ending dates of the period of time during which the agreement is in effect;

(10) A statement that the agreement may be terminated in writing by either party at any time, subject to (c) below; and

(11) A description of the private, HIPAA-compliant space to be utilized for collaborative practice.

(b) Collaborative agreements shall be renewed at least every 2 years, and signed by all practitioners who are a party to the agreement.

(c) When a collaborative agreement is terminated, the patient shall be provided written notification within 15 days. Such written notification shall include detailed information on how the patient may continue any medication therapy provided by the pharmacist without interruption.

(d) Collaborative practice agreements shall include quality metrics developed by pharmacist(s) and physician(s) or nurse practitioner(s) that shall be reported to the board on an annual basis.

(e) Collaborative agreements shall include, in a format determined by the parties to the agreement, written informed consent signed by the patient or the patient's authorized representative and containing the information specified in Ph 1105.02.

(f) Pharmacists shall keep a copy of each collaborative agreement, including any protocols specified in such agreements, to which they are a party at their place of practice.

(g) Collaborative agreements, protocols, and written informed consents shall be available for inspection and review by the board or its agents at any time during the pharmacist's normal business hours.

[Source.](#) #12464, eff 1-23-18 (from Ph 1104.01)

Ph 1105.02 Informed Consent of Patient or Patient's Authorized Representative.

(a) Patient informed consents shall include, but not be limited to, the following information:

- (1) A statement that the patient or the patient's authorized representative has read, understood, and consented to the pharmacist performing the duties outlined in the agreement;
- (2) The full name and address of the patient;
- (3) The full name and address of the collaborative attending practitioner; and
- (4) The full name and address of the collaborating pharmacist.

[Source.](#) #12464, eff 1-23-18 (from Ph 1104.02)

Ph 1105.03 Practice Under a Collaborative Practice Agreement.

(a) Practice by a pharmacist under a collaborative practice agreement shall not be delegable and shall be performed only by the pharmacist who is a party to the agreement.

(b) At least once per year, the pharmacist shall review the collaborative practice agreement and each protocol developed pursuant thereto so as to determine whether changes should be made to reflect the standard of care. If such a review reveals that a change should be made, the pharmacist shall inform the attending practitioner and the patient or the patient's authorized representative.

(c) Nothing in this chapter shall be construed to prohibit an authorized pharmacist from participating in medication therapy management by protocol or policy approved by the medical staff of the hospital, so



long as such participation is limited to drugs administered to a patient by an individual licensed to administer the drug to the patient in an in-patient or outpatient hospital setting.

(d) Nothing in this chapter shall be construed to prohibit a pharmacist from performing medication therapy management services that do not require a collaborative agreement, such as:

- (1) Performing patient assessment or comprehensive medication review;
- (2) Formulating a medication treatment plan;
- (3) Monitoring efficacy and safety of medication therapy;
- (4) Enhancing medication adherence through patient empowerment and education; and
- (5) Documenting and communicating medication therapy management services to prescribers in order to maintain comprehensive patient care.

(e) In the event the board places a restriction on a pharmacist license, that pharmacist shall cease working under any collaborative agreement immediately upon being restricted. Once the restriction has been removed by the board, the pharmacist may reapply for collaborative practice.

(f) In the event a licensing board places a restriction on an attending practitioner, the pharmacist shall cease working under any collaborative agreement with that attending practitioner. Once the restriction has been removed by the respective licensing board, the pharmacist may reapply for collaborative practice with that attending practitioner.

[Source.](#) #12464, eff 1-23-18 (from Ph 1104.03)

#### Ph 1105.04 Audits.

(a) The board shall, at its annual January meeting, randomly select at least 10 percent and not more than 20 percent of active collaborative agreements for an audit.

(b) The continuing education advisory council shall audit the continuing education requirements of randomly selected collaborative practice agreements and submit its finding to the board at its annual April board meeting.

(c) Audits shall include the elements outlined in Ph 1104.

(d) Violations discovered by an audit shall be reported to the board.

[Source.](#) #12464, eff 1-23-18

### CHAPTER Ph 1200 CENTRAL PRESCRIPTION PROCESSING

#### PART Ph 1201 PURPOSE AND SCOPE

Ph 1201.01 Purpose. The purpose of this chapter is to set forth the requirements, limitations, and prohibitions for pharmacies that engage in central prescription processing so as to ensure that, for the protection of the public, all central prescription processing activities regulated by the board are performed in compliance with applicable state law and rules by those who are licensed by the board.

[Source.](#) #9469, eff 5-16-09, EXPIRED: 5-16-17

[New.](#) #12485, eff 2-24-18

## *NH Pharmacy Laws & Rules as of 10/29/2019*

Ph 1201.02 Scope. This chapter shall apply to all persons whose activities come under the jurisdiction of the board and who engage in central prescription processing activities.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

### PART Ph 1202 DEFINITIONS

Ph 1202.01 “Central fill pharmacy” means a licensed pharmacy, in this or any other state, district or commonwealth of the United States, engaging in central prescription handling by filling, refilling, or both, prescriptions including the preparation, packaging, and labeling of the medication.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

Ph 1202.02 “Central prescription processing” means “central prescription processing” as defined in RSA 318: 1, XXIII, namely, “the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions, such as dispensing, drug utilization review, claims adjudication, refill authorizations, and therapeutic interventions.”

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

Ph 1202.03 “Central processing pharmacy” means a licensed pharmacy, in this or any other state, district, or commonwealth of the United States, that engages in prescription review by performing functions that include but are not limited to:

- (a) Data entry;
- (b) Prospective drug review;
- (c) Refill authorizations;
- (d) Therapeutic interventions;
- (e) Patient counseling;
- (f) Claims submission;
- (g) Claims resolution; and
- (h) Claims adjudication.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

Ph 1202.04 “Claims adjudication” means the process by which a prescription is submitted and processed through a third-party payor.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

## ***NH Pharmacy Laws & Rules as of 10/29/2019***

Ph 1202.05 “Dispensing pharmacy” means a licensed pharmacy, in this or any other state, district or commonwealth of the United States, that receives the processed prescription, the filled or refilled prescription, or both, for dispensing to the patient or to the patient’s authorized representative and providing patient counseling as required.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

Ph 1202.06 “Intake pharmacy” means a licensed pharmacy, in this or any other state, district or commonwealth of the United States, that receives the patient’s or prescribing practitioner’s request to fill or refill a prescription, including a central processing pharmacy or a central fill pharmacy, as defined below, if the prescription was transmitted by the prescribing practitioner directly to such pharmacy or if the patient requested the refill from that pharmacy.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

### **PART Ph 1203 CENTRAL PRESCRIPTION PROCESSING**

Ph 1203.01 General Requirements for Engaging in Central Prescription Processing. A pharmacy may perform or outsource central prescription processing and handling services provided that:

(a) All pharmacies involved in the transactions pursuant to which the prescription is dispensed shall have either:

(1) The same owner; or

(2) A written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws, regulations, and rules;

(b) The pharmacies shall share a database to allow access to information necessary or required to fill or refill a prescription drug order;

(c) All participating pharmacies located in this state shall maintain a pharmacy license for each location or if located in another state shall be registered in New Hampshire as a mail-order pharmacy according to Ph 900;

(d) All pharmacists participating in, providing, or both, central prescription processing services shall be licensed in this state or in the case of a non-resident pharmacy, the state in which the pharmacy is located; and

(e) Each pharmacy and pharmacist engaging in central prescription processing and handling shall be responsible for properly filling the prescription and complying with the requirements of Ph 706 or each relevant and applicable provision adopted by the state in which the pharmacy or pharmacist is registered or licensed. If such other state does not have a relevant or applicable provision, the owner or contract referred to in (a) above shall comply with or require compliance with the substance of Ph 706.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

Ph 1203.02 Policy and Procedure Manual Required.

(a) Each participating pharmacy performing or contracting for the performance of centralized prescription processing and handling shall maintain a paper or electronic policy and procedure manual that includes at least the following:

(1) A policy that shall require every participating intake pharmacy to keep a record that includes at least the name, address and DEA number for each central fill or central processing pharmacy authorized to fill or process prescriptions on its behalf;

(2) A policy that shall require each central fill or central processing pharmacy to keep a record that includes at least the name, address and DEA number of all intake pharmacies for which it is authorized to fill or process prescriptions;

(3) A policy that shall describe comprehensively the responsibilities of each of the participating intake, filling, processing and dispensing pharmacies;

(4) A procedure that shall be used for maintaining records sufficient to allow for tracking a prescription during each stage of the filling and dispensing process including at least:

a. The following information about the pharmacist(s) and technician(s) involved in filling and dispensing the prescription and counseling the patient:

1. The pharmacist's full name;
2. The state in which the pharmacist is licensed and his or her license number; and
3. The action or actions taken by the pharmacist; and

b. The following information about the technician(s) involved in filling and dispensing the prescription:

1. The technician's full name;
2. The state in which the technician is licensed and the license number; and
3. The action or actions taken by the technician;

(5) The policy and procedure that shall be used for providing adequate security to protect the confidentiality and integrity of patient information;

(6) The procedure that shall be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care; and

(7) The procedure that shall be followed in dispensing a prescription drug order when the filled order is not received or the patient comes in before the order is received.

(b) Each participating pharmacy and pharmacist shall review the policies and procedures at least annually and such review shall be documented.

(c) Each participating intake, processing, filling and dispensing pharmacy and pharmacist shall make the policies and procedures manual available to the board or its agents upon request.

[Source.](#) #9469, eff 5-16-09, EXPIRED: 5-16-17

***NH Pharmacy Laws & Rules as of 10/29/2019***

New. #12485, eff 2-24-18

Ph 1203.03 Patient Counseling. The dispensing pharmacy shall offer to counsel to the patient as required pursuant to Ph 706.03.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

Ph 1203.04 Prohibitions and Limitations.

