

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, *or device* 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) "scanned prescription" means the digital attachment of the exact visual image of a prescription or medication order document to the electronic documentation into the automated data processing system.

(i) ~~(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 including but not limited to Assisted, Group and Memory Care;
- (5) Infirmaries;
- (6) Correctional facilities; and
- (7) Clinics.

(8) Hospice Facilities

(j) ~~(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.

(k) ~~(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.

(l) ~~(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.

(m) ~~(l)~~ "Prescriber" means a practitioner, duly authorized by statute, who issues a drug order or prescription.

(n) ~~(m)~~ "Principal" means an officer, director, or primary stockholder of a business entity or corporation.

(o) ~~(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, pharmacy, or any other profession in which individual practitioners can lawfully possess, dispense, or distribute prescription drugs.

(p) ~~(o)~~ "Signature" means:

- (1) The handwritten name of an individual affixed by the hand of that individual to a document;

Comment [WT1]:
Research with DHHS, they license this group.

Comment [WT2]:
"publication of the board" - doesn't make sense, maybe "publication of the Board of Pharmacy Laws and Administrative Rules to include RSA 318, RSA 318-B and Ph100 - Ph 2000 and any future chapters."

(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.

(g)(+) "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.

(r)(+) "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.

(s)(+) "Unprofessional conduct" means conduct and practices which are hostile to the protection of public health, safety and welfare and includes *but not limited to*:

- (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.

(t)(+) "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.

(u)(+) "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.

(v) "Original Prescription" means

(w) "Electronic Script" means

(x) "Prescription" means

(y) "Authorized Agent" means

(z) "Consultant Pharmacist" means

(aa) "Administration" means

(bb) "Administer" means

Comment [WT3]:

Bob Stout will review and get back to us at the next meeting.

Comment [WT4]:

Do we need check with Karla to be certain this definition matches up with her definition and rules defining this license type?

~~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 (e) 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;
- (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.

(4) Private enclosed consultation room of adequate size and design to ensure patient confidentiality.

Comment [WT5]:
Tabled to a later date, to include "Sound Proof" And it will be "c"

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

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 is equipped with an alarm system which, when activated, shall emit a signal which is capable of alerting law enforcement or designated pharmacist or corporate representatives.

~~(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~~

~~(1)(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.

~~(2) be connected to a monitoring service with means of alerting both law enforcement, and Pharmacist on call or corporate representative.~~

~~(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 ~~physically~~ *physically* is on duty. At all times during which a pharmacist is not ~~physically~~ *physically* 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;~~

~~(5)(4) Qualified security personnel as shall be designated by the pharmacist in charge and permit holder 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.

(d) The pharmacy permit shall be issued to the pharmacy in the name of the permit holder and pharmacist-in-charge, who shall have ~~sole~~ joint control and responsibility, and accountability 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;

Comment [WT6]:
Move to Ph 1900
And keep the added in wording.

(4) A current reference library, or the ability to access references online, ~~as determined by the permit holder and 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 online within the licensed area the New Hampshire Pharmacy Law Book.

~~(6) High speed access to the internet with the ability for the Pharmacist to access sites they deem necessary, as well as access to internal and external email capabilities.~~

~~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.

~~(d) All pharmacies shall keep a readily retrievable record of prescription errors available upon Board inspection or request.~~

~~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;
- (9) Identifier of the packer; 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. And 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 within one business day.

(b) The pharmacist who discovered the loss shall complete a New Hampshire Drug Loss Form (revised 2/2018) 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.

Comment [WT7]:

Research with DHHS as it has defined "reportable condition"

Lindsey to talk to the Board; does the Board want to know if it is a suspected loss? Or do they want to know if it is a confirmed loss only.

Has the date of the form revised been changed (check with Jason re: 5/2015)

Bring this section to the Board and then bring back to the stakeholders to discuss.

(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 readily available upon inspection or board request.

(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.

(f) If a pharmacy reports more than 3 unrelated controlled substance loss reports on 3 separate occasions, in 12 consecutive months, then that pharmacy needs to institute the following steps:

1. Monthly cycle counts on all controlled substances (II-V),
2. All controlled substances (II-V) need to maintain a perpetual inventory,
3. All controlled substances (II-V) need to be locked,
4. A camera on the controlled substance storage areas must be installed and in working order,
5. Mandatory back sounds on all schedule II control substances,
6. Two person manual counts or one machine and one manual count on all controlled substances for prescription dispensing; and
7. This process will remain in place until there have been no controlled substance loss in 24 consecutive months.

