MEMORANDUM

TO: Joint Committee on Legislative Rules Date: May 11, 2022

FROM: Tina M. Kelley, Program Specialist IV
Office of Professional Licensure and Certification

RE: **Conditional Approval Request**
Notice Number 2021-92; Ph 700

Please find enclosed a conditional approval request for Final Proposal 2021-92, submitted on behalf of the N.H. Pharmacy Board.

I believe this request largely alleviates the Committee's Attorney's concerns. Please contact me directly with any questions or concerns.

Tina M. Kelley, Program Specialist
Office of Professional Licensure & Certification

Readopt with amendment Ph 701.02, effective 8-5-15 (Document #10903), to read as follows:

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 humans 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 humans 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) “Fit place to practice” means that an employee can safely complete professional and clinical duties and tasks in compliance with the board’s rules and statutes because the facility’s permit holder has established processes, policies, and procedures necessary to ensure safety.

(e) "Institution" means a health care facility which provides inpatient care and includes:

(1) Hospitals;

(2) Nursing homes;

(3) Extended care facilities;

(4) Residential care facilities;

(5) Infirmaries;

(6) Hospice house;

[~~(6)~~]**(7)** Correctional facilities; and

[(7)]**(8)** Clinics.

(f) "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.

(g) "Misbranded drug" means a drug:

(1) Whose label misrepresents the contents or is misleading;

(2) Dispensed by prescription with a label that 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.

(h) “Permit holder” means a person or entity to whom a license or permit has been issued under the provisions of RSA 318 and RSA 318-B for the purpose of operating a pharmacy.

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

(j) “Prescription” means a verbal, telephonic, written, or electronically transmitted order for drugs, medicines, and devices by a practitioner licensed in the United States, to be compounded and dispensed by licensed pharmacists in a duly registered pharmacy.

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

(l) "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.

(m) “Professional judgement” means the application of a combination of professional knowledge and experience to derive a resolution within standards of care, ethics, and objectives.

(n) “Scanned prescription” means the digital image of a prescription or medication order scanned into the data processing system.

(o) “Signature” means:

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

(2) An electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign a document or record; or

(3) An electronic signature.

(p) "Traditional physician-pharmacist-patient relationship" means a situation whereby the pharmacist knows either the physician, the patient, or both, and can readily and easily check on factors concerning the prescription.

(q) "Unit-dose" means a single-unit container that is designed to hold a quantity of drug product intended for administration as a single dose and labeled with the identity, quantity, and strength, name of the manufacturer, lot number, and expiration date of the drug product.

(r) "Unprofessional conduct" means conduct and practices which are hostile to the protection of public health, safety and welfare and includes:

(1) Knowingly engaging in any activity which violates state and federal statutes, regulations and rules governing the practice of pharmacy;

(2) Knowingly dispensing an outdated product;

(3) Knowingly charging for more dosage units than are actually dispensed;

(4) Knowingly altering prescriptions or other records which the law requires the pharmacy or pharmacist to maintain;

(5) Knowingly dispensing medication without proper authorization or prescription;

(6) Defrauding any persons or government agency receiving pharmacy services;

(7) Placing a signature on any affidavit pertaining to any phase of the practice of pharmacy which the pharmacist knows to contain false information***;***

(8) Not adhering to the written policy and procedures of the institution; **or**

(9) Failure to exercise or implement professional judgement or corresponding responsibility with regard to the practice of pharmacy[~~; or~~]**.**

[~~(10) The inappropriate exercise of education, training, or experience, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.~~]

[~~(s) "USP" means the United States Pharmacopeia, published by and issued under the authority of the Pharmacopeial Convention, which provides recognized standards and specifications for all drug entities in the U.S.~~]

[~~(t)~~]**(s)** "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**.**

Readopt with amendment Ph 701.03, effective 8-5-15 (Document #10903), to read as follows:

Ph 701.03 References.

(a) Persons subject to these rules shall comply with the following regulations and statutes as cited:

(1) RSA 146, Purity and Branding of Foods and Drugs;

(2) RSA 318, Pharmacists and Pharmacies;

(3) RSA 318-B, the New Hampshire Controlled Drug Act;

(4) 21 USC Sections 300 through 369, the Federal Food, Drug, and Cosmetic Act; and

(5) 21 CFR 1300 to end**.**

(b) Those institutional pharmacies subject to Ph 2300 shall not be subject to the Ph 700 rules except where specifically indicated.