(a) Prescriptions for Schedule II controlled substances shall not be allowed for central prescription filling but shall be filled and dispensed at the intake pharmacy.

(b) Prescriptions for Schedule III, IV, or V controlled substances shall be allowed for central prescription processing and filling.

(c) Prescriptions for legend or controlled substances listed in Schedule III, IV, or V may be transmitted electronically, as permitted by state and federal laws, including via facsimile, from an intake pharmacy to a central fill pharmacy, provided that the intake pharmacy transmitting the prescription information complies with all state and federal laws.

(d) An intake pharmacy transmitting prescription information pursuant to (c) above shall keep:

(1) Records that track the prescription drug order during each step in the filling process that shall identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any portion of the process, including:

- a. Transmission;
- b. Filling;
- c. Dispensing; or
- d. Delivery to either the patient or another pharmacy; and

(2) A record of the date the filled prescription was delivered to the intake pharmacy, the method of delivery, such as by private, common or contract carrier, and the identity of the carrier.

Source. #9469, eff 5-16-09, EXPIRED: 5-16-17

New. #12485, eff 2-24-18

Ph 1203.05 Record Keeping.

(a) The common electronic database shall maintain a record of all pharmacists and pharmacies involved in the intake, processing, filling, and dispensing of all prescriptions.

(b) There shall be record keeping systems between central prescription processing pharmacies with real-time, online access to those services provided by each pharmacy.

(c) Access to prescription information by 2 participating pharmacies shall not be considered a prescription transfer and shall not be subject to the provisions of Ph 704.04.

(d) All records required to be created and maintained pursuant to Ph 1203 shall be maintained for a period of not less than 4 years.

[Source.](#) #9469, eff 5-16-09, EXPIRED: 5-16-17

[New.](#) #12485, eff 2-24-18

## CHAPTER Ph 1300 PHARMACIST ADMINISTRATION OF VACCINES

### PART Ph 1301 PURPOSE AND SCOPE

Ph 1301.01 Purpose. The purpose of this chapter is to implement and regulate pharmacist administration of vaccines as a means to make vaccinations more easily accessible and therefore providing immunity to a larger patient population.

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12

Ph 1301.02 Scope. These rules shall regulate pharmacist administration of vaccines where the practice of pharmacy is permitted.

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12

### PART Ph 1302 DEFINITIONS

Ph 1302.01 “Administer” means “administer” as defined in RSA 318:1, I, namely, “an act whereby a single dose of a drug is instilled into the body of, applied to the body of, or otherwise given to a person or animal for immediate consumption or use.”

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12

Ph 1302.02 “Licensed pharmacist” or “pharmacist” means “licensed pharmacist” or “pharmacist” as defined in RSA 318:1, VII, namely, “when not otherwise limited, means a person holding a license under RSA 318:18 and who is, therefore legally authorized to practice the profession of pharmacy in this state.”

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12

Ph 1302.03 “Practitioner” or “licensed practitioner” means “practitioner” or “licensed practitioner” as defined in RSA 318:1, XV, namely, “means any person who is lawfully entitled to prescribe, administer, dispense, or distribute legend drugs to patients.”

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12

### PART Ph 1303 PHARMACIST ADMINISTRATION OF VACCINES QUALIFICATIONS AND APPLICATION

#### Ph 1303.01 Qualifications.

(a) A pharmacist who seeks to engage in the administration of vaccines shall meet the requirements of:

- (1) RSA 318:16-b, I, relative to education or experience;
- (2) RSA 318:16-b, II, relative to professional liability insurance coverage; and
- (3) RSA 318:16-b, III, relative to completion of continuing education.

(b) A pharmacist who seeks to engage in the administration of vaccines shall hold current basic or higher certification in cardiopulmonary resuscitation (CPR) from the American Heart Association, the

American Red Cross, or from another organization or entity that is nationally-recognized as an issuer of such certifications.

(c) A pharmacist shall not delegate the administration of vaccines to any person.

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12

Ph 1303.02 Application.

(a) A pharmacist who seeks to engage in the administration of vaccines shall file a completed "Pharmacist Administration of Vaccines Application" (February 2015) as specified in RSA 318:16-b, IV.

(b) An application fee of \$25.00 shall be filed with the board and included with the above application.

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12;  
ss by #10842, eff 6-3-15

PART Ph 1304 PHARMACIST ADMINISTRATION OF VACCINES PROCEDURAL AND  
RECORDKEEPING REQUIREMENTS

Ph 1304.01 Vaccine Administration Requirements. A pharmacist who engages in the administration of vaccines shall comply with the following procedures:

(a) Provide the patient with a Vaccine Information Statement (VIS) as provided by the Centers for Disease Control (CDC);

(b) Ensure that the patient has received and signed the Patient Consent Form and has been counseled and his or hers questions answered prior to administration of the vaccine;

(c) Maintain and follow written policies and procedures that establish a course of action the pharmacist shall follow to address:

(1) Adverse reactions;

(2) Anaphylactic reactions including a standard order for treatment;

(3) Accidental needle sticks; and

(4) Handling/disposal of used or contaminated equipment and supplies;

(d) Report all adverse events to the Vaccine Adverse Events Reporting System (VAERS) and to the primary care physician if applicable;

(e) Provide the patient with documentation of the vaccination and when appropriate report it to the immunization section of the New Hampshire department of health and human services to be added to the Vaccination Registry.

(f) Provide notice electronically, in writing or fax by within 30 days to the primary care provider, when the practitioner has been designated by the patient, of the administration of the pneumococcal and varicella zoster vaccine and maintain documentation of the record for a minimum of 4 years; and

(g) Be able to recognize anaphylaxis and maintain at least 2 doses of injectable epinephrine at all times to treat a reaction if it occurs.

[Source.](#) #9552, eff 9-23-09; ss by #10185, eff 9-18-12

## ***NH Pharmacy Laws & Rules as of 10/29/2019***

Ph 1304.02 Recordkeeping. A pharmacist who engages in the administration of vaccines shall, for a minimum of 4 years, keep a patient consent form that includes the:

- (a) Name and date of birth of the patient;
- (b) Name of the vaccine, manufacturer, lot number, and expiration date of the vaccine;
- (c) Description of the risks and possible side effects of the vaccine;
- (d) Date of administration;
- (e) Administering pharmacist's name; and
- (f) Signature of the patient.

Source. #9552, eff 9-23-09; ss by #10185, eff 9-18-12

### **CHAPTER Ph 1400 UNUSED PRESCRIPTION DRUG PROGRAM RULES**

#### **PART Ph 1401 PURPOSE**

Ph 1401.01 Purpose: The purpose of the rule is to allow the voluntary donation of unused prescription drugs and medical devices to the uninsured and the underinsured individuals.

(a) The rules of Ph 1400 describe the program to take unused prescription drugs and medical devices donated from nursing homes, pharmaceutical manufacturers, and other eligible donators and utilize them for dispensing to uninsured and underinsured persons who opt into the program.

(b) The rules of Ph 1400 describe the eligibility to donate. They describe the eligible prescription drug formulary, the eligible recipients, and the protection for participants. They describe pharmacies eligible to accept and dispense such drugs, and medical devices the requirements for eligible pharmacies, and the responsibilities for consultant pharmacists.

(c) The rules of Ph 1400 describe safe handling of drugs and medical devices to protect drug integrity, tracking, sanitation, security and dispensing requirements for these unused prescription drugs and medical devices. The rules of Ph 1400 describe confidentiality requirements as well as violations.

Source. #10064, eff 12-28-11

#### **PART Ph 1402 DEFINITIONS**

Ph 1402.01 "Abandoned drug" means a prescription only drug that was dispensed for a patient that was never in a patient's possession and is no longer needed by the patient or was left behind at a facility after discharge from the facility. The term includes Patient Assistance Program drugs when the manufacturer does not provide a shipping-paid option for the provider to return the drug to the manufacturer or the manufacturer's agent and:

(a) The provider has determined and documented that the patient should not receive or is unable to receive the drug, or

(b) The patient has not returned to receive the drug within 8 weeks of the time the prescriber received the drug.

Source. #10064, eff 12-28-11



***NH Pharmacy Laws & Rules as of 10/29/2019***

Ph 1402.02 “Agent” means any person who is legally authorized to make medical decisions for a patient.

[Source.](#) #10064, eff 12-28-11

Ph 1402.03 “Charitable Provider” means any pharmacist or practitioner licensed by this state to dispense drugs as defined by RSA 318:42 who chooses to participate in an unused prescription drug program.

[Source.](#) #10064, eff 12-28-11

Ph 1402.04 “Dispense” means to distribute, leave with, give away, dispose of, deliver, or sell one or more doses of a drug that will be administered or taken at a later date, time, or location and the transfer of more than a single dose of a medication from one container to another and the labeling or otherwise identifying a container holding more than a single dose of a drug.

[Source.](#) #10064, eff 12-28-11

Ph 1402.05 “Donate” means the giving free of charge of an eligible prescription drug to an unused prescription drug program.

[Source.](#) #10064, eff 12-28-11

Ph 1402.06 “Eligible prescription drug ” (EPD) means any unused prescription only drug that has not reached its expiration date, is contained in an unopened unit dose or other tamper evident packaging, has not been in the possession of the patient and has been stored properly and is not a radiopharmaceutical therapeutic or diagnostic drug. Drugs that can only be dispensed to a patient registered with the drug’s manufacturer in accordance with federal Food and Drug Administration (FDA) requirements are not eligible for the program.

[Source.](#) #10064, eff 12-28-11

Ph 1402.07 “Manifest” means an itemized invoice of EPD donated, accepted or destroyed.

[Source.](#) #10064, eff 12-28-11

Ph 1402.08 “Pharmacy” means “pharmacy” as defined by RSA 318:1 XI.

[Source.](#) #10064, eff 12-28-11

Ph 1402.09 “Practitioner” or “licensed practitioner” as defined by RSA 318:1 XV.