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~~ shall be readily retrievable in an electronic format or hard-copy printout.

(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

(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 electronic format, hard-copy printout or log book referenced in (g) above shall be kept accessible within 48 hours and maintained 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;

~~(i)(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 ~~or scanned, prescription or medication order~~ 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~~

~~(j)(4)~~ Computer-produced prescription container labels shall comply with RSA 318:47-a, RSA 318:47-b and RSA 318-B: 13, II.

Comment [WT8]:
Bob Stout to review and bring back to the next meeting.

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.

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 Inspections Report. The current compliance inspection report of the licensed location, conducted by the board, shall be kept on file in the prescription department.~~

- a. Registrant and licensees shall permit the Board investigators, Board inspectors and Board Commissioners to enter and inspect the premises and audit the records and operations of each registrant or licensee for compliance with the statutes and rules enforced by or under the Boards jurisdiction.
- b. Inspections shall be scheduled or unannounced in nature to the extent authorized by law, and upon presentation of appropriate identification.
- c. Inspections shall be for the following registrants licensee's as follows:
 - (1) Retail pharmacies- annually or based on risk assessment
 - (2) Institution pharmacies (hospitals, stand-alone emergency departments and long term care facilities) –annually
 - (3) Compounding pharmacies –annually
 - (4) Public Health and Methadone Clinics- annually
 - (5) Practitioner/Clinic inspections – every 5 years
 - (6) Veterinarians/veterinary clinics- every 3 years
 - (7) Manufacturer/Wholesaler- every 3 years
 - (8) Limited Retail Drug Distributor- every 3 years
 - (9) Naturopaths – every 3 years
- d. The following facilities possessing control substances shall be inspected every two years:
 - (1) Practitioner/Clinics
 - (2) Veterinarians/veterinary clinics
 - (3) Naturopaths
- e. Practitioner/Clinics/veterinarians/veterinary clinics/Naturopaths and non-institutional pharmacies involved in sterile and non-sterile compounding shall be considered as high risk inspections.
- f. A self-inspection shall be required after a change in Pharmacist in Charge within three days after board approval.
 - (1) A copy of the completed form ph538 shall be mailed to Board upon completion.
 - (2) Original form shall be filed and be readily available upon inspection.
- g. All retail pharmacies will be mailed a pre-inspection form ph505 that shall be completed by the Pharmacist In Charge and available upon inspection. Pre-inspection forms will be mailed to the pharmacy 1 to 3 months prior to inspection.
- h. All facilities shall have an addendum of current staff and licensure readily retrievable upon Board request with the following information:
 - (1) Staff name and license numbers
 - (2) Pharmacist vaccination training information
 - (3) Technician training information
 - (4) Collaborative practice agreement and training information
 - (5) Quality Assurance information
- i. Pharmacy inspections shall be done based on level of risk as assigned by the Board.

(1) Low risk inspections

- (a) Retail pharmacies with a proven record of compliance for period of three years.
- (b) Low to medium prescription volume.
- (c) Pharmacist in charge competency and stability of 2 years at site.
- (d) Physical Inspections will alternate with self-inspections bi-annually.

(2) Medium risk inspections.

- (a) Institutions not involved in sterile or non-sterile compounding.
- (b) In-patient institutions involved in sterile or non-sterile compounding as defined by USP 797.
 - (1). Self-inspection shall include a submission of environmental monitoring reports, if applicable, for board review.
- (c) High volume pharmacies with pharmacist in charge competency and stability of two years at site as identified by compliance.
- (d) Pharmacies with multiple minor violations or warnings
- (e) Non-Sterile compounding pharmacies
- (f) Inspections will occur annually with a 6 month self-inspection to be kept on file in readily retrievable format for Board review.

(3) High risk inspections.