Repeal Ph 702, effective 8-5-15 (Document #10903), as follows:

[~~PART Ph702 PHARMACY FACILITIES AND EQUIPMENT~~

~~Ph 702.01 Area, Space and Fixtures.~~

~~(a) Pharmaceuticals, library and equipment shall be housed in a well-li~~
~~or department with clean and sanitary surroundings devoted primarily to~~
~~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;~~

Note to the JLCAR. "Repeal" in rulemaking terms means that the agency is not intending to adopt such subject matter again, but it is not clear here if that is the case or if statutory revisions are the reason for this repeal. Once repealed, the rules cannot be enforced. The JLCAR may have questions about the reasons and intent for this repeal.

~~(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.~~

~~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.~~

~~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.~~

~~Ph 702.04 Security.~~

~~(a) That portion of a pharmacy wherein drugs are stored, manufactured, prepared or dispensed, shall, when the pharmacy is open, be so designed and constructed as to prevent entry into that area by any person or persons without the knowledge of the pharmacist then on duty, or when the pharmacy is not open to the public, by the activation of an alarm.~~

~~(b) The pharmacy shall be equipped with an alarm system which, when activated, shall emit a signal which is:~~

~~(1) Audible to the average person situated outside the building in which the pharmacy is located, at least 100 feet from any point of that building, or the public highway closest to that building, whichever is greater; or~~

~~(2) Observable by a law enforcement or security officer situated in a station of the law enforcement organization having jurisdiction over the area in which the pharmacy is located, an office of a security organization serving the area in which the pharmacy is located or an alarm monitoring company.~~

~~(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.~~

~~Ph 702.05 Limitations on Access.~~

~~(a) Except as provided in Ph 704.01(b), no pharmacy shall be open unless a pharmacist is on duty. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the licensed pharmacy area shall be barred by locked doors.~~

~~(b) The keys to the locked doors of a pharmacy shall be possessed only by:~~

~~(1) The pharmacist-in-charge;~~

~~(2) Pharmacists in the employ of the pharmacy;~~

(3) A non-pharmacist owner or owners of the pharmacy; or

(4) Store management and security personnel when secured in a locked safe in the building and kept separate from the alarm code needed to access the secured area.

(c) A non-pharmacist owner or owners may be on the premises of a pharmacy which he or she owns in the absence of a pharmacist employed by that pharmacy, provided that the pharmacy is not open and no drugs are prepared, dispensed or sold.

(a) Except as provided in Ph 704.01(b), no pharmacy shall be open unless a pharmacist is on duty in the pharmacy. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the pharmacy shall be barred by locked doors.

(b) The keys to the locked doors of a pharmacy shall be possessed only by:

(1) The pharmacist-in-charge;

(2) Pharmacists in the employ of the pharmacy;

(3) A non-pharmacist owner or owners of the pharmacy;

(4) Qualified security personnel as shall be designated by the pharmacist-in-charge and a list of such personnel shall be filed with the board by the pharmacist-in-charge; or

(5) If an institutional pharmacy, administrators of the institution and those nurses designated to enter the pharmacy to obtain medications in emergency situations.

(c) A non-pharmacist owner or owners may be on the premises of a pharmacy which he or she owns in the absence of a pharmacist employed by that pharmacy, provided that the pharmacy is not open and no drugs are compounded, dispensed or sold.

(d) The pharmacy permit shall be issued to the pharmacy in the name of the pharmacist-in-charge, who shall have sole control and responsibility for the operation of the pharmacy in accordance with all laws and rules pertaining to the practice of pharmacy in this state and always in the best interest of public health and safety.

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).

Ph 702.07 Minimum Standard of Technical Equipment and Stock.

(a) Permit holders shall provide that every pharmacy shall have contained therein, at all times, the following:

~~(1) Prescription labels showing the name, address, telephone number and DEA number of the pharmacy;~~

~~(2) All equipment, supplies and drugs that are relevant to the practice and meet all state and federal standards;~~

~~(3) An assortment of auxiliary labels or the software to produce them;~~

~~(4) A current reference library, or the ability to access references on line, as determined by the pharmacist-in-charge to meet the needs of the practice, and specialties, of that pharmacy and the patients it serves; and~~

~~(5) A current copy, with supplements, or the ability to access on line within the licensed area the New Hampshire Pharmacy Law Book.~~

Readopt with amendment and renumber Ph 703, effective 8-5-15 (Document #10903), as Ph 702 to read as follows:

PART Ph 702 RECORDS AND REPORTS

Ph 702.01 Recordkeeping Requirements.