[Source.](#) #10064, eff 12-28-11

Ph 1402.10 “Program Pharmacist” means any licensed pharmacist in New Hampshire that is participating in an unused prescription drug program.

[Source.](#) #10064, eff 12-28-11

Ph 1402.11 “Redispende” means to dispense an EPD that was accepted by an unused prescription drug program for the purpose of providing medication to an individual who is uninsured/underinsured.

[Source.](#) #10064, eff 12-28-11

***NH Pharmacy Laws & Rules as of 10/29/2019***

Ph 1402.12 “Underinsured” means a person who lacks adequate prescription related insurance coverage such that purchasing prescription drugs and/or devices create a financial hardship.

[Source.](#) #10064, eff 12-28-11

Ph 1402.13 “Uninsured” means a person who does not presently have an active insurance policy that reimburses fully or partially for prescription drugs or devices.

[Source.](#) #10064, eff 12-28-11

**PART Ph 1403 ELIGIBILITY TO DONATE PRESCRIPTION DRUGS (EDP) AND MEDICAL DEVICES**

Ph 1403.01 Eligible Donating Entities. The following entities shall be eligible to donate prescription drugs and medical devices:

- (a) A pharmacy;
- (b) A licensed practitioner;
- (c) A Hospice or outpatient clinic if licensed pursuant to RSA 151;
- (d) A New Hampshire nursing home, if it is licensed with the New Hampshire department of health and human services (DHHS) and has a consultant pharmacist or program pharmacist;
- (e) A licensed manufacturer/wholesaler/distributor, who voluntarily donates samples or eligible prescription drugs or medical devices to eligible charitable providers in this program; and
- (f) A state or county correctional facility if it has a program pharmacist.

[Source.](#) #10064, eff 12-28-11

**Ph 1403.02 Unused Prescription Property.**

(a) A prescription drug shall be the property of the patient for whom it is prescribed, regardless of who paid for the prescription.

(b) The patient or agent of the patient may at any time authorize the donation of the unused prescription drugs or medical device.

(c) An unused prescription may be donated:

- (1) When a patient has died and
- (2) When a drug is abandoned.

(d) Prescription drugs donated under Ph 1400 shall only be transferred to charitable providers.

(e) Prescription drugs or medical devices donated under Ph 1400 shall not be sold, resold, offered for sale, traded, or returned for financial credit. This shall not prohibit transfer between charitable providers.

(f) A charitable provider shall be responsible for determining that the patient has authorized the donation of the drugs or medical devices.

(g) A charitable provider shall make certain that the name of the patient, and all patient information and directions on the label will be redacted or removed before sending to the accepting entity to protect confidentiality.

(h) Manifests shall be maintained for internal and external transfer of product.

[Source.](#) #10064, eff 12-28-11

Ph 1403.03 Conditions Required for Unused Prescription Drugs. The following conditions shall apply to unused prescription drugs and medical devices.

(a) Licensed healthcare personnel shall in order to be eligible keep control of such unused prescription drugs and medical devices in sanitary and secure conditions as required under RSA 318:58.

(b) Such unused prescription drugs and medical devices, in sanitary and secure conditions shall be eligible for donation.

(c) Nursing homes shall have a consultant pharmacist or a program pharmacist.

[Source.](#) #10064, eff 12-28-11

#### PART Ph 1404 ELIGIBILITY TO ACCEPT DONATIONS (EAD)

Ph 1404.01 Eligible Accepting Entities. The following entities shall be eligible to accept unused prescription drugs and medical devices.

(a) A pharmacy;

(b) A licensed practitioner;

(c) A hospice or public health clinic including (N.H. Hospital, Glencliff Home and N.H. Veterans Home) RSA 318:58 III;

(d) New Hampshire nursing homes if they are licensed and in good standing with DHHS;

(e) A manufacturer/wholesaler/distributor may accept samples or eligible prescription drugs for eligible charitable providers in this program; and

(f) A state or county correctional facility if it has a program pharmacist or a charitable provider.

[Source.](#) #10064, eff 12-28-11

#### PART Ph 1405 ELIGIBILITY TO REDISPENSE

Ph 1405.01 Eligible Redispensing Entities. Entities that are eligible to redispense shall include:

(a) A pharmacy; and

(b) Any licensed prescriber.

[Source.](#) #10064, eff 12-28-11

#### PART Ph 1406 PROGRAM PHARMACIST RESPONSIBILITIES

Ph 1406.01 Program Pharmacist.

(a) All entities eligible to accept shall have the program pharmacist approved by the New Hampshire board of pharmacy.

(b) Program pharmacists for the nursing home eligible to donate unused prescription drugs and medical devices shall:

- (1) Review quality and suitability of the unused prescription drugs for reuse as follows:
  - a. The drugs and medical devices shall be kept under the control of a health care professional;
  - b. The drugs and medical devices shall be stored properly against heat, cold and moisture;
  - c. The drugs shall be identifiable; and
  - d. The drugs are not adulterated, misbranded or mutilated.
- (2) Determine that the expiration date exceeds 90 days to allow time for redistribution;
- (3) Make sure a manifest contains the following if applicable: supplier (donor) name, and receiver name, donor and receiver address, phone numbers, state permit numbers, signatures, date sent, date received, date destroyed, name, strength and dosage form of drug, NDC #, package size, quantity, initials;
- (4) Provide a copy of this manifest to the accepting entity and maintain a copy at the donating entity for at least 2 years;
- (5) Assure controlled substances, that is, Drug Enforcement Agency (DEA) controlled substances are not donated or accepted;
- (6) Assure that the accepting and donating entities are eligible to receive unused prescription drugs and medical devices under these rules; and
- (7) Have transportation of product and manifest be the responsibility of both the donating and accepting entities to ensure that product integrity is maintained.

[Source.](#) #10064, eff 12-28-11

#### PART Ph 1407 ELIGIBLE PRESCRIPTION DRUG FORMULARY

Ph 1407.01 Formulary. All Food and Drug Administration (FDA) approved prescription drugs excluding controlled substances shall be subject to the following:

- (a) They shall not have been in the possession of the patient or other member of the public;
- (b) They shall not have reached within 90 days of their expiration date;
- (c) They shall be contained in unopened unit dose or other tamper-evident packaging and show no evidence of contamination;
- (d) Medical devices shall not be unsanitary, broken, dangerous or otherwise unfit for practical use;
- (e) They shall not be compounded drugs;
- (f) Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer shall only be donated or accepted if the program pharmacist(s) can ascertain the proper storage has been maintained at all times and transferred internally under the same ownership; and

(g) Drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration (FDA) requirements shall not be accepted or distributed.

[Source.](#) #10064, eff 12-28-11

PART Ph 1408 REQUIREMENTS FOR PHARMACIES DISPENSING UNUSED PRESCRIPTION DRUGS

Ph 1408.01 Dispensing Requirements. Unused prescription drugs shall be dispensed in compliance with the following:

- (a) Pharmacies shall follow the requirements established in RSA 318;
- (b) New Hampshire licensed pharmacies dispensing unused prescription drugs shall:
  - (1) Maintain a current drug identification book, or shall have a current computer program or online service for the same;
  - (2) Provide information to all recipients regarding the program and maintain a participation consent form for each eligible recipient or patient representative agent of any unused prescription drug; and
  - (3) Maintain samples in the original package as required under federal law, and the samples shall not be removed from original packaging for dispensing.
- (c) If it is determined by the pharmacist's professional judgment that it would be best for the patient, the drugs can be removed from patient specific packaging or unit dose packaging (UDP), commonly referred to as bingo cards, and repackaged.
- (d) Eligible New Hampshire pharmacies shall establish the following policies and procedures for the dispensing of unused prescription drugs to the uninsured or underinsured patients as follows:
  - (1) They may limit the number of prescriptions per patient per visit or per month, to allow a greater number of individuals access to such prescription drugs;
  - (2) If no underinsured or uninsured patients are available, donated medications may be made available to other patients; and
  - (3) There shall be a written policy that is enforced equally to prevent discrimination.
- (e) Pharmacies may transfer unused prescription drugs to another pharmacy in the program when one pharmacy has the need for a drug and another pharmacy has it available. The transferring pharmacy shall follow the rules of the donating entity and the receiving pharmacy shall follow the rules of the accepting entity.
- (f) Unused prescription drugs and medical devices shall not be resold.

[Source.](#) #10064, eff 12-28-11

PART Ph 1409 RESPONSIBILITIES OF CHARITABLE PROVIDERS

Ph 1409.01 Charitable Providers. A charitable provider shall:

(a) Coordinate retrieval of donated unused prescription drugs and medical devices from entities eligible to donate;

(b) Check unused prescription drugs (UPD) against the manifest and document any discrepancies and communicate those discrepancies to the entity eligible to donate;

(c) Store and secure these UPDs in a manner that distinguishes them from general stock and store them according to state and federal laws, rules and regulations;

(d) Check the unused prescription drugs for adulteration or misbranding;

(e) Assure expired, adulterated, misbranded, and controlled drugs are not dispensed;

(f) Segregate unacceptable drugs for destruction or return and prepare a manifest that is signed by both the pharmacist and a witness when it comes time for destruction;

(g) Have access to FDA or manufacturer drug recall information. If a drug is recalled by the FDA or manufacturer and the eligible provider can not ascertain the lot number on the label to differentiate between the recall and non-recalled drug, all such donated drugs shall be considered recalled and destroyed or returned in the manner specified by the recall; and

(h) Assure destruction as defined by Department of Environmental Service of expired, adulterated, and/or recalled unused prescription medications as follows:

(1) A manifest shall be made of unused prescription drugs expired, adulterated, misbranded and/or recalled to be destroyed;

(2) Following destruction such manifest shall be signed by the pharmacist and witness verifying such destruction; and

(3) The drug destruction manifest shall be kept in the files of the pharmacy for at least 2 years.