- (a) Outpatient Pharmacies involved in sterile and complex nonsterile compounding as defined by USP 797.
- (b) Retail pharmacies with previous record of non-compliance with Board rules or state and federal laws.
 - a. Previous cases of drug diversion
 - b. Repeat disciplinary issues involving pharmacy staff or permit holder over a three year period.
- (c) Inspections will occur twice a year with two inspectors if required.
- (d) Pharmacies involved in sterile and complex nonsterile compounding shall provide a bi-annual submission of environmental monitoring reports for board review.

j. Annual and bi-annual Self-inspection and audit forms ph506 shall be mailed to Board office within 3 days of receipt.

- (1) Pharmacist in charge self inspection forms shall be kept on file in the pharmacy in readily retrievable form for board review and upon inspection.

k. The Board shall audit all permit holders and pharmacies.

- (1) Audit shall be conducted by pharmacist on duty.
- (2) Audits may be followed by up physical inspection.
- (3) Audits may be specific to individual issue or medication.
- (4) Audits will occur quarterly with 10% of previous quarters physical inspections.

Ph703.07 Inspection reports

⊕ Inspections shall include all aspects of pharmacy practice and all prescription and medication files requested by investigator/inspector shall be available on demand.

- b. Inspections shall include a New Hampshire Prescription Drug Monitoring Program Compliance Report Card for the respective pharmacy.
- e. Inspection reports results shall be Verbal Warning, Violation, Satisfactory or Unsatisfactory.
- e. Inspections shall be reviewed with the compliance investigator/inspector and signed by the pharmacist on duty at completion of inspection.
- e. A copy shall be provided to licensee or registrant and shall be retained and available in readily retrievable manner.
- f. If an unsatisfactory result on inspection occurs the pharmacist-in-charge shall be required to do the following:
 - (1) Immediately fix the issues noted by the investigator/inspector and respond in writing to the board within 10 days with detailed response.
 - (2) Schedule an immediate follow up inspection with Board compliance.
- g. Inspection that results in a major violation shall be noted on report for board review and follow up inspection within two months of notice.
- h. The current compliance inspection report of the licensed location, conducted by the board, shall be kept on file in the prescription department per Ph703.06.
- i. Inspection reports shall be stored in appropriate licensing data base in files of permit holder and pharmacist-in-charge.

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 determined by the pharmacist in charge, permit holder and based on the needs of the pharmacist, 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;

Comment [WT9]:
This whole section will move to the Inspection section.

Comment [WT10]:
Move to Ph 1900
Not sure if the whole chapter, or

(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 *to the patient* 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~~

a. all transactions shall be noted in a log book and initialed by the pharmacist upon returning from break. The log book shall be available upon board inspection or request.

(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.

~~(b)(4)~~ **A** While on break the 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. **Following all laws and regulations for proper prescription dispensing.** 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.

(c)(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.~~

Ph 704.02 PRESCRIPTIONS

(a) 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;

(b) A facsimile prescription for a schedule II controlled substance shall not be accepted as an original written prescription except in circumstances when:

1. 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 ~~or issued to be filled for to~~ a patient in a private residence, long-term care facility, or hospice setting, by parenteral, intravenous, intramuscular, subcutaneous, oral administration or intraspinal infusion may be electronically transmitted, by the practitioner or the practitioner's designated agent to the dispensing pharmacy. ~~For a patient enrolled in a hospice care program, 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;

2. 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

3. 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,

(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, 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.

Comment [WT11]:

Lindsay:
This is the section I have marked that everyone take it and re-write it and bring back to the next meeting. However when I was reviewing the rules I took notes on and Mike's notes, he has to move to Ph 300 - the whole section. ** I have that we could have tried to combine b and c but since its in the CFR it has to stay as is mainly...so why take the time to fuss with it. I put it back to the original wording. I agree it should be moved out of this section.

Comment [12]:

Mike has this one moving to Ph 700's

Comment [13]:

Mike has this one deleted.

Comment [WT14]:

Move to Ph 300

(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) Unless a generic substitution or actions within a collaborative practice agreement, a prescription order must not give the pharmacist authority to change, alter, or manipulate the order without first contacting the prescriber, subsequent to the communication the pharmacist must document the change and who authorized it.~~

(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 ~~or issued to be filled for~~ to a patient in a private residence, long-term care facility, or hospice setting, by parenteral, intravenous, intramuscular, subcutaneous, oral administration or intraspinal infusion may be electronically transmitted, by the practitioner or the practitioner's designated agent to the dispensing pharmacy. For a patient enrolled in a hospice care program, 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

Comment [WT15]:

Lindsey to research and bring back to the next meeting.