(a) The requirements of Ph 702 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) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order, including refill orders from a schedule III, IV, or V controlled substances is correct shall be provided by:

(1) A hard copy printout of each day's-controlled substance prescription order refill data which shall be verified, dated, and signed by each pharmacist who refilled such prescription order; or

(2) In lieu of such a printout, the pharmacy shall maintain a bound logbook, 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.

Ph 702.02 Prepackaging of Drugs.

(a) Drugs shall be prepackaged in quantities suitable for internal distribution only by a pharmacist, licensed advanced pharmacy technician, or by supportive personnel under the direct supervision of a pharmacist.

(b) The label of a prepackaged unit shall indicate the:

(1) Name and strength of the drug and name of the manufacturer, manufacturers lot number, 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 or licensed advanced pharmacy technician 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 prepacker; and

(10) Signature of the responsible pharmacist or licensed advanced pharmacy technician.

(d) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

Ph 702.03 Controlled Drug Losses.

Unclear. The website does not include this form.

(a) The pharmacist on duty shall report to the board by completing, and submitting, a New Hampshire "Controlled Drug Loss Form", revised [~~January 2020~~] **5/2022**, found online at https://www.oplc.nh.gov/state-pharmacy and submitting to the board through the mail to the address in Ph 103.03(a) or by email to pharmacy.compliance@oplc.nh.gov any theft or significant loss described in Ph 702.03(e) of controlled substances within one business day.

(b) All instances of diversion shall be reported within one business day.

(c) In addition to the initial report of loss required per section (a) above, the pharmacist who discovered the loss shall submit a final report on the loss by completing, and submitting, a New Hampshire "Controlled Drug Loss Form", revised [~~January 2020~~] **5/2022** found online at https://www.oplc.nh.gov/state-pharmacy and submitting to the board through the mail to the address in Ph 103.03(a) or by email to pharmacy.compliance@oplc.nh.gov as soon as the investigation into the loss is complete but no later than 30 days after the discovery of the loss.

(d) 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 and be readily available upon board inspection or request.

(e) 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.

(f) 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.

(g) After 3 significant losses described in Ph 702.03(e) within a 12-month period and after investigation, the pharmacist in charge and the permit holder shall present to the board an action plan to remedy the issue. The board shall require, if necessary, additional security measures to address the issue. Failure to do so shall be subject to disciplinary action as provided in RSA 318:29.

Note to the JLCAR. The agency has deleted Ph 703.04 entitled "Automated Data Processing Systems". The deleted section is now part of rulemaking NN 2022-15.

Ph 702.04 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.

Ph 70[~~3.06~~]**2.05 Inspection Report**. The current compliance inspection report of the licensed location, conducted by the board, shall be kept on file in the prescription department.

Readopt with amendment and renumber Ph 704.01, effective 9-3-16 (Document #11189), as Ph 703.01, cited and to read as follows:

PART Ph 703 DISPENSING OF DRUGS AND DEVICES

See the unclear/Legis. Intent comment on page 20 regarding breaks and supervision of interns.

Ph 703.01 Presence of Pharmacists.

(a) No pharmacist shall work more than 8 hours without a rest break of 30 minutes. Breaks shall be scheduled as close as possible to the same time each day so that patients may become familiar with the approximate break times.

(b) The permit holder shall develop a written break policy and procedure that shall be available upon inspection or board request. Failure to follow the policy shall be subject to disciplinary action as provided in RSA 318:29.

Ph 703.02 **Schedule V Controlled Substances**. All cough syrups containing codeine shall require a valid prescription.

Adopt Ph 703.03 to read as follows:

Ph 703.[~~02~~]**03** Prescriptions.

(a) All schedule III through V controlled substance prescription drug orders, as described in RSA 318-B:1-b, and transmitted by facsimile or as an electronic prescription, shall include:

(1) The name and address of the patient;

(2) The name, strength, and quantity of the drug prescribed;

(3) Any directions specified by the prescribing practitioner;

(4) The full name of the prescribing practitioner which shall be printed, rubber stamped, or typewritten above or below his or her handwritten signature;

(5) The address of the prescribing practitioner;

(6) The federal drug enforcement administration (DEA) number assigned to the prescribing practitioner; and

(7) 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 described in RSA 318-B:1-b, to be compounded for the direct administration, to a patient in a private residence, long-term care facility, or hospice setting, by parenteral, intravenous, intramuscular, subcutaneous, oral administration**,** or intraspinal infusion. 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

(2) A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as described in RSA 318-B:1-b, for a resident of a long-term care facility or patient enrolling in hospice care program. Such prescriptions may be transmitted by the practitioner or the practitioner's designated agent, to the dispensing pharmacy. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I; and

(c) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the transmitted prescription drug order which shall be consistent with existing federal or state laws and rules.