[Source.](#) #10064, eff 12-28-11

Ph 1409.02 Labeling. Dispensed prescription(s) shall clearly indicate the final charitable provider and the current patient information to assure clarity for receiving patient and shall be properly labeled according to RSA 318:47 and shall include the expiration date.

[Source.](#) #10064, eff 12-28-11

Ph 1409.03 Handling Fee. Whenever possible the dispensing facility or service shall provide at least a 30 day supply and a handling fee may be charged according to RSA 318:58 V.

[Source.](#) #10064, eff 12-28-11

Ph 1409.04 Recordkeeping. Charitable providers shall comply with recordkeeping rules set forth by Ph 309.07.

[Source.](#) #10064, eff 12-28-11

## ***NH Pharmacy Laws & Rules as of 10/29/2019***

### PART Ph 1410 FORMS

#### Ph 1410.01 Transfer Manifests.

(a) Sample manifests shall be available by the New Hampshire board of pharmacy.

(b) All participants may use their own manifest, provided they include all current information listed on the current manifest. See Ph 1406.01 (b) (3).

[Source.](#) #10064, eff 12-28-11

### PART Ph1411 PARTICIPANT IMMUNITY

Ph 1411.01 Participant Immunity. Immunity shall be provided to the program as provided in RSA 318:60.

[Source.](#) #10064, eff 12-28-11

### PART Ph 1412 VIOLATIONS

#### Ph 1412.01 Violations of the Unused Prescription Drug Program.

(a) Theft or diversion of any of the unused prescription drugs shall be a violation of these rules. This shall include any expired, misbranded drug, adulterated drug, recalled drug, or other drug found to be unusable under the requirements of Ph 1400.

(b) Any violation by any person of the unused prescription drug program shall be reported by the licensed entity upon discovery to the appropriate licensing agency within 30 days and/or other proper authorities for possible action.

(c) Such violation by any person licensed by the board may result in action under RSA 318:55 or any licensee, permittee, registrant or certificate holder as provided in RSA 318:29.

[Source.](#) #10064, eff 12-28-11

## CHAPTER Ph 1500 NEW HAMPSHIRE CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM

### PART Ph 1501 PURPOSE

Ph 1501.01 Purpose. This rule implements the New Hampshire Controlled Drug Prescription Health and Safety Program created by RSA 318-B:31–38, which authorizes the pharmacy board to establish and contract with a third party for the implementation and operation of an electronic system to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II–IV controlled substances by prescribers and dispensers within the state to promote public health and safety through the prevention of and treatment for misuse and abuse of controlled substances and the reduction of the diversion of such substances, without interfering with the legal medical use of these substances.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

### PART Ph 1502 DEFINITIONS

#### Ph 1502.01 Definitions.

***NH Pharmacy Laws & Rules as of 10/29/2019***

(a) “Authorized representative” means a parent or guardian of a minor child, or a person who has been authorized in the manner required by law to make health care decisions, or gain access to health care records, on behalf of another.

(b) “Board” means “board” as defined in RSA 318-B:31, I, namely, “the pharmacy board, established in RSA 318:2.”

(c) “Controlled substance” means “controlled substance” as defined in RSA 318-B:31, II, namely, “controlled drugs as defined in RSA 318-B:1, VI.”

(d) “Credential” means information or a device provided by the program to a registered dispenser or prescriber that allows the dispenser or prescriber to electronically submit or access prescription monitoring information. Credentials include, but are not limited to, a user name and password, or an identification device that generates a user name and password.

(e) “Dispense” means “dispense” as defined in RSA 318-B:31, III, namely, “to deliver a controlled substance by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.”

(f) “Dispenser” means “dispenser” as defined in RSA 318-B:31, IV, namely, “a person lawfully authorized to deliver a schedule II-IV controlled substance, but does not include:

- (1) A licensed hospital pharmacy that dispenses less than a 48 hour supply of a schedule II-IV controlled substance from a hospital emergency department, or that dispenses for administration in the hospital;
- (2) A practitioner, or other authorized person who administers such a substance;
- (3) A wholesale distributor of a schedule II–IV controlled substance or its analog;
- (4) A prescriber who dispenses less than a 48 hour supply of a schedule II – IV controlled substance from a hospital emergency department to a patient; or
- (5) A veterinarian who dispenses less than a 48 hour supply of a schedule II-IV controlled substance to a patient.”

(g) “Patient” means “patient” as defined in RSA 318-B:31, V, namely, “the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance or other such drug is lawfully dispensed.”

(h) “Person” means “person” as defined in RSA 318-B:1, XXI, namely, “any corporation, association or partnership, or one or more individuals.”

(i) “Practitioner” means “practitioner” as defined in RSA 318-B:31, VI, namely, “a physician, dentist, podiatrist, veterinarian, pharmacist, APRN, physician assistant, naturopath, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance in the course of licensed professional practice.”

(j) “Prescribe” means “prescribe” as defined in RSA 318-B:31, VII, namely, “to issue a direction or authorization, by prescription, permitting a patient to lawfully obtain controlled substances.”

(k) “Prescriber” means “prescriber” as defined in RSA 318-B:31, VIII, namely, “a practitioner or other authorized person who prescribes a schedule II, III, and/or IV controlled substance.”



(l) “Program” means “program” as defined in RSA 318-B:31, IX, namely, “the controlled drug prescription health and safety program that electronically facilitates the confidential sharing of information relating to the prescribing and dispensing of controlled substances listed in schedules II-IV, established by the board pursuant to RSA 318-B:32.”

(m) “Program manager” means the person designated by the board to oversee the implementation and operation of the program by the program vendor.

(n) “Program vendor” means a third party with which the board contracts for the implementation and operation of the program.

(o) “Regulatory board” means the New Hampshire board of dentistry, board of medicine, board of nursing, board of registration in optometry, board of podiatry, board of veterinary medicine, and pharmacy board.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

## PART Ph 1503 REGISTRATION OF PRESCRIBERS AND DISPENSERS

### Ph 1503.01 Registration of Prescribers and Dispensers.

(a) All practitioners authorized to prescribe or dispense schedule II–IV controlled substances within the state of New Hampshire shall register with the program [no later than June 30, 2015], as follows:

(1) Practitioners who prescribe but do not dispense schedule II-IV controlled substances shall register with the program as a prescriber;

(2) Practitioners who dispense but do not prescribe schedule II-IV controlled substances shall register with the program as a dispenser if they fall under the definition of “dispenser” in RSA 318-B:31, IV; and

(3) Practitioners who prescribe and dispense schedule II-IV controlled substances shall register with the program as both a prescriber and a dispenser unless exempted pursuant to RSA 318-B:31, IV.

(b) Program registration shall be by one of the following methods:

(1) Automatic registration at the time of the program go-live date or at the time of initial licensure or license renewal, if permitted by the prescriber’s or dispenser’s regulatory board; or

(2) Completing and submitting to the program vendor a registration form provided by the program vendor.

(c) Before a program credential is issued, the registrant shall be verified as having a current and valid license, as follows:

(1) Those prescribers and dispensers who register in accordance with (b)(1) above shall be automatically verified; and

(2) Those prescribers and dispensers who register in accordance with (b)(2) above shall be verified by the program manager by confirming that the registrant has a valid license.

(d) On a monthly basis, each regulatory board shall submit to the program manager or program vendor a list of prescribers and dispensers:

- (1) Who have been issued a new license;
- (2) Whose license has been renewed; and
- (3) Who have had their license revoked, suspended, restricted, or not renewed.

(e) If the credentials issued by the program vendor are lost or missing, or if the security of the credentials is compromised, the prescriber or dispenser shall cause the program manager to be notified by telephone and in writing as soon as possible.

(f) Those dispensers licensed under RSA 318 who have not registered shall be subject to disciplinary action as established pursuant to RSA 318:29.

(g) Those prescribers and dispensers who are required to register but who have not done so shall, pursuant to RSA 318-B:36 III, be subject to penalties established by their respective regulatory board.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

## PART Ph 1504 REQUIREMENTS FOR DISPENSERS

### Ph 1504.01 Reporting of Controlled Substances Dispensed.

(a) Dispensers shall submit to the program the prescription drug monitoring information required by RSA 318-B:33, IV, and paragraph (b) below, for each dispensing of a schedule II–IV controlled substance, as follows:

(1) Electronically, through direct upload to the program software or website at <https://pmpclearinghouse.net>, unless a waiver is requested and granted in accordance with Ph 1504.02(a) below;

(2) Daily, by the close of business on the next business day after the prescription was dispensed, unless an extension is requested and granted in accordance with Ph 1504.03 below, with the following exceptions:

a. Veterinarians shall submit the information required under (a)(2) above no more than 7 days from the date the prescription was dispensed; and

b. Dispensers who have a federal Drug Enforcement Administration license but who do not dispense controlled substances may request a waiver as described in Ph 1504.02(c) below; and

(3) For registered dispensers located outside the state of New Hampshire, information only for patients who reside in New Hampshire.

(b) The required prescription drug monitoring information to be submitted shall be as follows:

(1) Dispenser's Drug Enforcement Administration (DEA) registration number and, if available, the dispenser's National Provider Identification (NPI) number;

(2) Prescriber's DEA registration number and, if available, the prescriber's NPI number;

(3) Date of dispensing;

(4) Prescription number;

(5) Number of refills granted;

- (6) National Drug Code (NDC) of drug dispensed;
- (7) Quantity dispensed;
- (8) Number of day's supply of drug;
- (9) Patient's name, including first name, middle initial, if applicable, last name, and, suffix, if applicable;
- (10) Patient's address;
- (11) Patient's date of birth, or, for animals, the owner's date of birth;
- (12) Patient's phone number, if available;
- (13) Date prescription was written by prescriber;
- (14) Whether the prescription is new or a refill;
- (15) Source of payment for prescription; and
- (16) The species code human (1) or animal (2), and if animal, the animal's name.