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~~

~~e. 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, ~~or a pharmacist and Intern;~~
- (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:

Comment [WT16]:

The group will take this section and attempt a re-write to get the proper wording and meaning.

Comment [WT17]:

Lindsey: I think we need to double check in the new Ph 800 rules.

- (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 full name of the ~~pharmacist~~ agent receiving the prescription information.
- (d) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.
- (e) The ~~pharmacist~~ receiving agent of the transferred prescription information shall:
- (1) ~~Include the word "transfer" on the face of the transferred prescription~~ Indicate in the computer record that the prescription is a transfer; 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.
- (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. Transfer of controlled drugs as in accordance with the DEA guidelines.

Comment [WT18]:

Someone to research the DEA

~~(k) New or on hold prescription orders for controlled substances shall not be transferred to another pharmacy. new or on hold prescription orders for electronic prescriptions for controlled substances (EPCS) may transfer an original unfilled prescription from hold.~~

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.

Comment [WT19]:

Move to Ph 300

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.

Comment [WT20]:

Move the whole section of Ph 704.06 and Ph 704.07 to Ph 300's and add in Bio Similar Language

(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 or payor is less than the price of the prescribed drug product.

(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.~~

(f) unless a generic substitution or actions within a collaborative practice or standing order agreement, a prescription cannot give the pharmacist authority to change, alter, or manipulate the order without first contacting the prescriber; subsequent to the communication the pharmacist must document the change and who authorized it.

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.

Comment [WT21]:
Move to Ph 300's

(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

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.

1. A photo ID shall be obtained and documented, either on the hard copy or in the patients record, for all schedule II medications. If the prescription is in electronic format, an ID is only required by the individual picking up the medication. If the prescription is presented as a hard copy, in addition, a photo ID shall be obtained and documented at the time the prescription is dropped off.

2. All schedule medications picked up by an individual other than the patient, a photo ID shall be obtained and documented either on the hard copy or in the patients record.

1. ~~All schedule medications dropped off for a patient for whom a prescription was written, the owner of an animal for which a prescription was written or an authorized representative of the patient or animal owner shall present picture identification and noted on hardcopy of prescription.~~
2. ~~All schedule medications picked up shall present picture identification to the pharmacist. Verification shall be noted in readily retrievable fashion or noted on the hardcopy prescription.~~
3. ~~If person picking up prescription is not patient, and is not known to the pharmacist, a picture identification and signature is required along with written note or verifiable phone conversation from patient for pickup and shall be noted in readily retrievable fashion or on the hardcopy prescription.~~
4. ~~Mail-order pharmacies dispensing new schedule II medications to the patient shall have "person to person" counseling or electronic equivalent and documentation readily retrievable on request by Board.~~

1. All schedule medications dropped off for a patient for whom a prescription was written, the owner of an animal for which a prescription was written or an authorized representative of the patient or animal owner shall present picture identification and noted on hardcopy of prescription.
2. All schedule medications picked up shall present picture identification to the pharmacist. Verification shall be noted in readily retrievable fashion or noted on the hardcopy prescription
3. If person picking up prescription is not patient, and is not known to the pharmacist, a picture identification and signature is required along with written note or verifiable phone conversation from patient for pickup and shall be noted in readily retrievable fashion or on the hardcopy prescription.

Comment [WT22]:

Tabled
Some of the discussion items are:
1) Get a gov't issued ID during drop off and pick up.
2) #4 needs to have its own section.
3) Combine 1 & 2
4) Delete section 3 altogether.
5) Add in (e) to state: "A signature log must be maintained by the office. But maybe put this into the inspection rules."

Comment [WT23]:

Lindsay's suggestions

4. Mail order pharmacies dispensing new schedule II medications to the patient shall have “person to person” counseling or electronic equivalent and documentation readily retrievable on request by Board.

(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 but not limited to 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~~ providers for non-controlled substances in a state other than New Hampshire may be dispensed to a patient only when the traditional physician-pharmacist-patient relationship exists.