(d) For controlled substances in schedules II, III, IV, or V, as described 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.

(e) All prescriptions dispensed by a health care provider or pharmacy containing an opiate shall:

(1) Affix an orange sticker to the cap or dispensing device with the word "opioid" in easily legible font;

(2) Have a warning label that states "Risk of Addiction or Overdose"; and

(3) Provide the person with handout provided by **the** [~~G~~]**g**overnor's [~~C~~]**c**ommission on [~~A~~]**a**lcohol and [~~D~~]**d**rug [~~A~~]**a**buse, [~~P~~]**p**revention, [~~T~~]**t**reatment, and [~~R~~]**r**ecovery on guidance for associated risks of opioid use and how to mitigate them.

(f) Pharmacists or a pharmacy that dispenses a drug containing an opioid that is to be administered to a patient treated in a health care facility required to be licensed under RSA 151 shall not be subject to the provisions of (e) above.

(g) Failure to comply with Ph 703.02 shall result in disciplinary action by the board.

Repeal Ph 704.02, effective 8-5-15 (Document #10903), as follows:

[~~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.~~

Repeal Ph 704.03, effective 8-5-15 (Document #10903), as amended effective 4-7-20 (Document #13015, Emergency) and expired 10-4-20, as follows:

~~Ph 704.03 Transmission of Prescription Drug Order by Prescriber.~~

~~(a) A prescription drug order may be transmitted to a pharmacy by an authorized prescriber or his designated agent in writing, orally, by facsimile or electronically.~~

~~(b) A facsimile or electronically transmitted prescription drug or device order shall:~~

~~(1) Be sent to the pharmacy of the patient's choice;~~

~~(2) For a non-controlled substance prescription drug or device order, include:~~

~~a. The name of the patient;~~

~~b. The name, strength, and quantity of the drug prescribed;~~

~~c. Any directions specified by the prescribing practitioner;~~

~~d. The name and address of the prescribing practitioner which shall be printed or typewritten;~~

~~e. The prescribing practitioner's phone number for verbal confirmation; and~~

~~f. The date the prescription was ordered;~~

~~(3) For a schedule III through V controlled substance prescription drug order, as defined in RSA 318-B:1-b and transmitted by facsimile or as an electronic prescription, shall include:~~

~~a. The name and address of the patient;~~

~~b. The name, strength, and quantity of the drug prescribed;~~

~~c. Any directions specified by the prescribing practitioner;~~

~~d. The full name of the prescribing practitioner which shall be printed, rubber stamped, or typewritten above or below his or her handwritten signature;~~

~~e. The address of the prescribing practitioner;~~

~~f. The federal drug enforcement administration (DEA) number assigned to the prescribing practitioner; and~~

~~g. The date the prescription was ordered;~~

~~(4) A facsimile prescription for a schedule II controlled substance shall not be accepted as an original written prescription except in circumstances when:~~

~~a. A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, to be compounded for the direct administration to a patient in a private residence, long-term care facility, or hospice setting, by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be electronically transmitted, by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I;~~

~~b. A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a resident of a long-term care facility may be electronically transmitted by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I; and~~

~~c. A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a patient enrolled in a hospice care program, may be electronically transmitted by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The practitioner or the practitioner's designated agent shall note on the prescription that the patient is a hospice patient. The printed copy of the transmission shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I;~~

~~(5) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the electronically transmitted prescription drug order which shall be consistent with existing federal or state laws and rules;~~

~~(6) For controlled substances in schedules II, III, IV or V, as defined in RSA 318-B:1-b, a pharmacy may receive an electronically transmitted drug order from the prescriber for filling provided that it is transmitted in accordance with federal law with an electronic signature meeting security requirements required by the Drug Enforcement Agency (DEA) for electronic prescriptions; and~~

~~(7) The devices used for the receipt of facsimile or electronically transmitted prescription drug orders shall be located in the prescription department of the pharmacy in order to protect patient confidentiality and to assure security.~~]

Readopt with amendment and renumber Ph 704.04, effective 8-5-15 (Document #10903), as Ph 703.03 to read as follows:

Ph 703.[~~03~~]**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, licensed advanced pharmacy technicians, certified pharmacy technicians, or pharmacy interns; [~~and~~]

(c) The transferring pharmacist, licensed advanced pharmacy technician, certified pharmacy technician, or pharmacy intern shall notate in the computer record the following:

(1) That a copy has been issued, the date of transfer, and the name of the individual 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 agent receiving the prescription information.