(c) Dispensers licensed by the board under common ownership, including those located outside of New Hampshire, may submit the required prescription drug monitoring information in (b) above in a single joint report provided that each dispenser is clearly identified for each prescription dispensed.

(d) The program vendor shall perform data checks to ensure that the required prescription drug monitoring information submitted is accurate, complete, and timely.

(e) The program vendor shall notify the dispenser, the program manager, and the board:

- (1) When the dispenser fails to submit the required prescription drug monitoring information within the required timeframe;
- (2) When there are inaccuracies or omissions in the required prescription drug monitoring information submitted; and
- (3) When a dispenser fails to correct any inaccuracies or omissions.

(f) Dispensers shall:

- (1) Correct any failures, inaccuracies, or omissions, within 72 hours of the date of receipt of notice from the program vendor;
- (2) Correct their own records and submit corrected information to the program or program vendor whenever they become aware of errors, omissions, or reversals;
- (3) Comply with any provision of this section or be subject to disciplinary action as established pursuant to RSA 318:29; and
- (4) If a dispenser has no dispensing transactions to report for the preceding reporting period, report this information to the New Hampshire Controlled Drug Prescription Health and Safety Program by filing a "zero report," as described in the Reporting Zero Dispensing topic in the Data Submission Dispenser Guide, effective June 29, 2017.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

Ph 1504.02 Waivers.

(a) Dispensers that are unable to electronically submit, through direct upload to the program software or secure website, the required prescription drug monitoring information may request a waiver to submit the information by other means by completing and submitting a “Request for Waiver of Reporting Requirements for New Hampshire Prescription Drug Monitoring Program” form, effective October 28, 2016, to the program manager, along with any supporting documentation.

(b) A waiver request submitted pursuant to (a) above shall:

- (1) Demonstrate that, for any reason, including low volume of controlled substances being dispensed, financial hardship will result from the requirement of electronic submission[-]; and
- (2) Include an alternative method by which the dispenser will submit the required prescription drug monitoring information with the time frame specified in Ph 1504.01(a)(2). Alternative methods of submission shall include but not be limited to, e-mail, flash drive, CD, or paper.

(c) Dispensers that are authorized to dispense schedule II-IV controlled substances, but do not do so, may request a waiver from the program submission requirements by completing and submitting a “Request for Waiver of Reporting Requirements for New Hampshire Prescription Drug Monitoring Program” form, effective October 28, 2016, provided that such dispensers demonstrate that no schedule II-IV controlled substances have been dispensed in the 3 months immediately preceding the waiver request.

(d) Dispensers shall be notified of the decision to grant a waiver within 30 days of the date of the receipt of the completed waiver request.

(e) A waiver shall be specific to one United States DEA number and non-transferable.

(f) A waiver shall be time-limited, not to exceed the dispenser’s license expiration date.

(g) A waiver shall be subject to revocation if the bases for granting the waiver are determined to be no longer true.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

Ph 1504.03 Extensions.

(a) Dispensers that are unable to submit required prescription information within the required timeframe may request from the program manager an extension of the timeframe by telephone confirmed by email from the program manager.

(b) The program manager shall allow an extension for as long as the dispenser is making a good-faith effort to submit the required information, but no later than 10 calendar days after the established 7 day timeframe.

(c) The program manager shall notify the board if a dispenser ceases to demonstrate good faith in its efforts to submit the required information or if the dispenser fails to submit the required information by the extended timeframe.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

**PART Ph 1505 ACCESS TO PRESCRIPTION DRUG MONITORING INFORMATION**

Ph 1505.01 Patient Access.

(a) A patient for whom a prescription for a schedule II–IV controlled substance is dispensed, or his or her authorized representative, may request and obtain a report listing all prescription monitoring information that pertains to that patient.

(b) The request in (a) above shall be submitted to the program manager, either by mail or in person, on a complete, “Patient Prescription Monitoring Information Request” form (February 2014 Edition) signed by the patient, or the patient’s authorized representative.

(c) Patient information shall not be mailed or otherwise transmitted to the patient, or the patient’s authorized representative, except as allowed by (d) below.

(d) Upon notice that the requested information is available, the patient, or the patient’s authorized representative, shall receive the information in person, only after he or she produces valid government-issued photographic proof of identity. With the consent of the patient, or the patient’s authorized representative, the program manager shall photocopy the identification. If the patient, or patient’s authorized representative, does not consent to the photocopying of the identification, the patient, or patient’s authorized representative, shall provide written verification attesting to their identity.

Source. #10526, eff 2-26-14; ss by #12465, eff 1-23-18

Ph 1505.02 Prescriber and Dispenser Access.

(a) Registered prescribers and dispensers, or their designees, and federal health prescribers and dispensers working in federal facilities located in New Hampshire, Massachusetts, Maine, and Vermont shall have electronic program access to information on a specific patient, and in the case of veterinarians a specific patient’s owner(s), both past and present, for which a prescription was written or an appointment was scheduled or conducted.

(b) Requests shall be made by electronically or in writing.

(c) Electronic requests shall be made through the program’s secure web portal.

(d) Written requests shall:

(1) Be made by submitting to the program a completed “NH Prescriber/Dispenser Prescription Monitoring Information Request” form, effective 11/2017; and

(2) Be fulfilled by secure mail or fax.

(e) To enable the timely and efficient delivery of medical or pharmaceutical care for a specific patient, a prescriber or dispenser registered with the program may delegate the task of retrieving program information for a specific patient to an individual working under the direction and supervision of the registered prescriber or dispenser provided that written documentation of the delegation to the individual is provided to the program. Both the prescriber or dispenser who authorized the delegation and the individual to whom the task of retrieving the program information was delegated shall be subject to the provisions and penalties in RSA 318-B:36 regarding proper access to and use of program information.

(f) All program information, as listed in Ph 1504.01(b), to the extent that it is medical information shall be treated and protected as all protected health information.

(g) The program information may be placed in the patient medical records.

Source. #10526, eff 2-26-14; ss by #12465, eff 1-23-18

Ph 1505.03 Law Enforcement Access.

(a) Authorized law enforcement officials may request and obtain information from the program on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense.

(b) For the purposes of (a) above, a law enforcement official shall be considered authorized if he or she provides a court order based on probable cause, or a search warrant signed by a judge, which includes sufficient information to correctly identify the patient, prescriber, or dispenser whose prescription monitoring information is the subject of the court order.

(c) A law enforcement official shall present the court order or search warrant to the representative of the board designated by the board to receive such orders, who shall notify the program manager to provide the information identified in the court order in the format requested by the court order.

Source. #10526, eff 2-26-14; ss by #12465, eff 1-23-18

Ph 1505.04 Regulatory Board Access.

(a) New Hampshire regulatory boards, and equivalent out-of-state boards, may request and obtain information from the program, provided, however, that the request is pursuant to the regulatory board's official duties and responsibilities and the disclosures to each regulatory board relate only to its licensees and only with respect to those licensees whose prescribing or dispensing activities indicate possible fraudulent conduct.

(b) Requests in (a) above shall be in writing, signed by the regulatory board's executive director, investigator, or other person authorized to discharge equivalent functions of the regulatory board, and sent to the program manager via mail or electronically as an email attachment or facsimile.

(c) The address for the program shall be:

Pharmacy Board  
Program Manager  
Prescription Drug Monitoring Program  
121 South Fruit Street  
Concord New Hampshire 03301  
[nhpdp@nh.gov](mailto:nhpdp@nh.gov)  
(603) 271-2856 (fax)

Source. #10526, eff 2-26-14; ss by #12465, eff 1-23-18

Ph 1505.05 Other Access.

(a) Requests in (b) - (c) below shall be completed electronically via email or facsimile, or legibly in ink, signed by an authorized individual, and sent to the program manager at the address in Ph 1505.04(c).

(b) Out-of-state prescription drug monitoring programs may request and obtain information from the program on a case-by-case basis provided that an agreement is in place with the other state to ensure that the information is used and disseminated pursuant to the applicable requirements of the NH controlled drug prescription health and safety program.

(c) Entities that operate a secure interstate prescription drug data exchange system for the purpose of interoperability and the mutual secure exchange of information among prescription drug monitoring programs may request and obtain information from the program on a case-by-case basis provided that an

agreement is in place with the entity to ensure that the information is used or disseminated pursuant to the applicable requirements of the NH controlled drug prescription health and safety program.

(d) The office of the chief medical examiner may request and obtain information from the program on a case by case basis to determine the cause of death of an individual, provided the information is used or disseminated pursuant to the applicable requirements of the NH controlled drug prescription health and safety program.

(e) Requests in (d) above shall be made by submitting a board provided “NH Medical Examiner Office PDMP Data Request Form,” effective August 2016.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

PART Ph 1506 REVIEW AND REPORTING OF PRESCRIPTION DRUG MONITORING INFORMATION

Ph 1506.01 Review of Program Data.

(a) The program vendor shall collect and monitor all prescription drug monitoring information required by RSA 318-B:33, IV, and Ph 1504.01(b).

(b) The program vendor shall review and evaluate the collected information in order to identify behavior that suggests possible drug abuse, misuse, or diversion, or possible violations of law or breaches of professional standards.

(c) The program vendor shall consider, at a minimum, the following patient-related factors in its evaluation in (b) above:

- (1) Number of in-state prescribers;
- (2) Number of out-of-state prescribers;
- (3) Number of prescriptions;
- (4) Number of doses;
- (5) Overlapping prescriptions;
- (6) Unhealthy combinations of controlled substances;
- (7) Method of payment;
- (8) Number and frequency of pharmacies used; and
- (9) Dangerous levels of controlled substances.