A. Providers prescriptions for controlled substances in schedule III-V may be filled for no more than a 34 day supply.

B. Providers prescriptions for controlled substances in Schedule II may be filled if originating from Connecticut, Rhode Island, or a state contiguous with New Hampshire wherein such provider resides or practices.

- 1. Prescriptions for controlled substances in schedule II and III shall be filled for no more than a 34 day supply or maximum of 100 dosage units.**
- 2. A prescription for schedule II and III controlled substances shall not be valid unless contains a diagnosis code or disease state indication.**
- 3. Prescriptions for controlled substances in Schedule II and III shall be fillable within 7 days of date on prescription.**

Comment [WT24]:
Check the Massachusetts Regulations because they are written better.

Comment [WT25]:
This section needs its own section

4. Pharmacist shall verify all Schedule II prescriptions from out of state providers and note on hardcopy or electronic copy of prescription.
5. A pharmacist shall not fill a prescription for which verification cannot be obtained.
6. A pharmacist shall not be liable for refusing to fill a prescription for which verification cannot be obtained provided that documented good faith efforts were made to determine the authenticity and validity of such prescription.

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.

Comment [WT26]:
Move to Ph 1900

- (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;~~
 - ~~(5)(6)~~ Determining who will have keys and access to the pharmacy with the exception of security personnel;
 - ~~(6)(7)~~ Establishing quality assurance guidelines to ensure the medication dispensed is in conformance with the prescription received;
 - ~~(7)(8)~~ Prohibiting the presence of adulterated or misbranded drugs in the pharmacy;
 - ~~(8)(9)~~ Ensuring compliance with the provisions of RSA 318 and RSA 318-B and any other state or federal pharmacy-related laws or rules;

~~(9)(10)~~ Supervising personnel in the prescription department; and

~~(10)(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

(8) Maintaining the security of the prescription department and its contents;

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 *within 15 days of termination of duties*. 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

Comment [WT27]:
Move to Ph 300's

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 responsibilities.~~ Whenever a pharmacist-in-charge shall cease performing that function in a pharmacy, the new pharmacist-in-charge shall, within 3 days of Board approval, 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. A self inspection form ph 538 shall be completed within 7 business days of board approval and kept on file in the pharmacy. This form shall be readily retrievable upon inspection or Board review.

Comment [WT28]:
Move to Ph 300's

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:
 - (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

Comment [WT29]:
Short Fill - Lindsey to review & look at the North Dakota wording. ** still need to do

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.

Comment [WT30]:
Move to Ph 1900 (In-State Pharmacy)

1. 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 is prohibited. This prohibition shall include ownership by individuals or immediate family members employed by an individual licensed to prescribe medicine, or a corporation, professional association or partnership consisting of such prescriber or prescriber's immediate family members. 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.

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

Ph 704.16 Automated Filling Systems

Comment [WT31]:
Move to Ph 1900

(a) Definitions. The following definitions shall be applicable for purposes of this rule:

(1) "Automated filling system"—Automated filling system used by a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing;

(2) "Electronic verification system"—An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly prepared for dispensing by an automated filling system;

(3) "Manufacturer unit of use package"—drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager;

(4) "Repackager"—A repackager registered with the United States Food and Drug Administration; and

(5) "Prepacked"—Any drug that has been removed from the original packaging of the manufacturer or a repackager's packaging and is placed in a container for use in an automated filling system.

(b) Medication Stocking. Automated filling systems may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the supervision of a pharmacist, exercised via an audio, video, or electronic communication method.

Comment [WT32]:
Sync up with the new Ph 800's

(c) Verification. Except as provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any medication filled or packaged by an automated filling system, and any label affixed thereto, prior to dispensing.