(d) The program vendor shall consider, at a minimum, the following prescriber/dispenser-related factors in its evaluation in (b) above:

- (1) Number of prescriptions;
- (2) Number of doses;
- (3) Overlapping prescriptions;
- (4) Unhealthy combinations of controlled substances;

- (5) Number and frequency of pharmacies used;
- (6) Dangerous levels of controlled substances;
- (7) Electronic program access and use; and
- (8) For dispensers only, method of payment.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

Ph 1506.02 Reporting of Program Data.

(a) The program shall report to the appropriate regulatory boards identified in RSA 318-B:35, I(b)(2), relevant information to be used by the regulatory board for further investigation:

- (1) When there is cause to believe a potential violation of law or a breach of professional standards may have occurred; and
- (2) When there is cause to believe that a failure to report the dispensing of a schedule II–IV controlled substance conceals a potential pattern of diversion of controlled substances into illegal use.

(b) The program shall notify prescribers and dispensers:

- (1) When there is cause to believe a potential violation of law or a breach of professional standards may have occurred, unless such notice is likely to interfere with an investigation conducted by the regulatory board; and
- (2) When there is cause to believe a patient might be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances, including obtaining controlled substances from multiple practitioners or dispensers.

(c) The program vendor shall report to the board on at least a quarterly basis all the reports made in (a) and (b) above.

(d) The board may use and release information and reports from the program for program analysis and evaluation, statistical analysis, public research, public policy, and educational purposes, provided the data are aggregated or otherwise de-identified.

[Source.](#) #10526, eff 2-26-14; ss by #12465, eff 1-23-18

CHAPTER Ph 1600 PHARMACY INTERNS

PART Ph 1601 PURPOSE AND SCOPE

Ph 1601.01 Purpose and Scope. The provisions of this chapter shall apply to, and impose duties upon, all pharmacy interns holding registrations issued by the board.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

PART Ph 1602 DEFINITIONS

Ph 1602.01 Definitions. Except where the context makes another meaning manifest, the following definitions shall apply:



(a) “Registered pharmacy intern” means a person:

- (1) Who is enrolled in a professional degree program of a school or college of pharmacy that has been approved by the board and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;
- (2) Who is a graduate of an approved professional degree program of a school or college of pharmacy or is a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate, who is currently licensed by the board of pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;
- (3) Who is a qualified applicant awaiting examination for licensure or meeting board requirements for re-licensure; or
- (4) Who is participating in a residency or fellowship, except individuals that hold an active license to practice pharmacy in the State of New Hampshire.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

#### PART Ph 1603 IDENTIFICATION

Ph 1603.01 Identification. The pharmacy intern shall be so designated in his or her professional relationships, and shall in no manner falsely assume, directly or by inference, to be a pharmacist. The board shall issue to the pharmacy intern a registration for purposes of identification and verification of his or her role as a pharmacy intern, which registration shall be surrendered to the board upon discontinuance of pharmacy practice experiences for any reason including licensure as a pharmacist. Only individuals properly registered by the board as a pharmacy intern shall take, use, or exhibit the title of pharmacy intern, or any other term of similar like or import.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

#### PART Ph 1604 REGISTRATION

Ph 1604.01 Application.

(a) No person shall perform the functions or duties of a pharmacy intern unless such person is registered by the board.

(b) Application form “Pharmacy Intern Initial Registration Form” for registration of pharmacy interns in New Hampshire may be obtained from and shall be filed at the office of the board, identified in Ph 103.03.

(c) Each applicant shall provide the following on form PI-1:

- (1) Name, gender, current mailing address, and home telephone number;
- (2) Social security number, date of birth, and email address;
- (3) Name and address of the college or university where currently enrolled in, or graduated from, the pharmacy program;
- (4) Anticipated date of graduation from accredited pharmacy program;

- (5) Record of convictions of violations of federal, state, or local drug or pharmacy- related laws or regulations;
  - (6) An indication as to whether the applicant is or ever has been registered or licensed as a pharmacy intern in New Hampshire or any other state and, if so, an indication as to which state(s) and whether such registration or license is currently valid;
  - (7) An indication as to whether the applicant has ever voluntarily surrendered his or her pharmacy intern registration in this or any other state or jurisdiction and, if so, an explanation of such surrender; and
  - (8) Applicant's signature and date.
- (d) The applicant shall submit with application form PI-1, the prescribed fee of \$25.
- (e) An applicant for registration as a registered pharmacy intern shall meet the following requirements:
- (1) Be at least 18 years of age;
  - (2) Be enrolled in or possess a pharmacy degree from an accredited college or university pharmacy program;
  - (3) Be of good moral character, as demonstrated by the information provided by the applicant on the registration form and any attachments; and
  - (4) Has not been convicted of a felony or a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule, or regulation.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

## PART Ph 1605 REGISTRATIONS – CHANGES IN SUPPORTING DATA

### Ph 1605.01 Reporting Changes.

- (a) The person to whom a pharmacy intern registration has been issued shall notify the board within 15 days if a change of one or more of the following occur:
- (1) Name;
  - (2) Address;
  - (3) Transfer of enrollment from accredited college or university pharmacy program to another; or
  - (4) Permanent separation of enrollment from his or her accredited pharmacy program, not to include graduation.
- (b) The notice shall contain the following:
- (1) Name of the registrant;
  - (2) Address of the registrant including old and new, if applicable;
  - (3) Registrant's registration number;

- (4) Name of the school of pharmacy attending, including former and current, if applicable;
- (5) Graduation date or anticipated date of graduation from accredited pharmacy program;
- (6) Certification status, if applicable; and
- (7) All new violations of law, convictions, fines, discipline or any registration, certification or license revocations for violation of pharmacy-related drug laws or regulations in this or any other state.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

#### PART Ph 1606 PHARMACY INTERNS – STANDARDS OF PRACTICE

##### Ph 1606.01 Responsibilities and Duties.

(a) The pharmacist-in-charge shall identify pharmacy interns and assure that such persons are registered with the board as pharmacy interns prior to employment or experiential pharmacy rotation.

(b) All pharmacy interns shall wear a name tag, identifying them as a “Pharmacy Intern” while on duty.

(c) The pharmacist-in-charge shall determine the duties of each pharmacy intern based upon the needs of the pharmacy and experiential site.

(d) A pharmacy intern shall be allowed to engage in all activities in the practice of pharmacy provided that such activities are under the supervision of a pharmacist with the one exception of product verification.

(e) A pharmacist shall be in contact with, and actually giving instructions to, the pharmacy intern during all professional activities.

(f) Only pharmacy interns in their last professional year or graduates of an approved professional degree program of a school or college of pharmacy or graduates of an approved professional degree program of a school or college of pharmacy or graduates who have established educational equivalency by obtaining a Foreign Graduate Examination Committee (FPGEC) certificate may perform product verification. Direct supervision shall not be required for product verification.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

#### PART Ph 1607 REVOCATION AND DENIAL

##### Ph 1607.01 Effect of Revocation and Denial.

(a) The board shall refuse to issue a registration, or after notice and hearing, shall revoke a registration whenever the board finds by the preponderance of the evidence any of the following:

- (1) That the applicant, or registrant, has willfully violated any of the provisions of RSA 318 or Ph 1600;
- (2) That the applicant has been convicted of a felony or a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule, or regulation;

(3) That the applicant has attempted to obtain a pharmacy intern registration by fraudulent means;

(4) That the applicant is unable to engage in the performance of pharmacy intern functions with reasonable skill and safety by reason of illness, inebriation, misuse of drugs, narcotics, alcohol, chemicals or any other substance, or as a result of any mental or physical condition;

(5) The suspension, revocation, or probation by another state of the applicant's license, permit, or registration to practice as a pharmacy intern;

(6) That the applicant refused to appear before the board after having been ordered to do so in writing; or

(7) That the applicant made any fraudulent or untrue statement to the board.

(b) The pharmacist-in-charge or other staff pharmacist shall notify the board, in writing, within 7 calendar days after becoming aware that a pharmacy intern has adulterated, abused, stolen, or diverted drugs.

(c) The board shall reinstate a registration after review, provided that the reason for revocation no longer exists, or it is determined that there is no longer a threat to public safety.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

#### PART Ph 1608 RENEWAL OF REGISTRATIONS

Ph 1608.01 Renewal Registrations Required. All pharmacy intern registrations shall expire annually on September 30.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

Ph 1608.02 Renewal Application Where Obtained and Filed. Applications for the renewal of a registration for a pharmacy intern shall be filed online at <https://nhlicenses.nh.gov/eGov/Login.aspx>.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-

18

Ph 1608.03 Renewal Application Contents and When Filed. Renewal applications shall be filed with the board in accordance with the following:

(a) Applications for renewal of pharmacy intern registration shall be made online at <https://nhlicenses.nh.gov/eGov/Login.aspx>.

(b) Each applicant shall provide the following information online as part of his or her renewal:

(1) Original registration number;

(2) Name, current mailing address, and home telephone number;

(3) Social security number, date of birth, and email address;

(4) Name and address of the college or university where currently enrolled in, or graduated from, the pharmacy program;

- (5) Date or anticipated date of graduation from accredited pharmacy program;
  - (6) Record of convictions of violations of federal, state, or local drug or pharmacy-related laws or regulations;
  - (7) Applicant's signature and date; and
  - (8) Employment name, address, phone number, and the name of the supervisor and pharmacist-in-charge;
- (c) The application and the prescribed fee of \$25 shall be filed with the board no later than September 30.

[Source.](#) #10721, eff 11-22-14; ss by #12670, eff 11-17-18

Ph 1608.04 Reinstatement.

(a) A registered intern's failure to renew his or her registration by September 30 shall result in a lapsed registration.

(b) Any intern that wishes to reinstate a lapsed license shall do so by completing and submitting an "Intern Reinstatement Application", effective October 2018 and available on the board's website at [www.oplc.nh.gov/pharmacy](http://www.oplc.nh.gov/pharmacy).

(c) A reinstatement applicant shall also submit a dated and signed letter explaining why he or she allowed his or her registration to lapse and an indication as to whether he or she practiced as a pharmacy intern with a lapsed registration.

[Source.](#) #12670, eff 11-17-18

CHAPTER Ph 1700 CONTINUOUS QUALITY IMPROVEMENT

PART Ph 1701 PURPOSE AND SCOPE

Ph 1701.01 Purpose. The purpose of this chapter is to require that a pharmacy permit holder establish and manage a continuous quality improvement program in each pharmacy licensed by the permit holder. Said continuous quality improvement program is to assess errors that occur during the review, preparation, dispensing or administration of medications by pharmacy staff, and to ensure appropriate action is taken to prevent or reduce the likelihood of a recurrence of identified errors. Programs established pursuant to this section are for public safety, and shall be non-punitive and seek to identify improvements that can be made in processes, systems, technology, or training in order to make appropriate changes to improve them.

[Source.](#) #12758, eff 4-19-19

Ph 1701.02 Scope. This chapter shall apply to all pharmacies licensed by the board of pharmacy.

[Source.](#) #12758, eff 4-19-19

PART Ph 1702 DEFINITIONS

Ph 1702.01 Definitions. In this section the following definitions apply:

(a) "Continuous quality improvement (CQI)" means a system of standards and procedures to identify and evaluate quality-related events to improve patient care;

(b) “Continuous quality improvement (CQI) program” means a planned process to record and assess quality related events that includes a procedure for documenting actions to improve the quality of patient care, and maintenance of a summary of the documented actions;

(c) “Quality-related event” means an error, adverse incident, near miss, or unsafe condition that occurs in the review, preparation, dispensing or administration of medications by pharmacy staff; and

(d) “Patient Safety Organization” means an entity that has the same meaning as the term used in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C section 299b-21(7), a private or public entity or component thereof that is listed by the Secretary of Health and Human Services pursuant to 42 U.S.C. section 299b-24(d).

[Source.](#) #12758, eff 4-19-19

## PART Ph 1703 PROGRAM REQUIREMENTS

### Ph 1703.01 General Requirements

(a) A pharmacy shall either submit quality-related events to a patient safety organization (PSO) or shall create and maintain an internal program that captures and analyzes quality-related events that comply with this chapter.

(b) Licensed pharmacies shall ensure that all reasonably necessary steps have been taken to prevent or minimize patient harm following any quality-related event that reaches a patient.

(c) The permit holder of the pharmacy shall maintain within the pharmacy a current written policy and procedures manual that clearly states the organization philosophy and goals for a continuous quality improvement (CQI) program, delineate the parameters in which the organization interacts with its employees related to such a program, and provides a sound framework for operating and maintaining such a program.

(d) Said current policy and procedures manual shall include at least the following:

- (1) Purpose of the program;
- (2) Definitions used in the program;
- (3) Policy on how to report a quality-related event;
- (4) Policy for program meetings including frequency of meetings, staff to attend, and involvement of either the pharmacist-in-charge or consultant pharmacist;
- (5) Policy for maintaining program integrity and confidentiality of information;
- (6) Policy for staff education and ongoing training of employees related to CQI program;
- (7) Policy for employee engagement and communication of changes made related to the program; and
- (8) Policy for maintaining summarization documents for board inspection.

[Source.](#) #12758, eff 4-19-19

## PART Ph 1704 CONFIDENTIALITY OF QUALITY-RELATED EVENT REPORTS

## ***NH Pharmacy Laws & Rules as of 10/29/2019***

Ph 1704.01 Availability of Quality-Related Event Reports. All quality-related events and quality-related reports that are reported to a PSO shall be deemed by the board to be confidential and privileged patient safety work product under the Patient Safety and Quality Improvement Act of 2005 and shall not be required to be made available for inspection by or reported to the board. Quality-related events and quality-related event reports that are not reported to a PSO shall be considered confidential peer review documents not subject to discovery in civil litigation or administrative actions.

[Source.](#) #12758, eff 4-19-19

### **PART Ph 1705 CONTINUOUS QUALITY IMPROVEMENT MEETINGS**

Ph 1705.01 Requirements for Continuous Quality Improvement Meetings.

(a) A pharmacy shall hold a continuous quality improvement (CQI) meeting at least once every 3 months.

(b) The pharmacist-in-charge or consultant pharmacist for the licensed pharmacy, or their designee, shall attend each meeting.

[Source.](#) #12758, eff 4-19-19

### **PART Ph 1706 SUMMARIZATION DOCUMENT**

Ph 1706.01 Requirements for the Summarization Document.

(a) A summarization document shall be created after each CQI meeting and shall be retained onsite within the licensed pharmacy for a minimum of 4 years and made available within 3 business days upon request by the board.

(b) The summarization document shall not contain identifiable patient information, or information that would identify individuals involved in a quality-related event, or any information that can be used to identify the quality-related event.

(c) The summarization document shall include, at a minimum, the following information:

(1) A list of all individuals in attendance at the meeting; and

(2) A summary of steps or actions taken since the last meeting intended to improve processes, systems, technology or training related to the review, preparation, dispensing, or administration of medications.

[Source.](#) #12758, eff 4-19-19

### **PART Ph 1800 - 1900 – RESERVED**

## **CHAPTER Ph 2000 LICENSING OF OUTSOURCING FACILITIES IDENTIFIED AS 503B FACILITIES BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

### **PART Ph 2001 PURPOSE AND SCOPE**

Ph 2001 Purpose. The purpose of these provisions is to regulate the licensing of outsourcing facilities, as defined and registered by the Food and Drug Administration pursuant to section 503B of the Federal Food, Drug and Cosmetic Act, codified as 21 USC 353b.

[Source.](#) #12336, eff 7-22-17

PART Ph 2002 DEFINITIONS

Ph 2002.01 Statutory Definitions Adopted. All terms used in these rules shall have the same meaning as in RSA 318:1, RSA 318-B:1, and RSA 541-A:1.

Source. #12336, eff 7-22-17

Ph 2002.02 Other Definitions.

(a) “Outsourcing facility” means “outsourcing facility” as defined in RSA 318:1, XXX, namely, “a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility, and complies with all of the requirements of section 503B of the Federal Food, Drug, and Cosmetic Act.”

Source. #12336, eff 7-22-17

PART Ph 2003 STANDARDS OF PRACTICE FOR OUTSOURCING FACILITIES

Ph 2003.01 Standards of Practice and Requirements for Outsourcing Facilities.

(a) Outsourcing facilities shall maintain a human drug compounding outsourcing facility registration from the United States Food and Drug Administration (FDA) when compounding or manufacturing drugs for sale in New Hampshire.

(b) Outsourcing facilities shall be in compliance with applicable United States Drug Enforcement Administration (DEA) regulations.

(c) Outsourcing facilities shall be required to test all lots or batches of finished drug products compounded from bulk active pharmaceutical ingredients (API) to determine whether they meet final product specifications for sterility, endotoxin, and potency before their release for distribution. No products shall be released for use until this testing is conducted and the results confirm that the finished drug product meets specifications. Copies of the test results shall be readily available and included with each batch sent to New Hampshire customers and available for inspection by the pharmacy board.

(d) Outsourcing facilities compounding drug products from sterile, commercially available raw materials shall be required to test all lots or batches of finished drug products to determine whether they meet final product specifications for sterility, endotoxin, and potency before their release for distribution. No products shall be released for use until this testing is conducted and the results confirm that the finished drug product meets specifications. Copies of the test results shall be readily available for each batch sent to New Hampshire customers and available for inspection.

(e) All facilities at which sterile drugs are compounded shall provide storage areas that ensure adequate lighting, ventilation, temperature, sanitation, humidity, equipment, and security conditions. All sterile compounded products shall be stored at appropriate temperatures per label requirements or in compliance with the latest edition of the official United States Pharmacopeia (USP) compendium requirements to help ensure that the identity, strength, quality, and purity of the products are not affected. If no temperature requirements are listed, compounded products may be stored at room temperature. A separate storage section shall be provided for compounded products that are deteriorated, outdated, misbranded, or otherwise adulterated.

(f) All buildings at which sterile drugs are compounded shall be of a size, construction, and location that facilitates cleaning and maintenance. The 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.



(g) Each outsourcing facility 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 to a 24-hour control station operated by the outsourcing facility.

(h) Outsourcing facilities 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 that deters unauthorized entry into the premises.

(i) Internal security policies shall be developed by the outsourcing facility to provide protection against theft by personnel.

(j) No outsourcing facility shall distribute sterile compounded drugs directly to a consumer or a patient, or operate in such a manner as to endanger the public health.

(k) Any person who compounds sterile drugs in violation of RSA 318:51-d or the provisions of Ph 2000 shall be subject to disciplinary action as provided in RSA 318:29.

[Source.](#) #12336, eff 7-22-17

Ph 2003.02 License Required.

(a) No person shall compound legend drugs or controlled drugs, as defined in RSA 318-B:1, VI, and no person acting as or employed by an outsourcing facility shall supply such drugs, without first having obtained a license from the board. No license shall be issued or renewed for an outsourcing facility unless the same shall be operated in a manner prescribed by law and according to Ph 2000. The license shall expire annually on June 30. The license shall not be transferable.

(b) Separate licenses shall be required for each compounding site owned or operated by an outsourcing facility. Provided, however, that an agent or employee of any licensed outsourcing facility shall not be required to be licensed under this section and may lawfully possess sterile compounded products if he is acting in the usual course of his business or employment.

(c) The board shall provide, on an annual basis, a license renewal form to all licensed outsourcing facilities.

(d) The prescribed fee for original and annual renewal licenses for outsourcing facilities shall be \$250.00.

[Source.](#) #12336, eff 7-22-17

Ph 2003.03 Obtaining and Filing a License Application.