(d) The pharmacist verification requirements of section (c) shall be deemed satisfied if—

(1) The pharmacy establishes and follows a policy and procedure manual that complies with section (e) of this rule;

(2) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the automated filling system that is ready for dispensing to the patient. The pharmacist verification requirements of section (c) shall be deemed satisfied for a system that is not fully automated when all or part of the system is used for Manufacturer Unit of Use Packages if:

(i) The system utilizes an Electronic Verification Process to verify that the correct drug matches the correct prescription label;

(ii) The Electronic Verification Process activities are undertaken by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist;

(iii) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintained for two (2) years;

(3) A pharmacist verifies the accuracy of the prescription information used by or entered into the automatic filling system for a specific patient prior to initiation of the automatic fill process. The name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for two (2) years after dispensing;

(4) A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the automated filling system prior to initiating the fill process. Alternatively, an electronic verification system may be used for pharmacist;

(5) The medication to be dispensed is filled, labeled, and sealed in the prescription container by the automated filling system or dispensed by the system in a manufacturer's unit of use package or a repacked pharmacy container;

(6) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient; and

(7) Random quality testing is conducted by a pharmacist or technician on a sample size of prescriptions filled by the automated filling system as specified in policies and procedures. Proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy's records.

(e) Policies and Procedures. Pharmacies verifying prescriptions pursuant to section (d) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy's records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy's records and made available upon request.

At a minimum, the pharmacy shall establish and follow policies and procedures for-

(1) Maintaining the automated filling system and any accompanying electronicsystem in good working order;

(2) Ensuring accurate filling, loading, and stocking of the system;

(3) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(4) Reporting, investigating, and addressing filling errors and system malfunctions;

(5) Testing the accuracy of the automated filling system and any accompanying electronic verification system. At a minimum, the automated filling system and electronic verification

system shall be tested before the first use of the system or restarting the system and upon any modification to the automated filling system or electronic verification system that changes or alters the filling or electronic verification process;

(6) Training persons authorized to access, stock, restock, or utilize the automated filling system in equipment use and operations;

(7) Conducting routine and preventive maintenance and, if applicable, calibration;

(8) Removing expired, adulterated, misbranded, or recalled drugs;

(9) Preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;

(10) Identifying and recording persons responsible for stocking, loading, and filling the system;

(11) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements; and

(12) Maintaining an ongoing quality assurance program that monitors performance of the automatic fill system and any electronic verification system to ensure proper and accurate functioning.

(f) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of two (2) years. When the verification requirements of subsection (d)(4) of this rule are completed by a pharmacist, the name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for two (2) years after dispensing. Records shall be made available for inspection and produced to the board or the board's authorized designee upon request.

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.

(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.

Comment [WT33]:

This should be in Ph 1900 and also Ph 700's.
This may preclude or prevent automated.

Comment [WT34]:

This should be in Ph 1900 and also here in Ph 700

(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~~ *or* 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:

(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~~ *certified* 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~~ *or* director of nursing services;
 - b. Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist, ~~registered~~ *certified* 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 by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21; and

Comment [WT35]:
Sync up with Ph 800

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

Comment [WT36]:

Start here at the next meeting.

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, *and email address* 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; including but not limited to:~~
 - 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;
- (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 *new to the patient not previously prescribed* 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.~~

(4) Gabapentin

~~(b) 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. Control drug medications schedule II-IV~~
- ~~2. Multiple control drug medications~~
- ~~3. Morphine equivalent doses greater than 100~~
- ~~4. Counseling shall include~~
 - ~~a. Addiction~~
 - ~~b. Overdose and death~~
 - ~~c. Physical dependence~~
 - ~~d. Physical side effects~~
 - ~~e. Hyperanalgesia~~
 - ~~f. Tolerance.~~

~~(c) Pharmacists, pharmacy interns or New Hampshire-certified technicians shall document that counseling was given. Pharmacy personnel shall document that counseling was accepted or rejected. Failure to document the patient's refusal of counseling shall imply that counseling was provided.~~

- ~~1. All schedule II medications shall be counseled and verified by the pharmacist at pickup and documented by biometric scan or other indication in patient record or on hardcopy of prescription with date and time of pickup.~~
- ~~2. all schedule II prescriptions over 100 morphine equivalent units shall be counseled on abuse potential by pharmacist and noted on hardcopy or electronic copy of prescription~~
 - ~~a. the pharmacist shall offer counseling on naloxone to patient or caregiver and document on hardcopy or electronic copy of prescription~~

~~(d)(e) 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;~~
- ~~e. 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.~~

~~(e) Patient counseling shall be appropriate based on the pharmacist's best professional and clinical judgement according to current standards of practice.~~

~~(f) Alternative forms of patient information may be used to supplement patient counseling. Examples shall include written information leaflets, pictogram labels, or video programs.~~

~~(f)(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.