(a) An “Application for Permit – Bulk Sterile & Non-Sterile Compounders (Including FDA Registered 503B Outsourcing Facilities)”, form Ph OF-1, revised June 2017, for a permit to license FDA registered 503B outsourcing facilities in New Hampshire may be obtained from the board or board website;

(b) Form Ph OF-1 shall be used for:

- (1) Applying for a permit to license a 503B outsourcing facility;
- (2) Changing the location of a currently licensed 503B outsourcing facility; and
- (3) Changing the ownership of a currently licensed 503B outsourcing facility.

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(c) Form Ph OF-1 shall be filed at the board office as identified in Ph 103.03.

[Source.](#) #12336, eff 7-22-17

Ph 2003.04 Application Contents.

(a) The applicant for a license to operate an outsourcing facility in New Hampshire shall complete and file the form described in Ph 2003.03.

(b) The applicant shall indicate his or her title, and sign and date the application form under the following affirmation:

“I affirm that I am the person authorized to sign this application for licensure and affirm that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State. I understand that as an outsource facility I am required to comply with current Good Manufacturing Practice (cGMP) standards. I have read and understand the testing requirements required for shipping compounded products into New Hampshire.”

(c) The applicant shall submit the following documents with the application form:

- (1) If shipping controlled drugs, a copy of the facility’s current DEA registration;
- (2) If licensed by the applicant’s home state, a copy of the current license; and
- (3) If applicable, a copy of the most recent inspection report from the applicant’s home state; and
- (4) If applicable, a copy of:
  - a. The most recent FDA inspection report;
  - b. The FDA issued Form 483; and
  - c. The applicant’s response to the Form 483.

(d) The applicant shall submit scale drawings of the facility, detailing usage of all space.

(e) The applicant shall supplement the application with any certificates, affidavits, plans, documents, or other information sufficient to show full compliance with all of the requirements for licensure.

(f) If the applicant is a corporation, or if the outsourcing facility will be operated under a corporate name, the applicant shall submit a certificate from the secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the State of New Hampshire under the corporate name.

(g) The application shall be filed with the prescribed fee of \$250.00.

[Source.](#) #12336, eff 7-22-17

Ph 2003.05 Additional Requirements. In addition to the requirements imposed by Ph 2003.04, an applicant for an outsourcing facility license shall demonstrate that he or she is of good moral character or, if the applicant is an association or corporation, that the managing officers are of good moral character, as

evidenced by the absence, within the last 5 years, of conviction of any felony, or of a misdemeanor resulting from a violation of any drug related law of the United States or of any state.

[Source.](#) #12336, eff 7-22-17

Ph 2003.06 Issuance, Denial and Revocation of License.

(a) If an applicant files an application, complete in all respects and demonstrates fulfillment of all requirements of these rules and RSA 318, the board shall issue a license which shall authorize the operation of an outsourcing facility in the location, and only under the name specified in the license.

(b) After consideration of the application, the board shall notify the applicant in writing of all deficiencies in the application which, in the absence of correction, shall result in the denial of the application. The applicant shall, within 20 days of the date of the notice of deficiency, deliver to the board either documents evidencing the correction of those deficiencies, or a written request for an appeal before the board. In the absence of a timely filing of either documentation or a request for an appeal, the application shall, without further action or notice by the board, be denied effective as of the expiration of 20 days after the date of the notification of deficiency.

(c) The revocation of an outsourcing facility license shall permanently withdraw the authority to supply compounded sterile products in New Hampshire unless a subsequent license is issued pursuant to (d) below.

(d) A subsequent license may be obtained only by:

- (1) Complying with all the requirements of RSA 318 and these rules regarding the original licensing of outsourcing facilities;
- (2) Paying all penalties assessed in connection with the cause for revocation; and
- (3) By demonstrating that the cause for revocation does not exist at the time of the subsequent application.

[Source.](#) #12336, eff 7-22-17

PART Ph 2004 NOTIFICATION REQUIREMENTS

Ph 2004.01 Reporting Changes. The person to whom a license to operate a 503B outsourcing facility has been issued in New Hampshire shall, within 30 days of that person's discovery of a change in any of the data contained in the application for an original or renewal permit, report that change to the board in writing. An original new permit application, "Application for Permit – Bulk Sterile & Non-Sterile Compounding (Including FDA Registered 503B Outsourcing Facilities)", form Ph OF-1, revised June 2017, shall be completed and filed in addition to the written notice when the name, location, ownership, or licensed area are changed.

[Source.](#) #12336, eff 7-22-17

Ph 2004.02 Notice of Disciplinary Action. An outsourcing facility 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 and provide a copy of the action to the board office, identified in Ph 103.03.

[Source.](#) #12336, eff 7-22-17

PART Ph 2005 RENEWAL LICENSES

***NH Pharmacy Laws & Rules as of 10/29/2019***

Ph 2005.01 Renewal Permits Required. The person to whom a license to operate a 503B outsourcing facility has been issued shall renew that license by June 30<sup>th</sup> of each year.

Source. #12336, eff 7-22-17

Ph 2005.02 Renewal Application Where Obtained and Filed.

(a) Applications for the renewal of a license to operate a 503B outsourcing facility, “Renewal – Bulk Sterile & Non-Sterile Compounders (Including FDA Registered 503B Outsourcing Facilities)”, form Ph OF-2, revised June 2017, may be obtained from the board’s website at [www.oplc.nh.gov/pharmacy](http://www.oplc.nh.gov/pharmacy), and shall be filed at, the board office.

(b) The applicant shall indicate his or her title, and sign and date the application form under the following affirmation:

“I affirm that I am the person authorized to sign this application for licensure and affirm that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State. I understand that as an outsource facility I am required to comply with current Good Manufacturing Practice (cGMP) standards. I have read and understand the testing requirements required for shipping compounded products into New Hampshire.”

(c) The applicant shall submit the following documents with the application form:

- (1) If shipping controlled drugs, a copy of the facility’s current DEA registration;
- (2) If licensed by the applicant’s home state, a copy of the current license; and
- (3) If applicable, a copy of the most recent inspection report from the applicant’s home state; and
- (4) If applicable, a copy of:
  - a. The most recent FDA inspection report;
  - b. The FDA issued Form 483; and
  - c. The applicant’s response to the Form 483.

Source. #12336, eff 7-22-17

Ph 2005.03 Renewal Application Contents and When Filed.

(a) Applications for renewal of a license to operate a 503B outsourcing facility shall consist of a completed application form as described in Ph 2005.02 and the prescribed fee of \$250.

(b) Renewal applications as required pursuant to Ph 2005.01 shall be submitted to the board office identified in Ph 103.03 no later than the 15th day of June of each year.

Source. #12336, eff 7-22-17

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Ph 2005.04 Renewal Application Deficiencies. The board shall notify the applicant in writing as to whom the application for renewal is deficient. The applicant may, within 10 days after the date of the notice of deficiency, correct the deficiency or file with the board a written request for an appeal.

[Source.](#) #12336, eff 7-22-17

Ph 2005.05 Issuance and Denial of Renewal License.

(a) If an applicant shall timely file an application, complete in all respects, that demonstrates the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal permit.

(b) An application which continues to fail to meet the requirements of these rules and RSA 318 shall, after the notice and opportunity for a hearing, be denied.

[Source.](#) #12336, eff 7-22-17

### PART Ph 2006 POLICIES, PROCEDURES AND RECORDKEEPING

Ph 2006.01 Written Policies and Procedures.

(a) Written policies and procedures shall be developed by management personnel to assure that the outsourcing facility prepares for, protects against, and handles crises 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 outsourcing facility's view, does not allow sufficient time for repacking or resale, shall be prepared for return to the outsourcing facility or otherwise destroyed; and

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

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

[Source.](#) #12336, eff 7-22-17

Ph 2006.02 Responsibility for Operation. An outsourcing facility shall maintain a list of principals and persons in charge including officers, directors, or primary stockholders and their qualifications.

[Source.](#) #12336, eff 7-22-17

Ph 2006.03 Returned Goods. An outsourcing facility shall maintain a procedure for the handling and disposal of returned goods.

[Source.](#) #12336, eff 7-22-17

Ph 2006.04 Handling Recalls.

(a) An outsourcing facility 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 compounded sterile products due to:

- (1) A voluntary action on the part of the compounder;
- (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 design.

[Source.](#) #12336, eff 7-22-17

Ph 2006.05 Recordkeeping.

(a) The requirements of Ph 2006.05 shall be in addition to all record keeping and reporting requirements contained in all federal regulations and state rules.

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

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

[Source.](#) #12336, eff 7-22-17

Ph 2006.06 Inspections.

(a) Outsourcing facilities shall be subject to inspections by the FDA on a risk-based schedule.

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

[Source.](#) #12336, eff 7-22-17

PART Ph 2007 DISPENSING AND DISTRIBUTION REQUIREMENTS

Ph 2007.01 Dispensing and Distribution Requirements. Compounded sterile drugs shall be dispensed in accordance with Ph 704.

[Source.](#) #12336, eff 7-22-17

PART Ph 2008 LEGAL REQUIREMENTS

Ph 2008.01 Compliance with State and Federal Law.

(a) All outsourcing facilities licensed under this chapter shall comply with all applicable state and federal laws, rules, and regulations.

(b) All outsourcing facilities licensed and doing business in New Hampshire, shall, before shipping or distributing any compounded sterile drugs, verify that the recipient is properly licensed to receive and possess such drugs.

(c) All outsourcing facilities licensed and doing business in New Hampshire shall not provide unsolicited compounded sterile drug samples to licensed practitioners.

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(d) Except as provided in (c) above, a duly authorized agent of an outsourcing facility licensed and doing business in New Hampshire, may possess and distribute compounded sterile drugs to individuals who may lawfully possess such drugs as may be necessary to further the licensed activity of the outsourcing facility.

[Source.](#) #12336, eff 7-22-17