~~(g)(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.

1. A pharmacist shall verify the patients demographic data and medication history with the prescription drug monitoring program on all schedule II, III, and IV medications.
2. The Pharmacy shall develop and have readily retrievable a policy for verification with the Prescription Drug Monitoring Program.

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:

(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~~ transferred 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
- (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.

(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.

(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.

And be in compliance with USP 797 if they produce 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.

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.

(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;
- (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 AND DISCIPLINARY ~~FINES~~-VIOLATIONS

PH 710.01 A violation notice shall be given as a notification of non-compliance with Federal, State, or local laws.

PH 710.02 Board issued Violations

a. Minor violation notice.

- 1. Are administrative violations*
- 2. Minor violations are listed on form ph537.*
- 3. Minor violations are the responsibility of the pharmacist in charge and the permit holder.*
- 4. All corrective action taken by pharmacy shall be completed and mailed to Board office with 15 days.*
- 5. Minor violations are kept on file in appropriate licensing data base of pharmacist in charge and permit holder.*

6. *Minor violations shall be issued as a needs improvement, verbal warning, or violation with fine.*
 7. *Repeat minor violations will result in Board review with consideration for further disciplinary action.*
 8. *Minor violations shall be kept on file and readily retrievable in pharmacy for period of two years.*
- b. *Major violation notice.*
1. *Major violations can be administrative or disciplinary actions and are the responsibility of the pharmacist in charge and permit holder.*
 2. *Major violation notices are reported on form PH532 (REV 1/15)*
 3. *The pharmacist in charge and/or pharmacist on duty at time of violation shall be responsible for completing violation notice within 15 days of issue.*
 4. *Major violation notices shall be returned to the Board investigator/inspector in writing with corrected action noted.*
 5. *Major violation notices shall be reviewed by the Board at next scheduled meeting for possible further disciplinary action.*
 6. *Investigator/inspectors shall follow up written violation notices no later than 60 days after action noted. A request may be made for photo of corrected action taken.*
 7. *Major violations, after Board review, shall be maintained in pharmacist and permit holders permanent file.*

PH710.03 Major Violation notices that result in Disciplinary Actions.

- a. *Disciplinary violations shall include but not limited to:*
1. *Subsequent or multiple violations of state laws and rules.*
 2. *Professional misconduct as determined by the Board.*
 3. *Dispensing or other errors that place the public in jeopardy.*
 4. *Violations of federal rules and standards affecting the pharmacy profession.*
- b. *Disciplinary action may include but not limited to:*
1. *Confidential Letter of Concern*
 2. *Reprimand*
 3. *Fine*
 4. *Additional continuing education*
 5. *Suspension or revocation of license.*
- c. *Disciplinary action concerning a reprimand, fine, additional continuing education or suspension or revocation of license, or any action resulting in a restriction on a pharmacy or pharmacist license shall be reported to the National Board of Pharmacy and National Provider databases.*

Ph710.04 Violation notices for practitioners.

- a. *All violation notices shall be forwarded to respective regulatory Board for review and discipline.*
- b. *Violation notices of RSA 318(b) under pharmacy statutes may result in a fine by the Board of Pharmacy.*
- c. *Follow up violation notices shall be the responsibility of the Board of Pharmacy.*
- d. *Regulatory boards may make a request of pharmacy board investigators/inspectors for follow up on Board actions.*

Ph 710.05 Prescription Drug Monitoring Program Violations.

- a. *Any person 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 person who subsequently fails to correct or fails to resubmit the information may be subject to discipline by the board in reference to RSA 318-B:36.

~~Ph 710.04~~ **06 Liability for Administrative and Disciplinary 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.

~~Ph 710.02~~ **07 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) Minor violation fines shall be subject to a fine of \$25.00 for each offense with a maximum of \$250.00 per 710.01 and 710.02.

- (1) Fines shall be paid within 15 days or request a hearing in front of the Board.

~~(b)~~ (c) 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)~~ (d) 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)~~ (e) 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)~~ (f) 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)~~ (g) 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;
- (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