(d) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy[~~.~~]**;**

(e) The receiving agent of the transferred prescription information shall:

(1) Include the word “transfer” on the face of the transferred prescription; and

(2) Provide all information required to be on the prescription including the:

a. Patient's name and address;

b. Doctor's name and address;

c. Date of issuance of the original prescription and date of transfer;

d. Number of valid refills remaining and date of last refill;

e. Pharmacy name, address, and original prescription number from which the prescription information was transferred;

f. Full name of the transferor pharmacist, certified pharmacy technician, licensed advanced 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) Two 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[~~.~~]**; and**

(j) New or on-hold prescription orders for prescription drugs 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 substance prescriptions shall be done in accordance with current federal Drug Enforcement Administration (DEA) guidelines located in 21 CFR 1306.25.

Repeal Ph 704.05, effective 8-5-15 (Document #10903), as follows:

[~~Ph 704.05 Schedule V Controlled Substances. All cough syrups containing codeine shall not be dispensed without a prescription.~~]

Readopt with amendment Ph 704.06 through Ph 704.09, effective 8-5-15 (Document #10903) renumbering as Ph 703.04 through Ph 703.07, to read as follows:

Ph 703.04 Drug Product Selection.

(a) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug product prescribed by its trade or brand name may select a therapeutically equivalent drug product with the same established name, active ingredient, strength, quantity, and dosage form as the drug product identified in the prescription.

(b) Therapeutically equivalent drugs shall include only those drug products listed in "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations" Published by the United States Department of Health and Human Services, according to RSA 146-B:2, I, or any written notification or confirmation from the federal Food and Drug Administration (FDA) that a drug product is a therapeutically equivalent drug product.

(c) The pharmacist shall not select an equivalent drug product:

(1) If the prescriber handwrites “medically necessary” on the written prescription;

(2) If when ordering a prescription orally, the prescriber specifies that the prescribed drug is medically necessary; or

(3) If the prescription is electronically transmitted, the prescriber includes a statement on the face of the prescription indicating medically necessary.

(d) The pharmacist shall not select an equivalent drug product unless its price to the purchaser 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) A pharmacist shall adapt drugs:

(1) By changing the quantity of medication prescribed if:

a. The prescribed quantity or package size is not commercially available;

b. The change in quantity is related to a change in dosage form, strength, or therapeutic interchange;

c. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or

d. The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program;

(2) By changing dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed;

(3) By completing missing information on a prescription if there is evidence to support the change; and

(4) The adaptation is documented in the patient's record.

(g) A pharmacist may perform therapeutic substitutions if:

(1) The pharmacist filling a prescription for a specific drug substitutes a drug in the same therapeutic class, the patient agrees to the substitution, and the substitution is made to replace a drug that is on back order ensures formulary compliance with the patient's health insurance plan or in the case of an uninsured patient to the lower cost drug while maintaining safety; or

(2) The pharmacist is used by a long-term-care facility and the therapeutic interchange or a therapeutically equivalent selection for a patient, during the patient's stay at the facility, has been approved for the patient in accordance with written guidelines and procedures developed by the facility that in conjunction with the pharmacist and is current and readily available to the pharmacist at the pharmacy.

Ph 703.05 Return of Drugs and Devices.

(a) Except as provided in (b) below, 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 (a) above 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.

Ph 703.06 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, except as outlined in Ph 703.06(b).

(b) Identification requirements for schedule medication drop off and pick up, excluding delivered prescriptions, shall include receipt of a photo identification (ID), at the time the prescription is picked up, for all schedule II medications, and the receipt of the photo ID [~~is~~] **shall be** documented in the patients record.

(c) Mail order pharmacies dispensing new schedule II medications to the patient shall comply with the requirements set forth in Ph 704.03 patient counseling.

(d) This section shall not prohibit a licensee from picking up prescriptions or delivering prescribed medications at any location requested by the patient, by means of mail, an employee, a currier, or by use of a common carrier. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order accountability, and proper storage of prescription orders during transportation.

(e) 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.

(f) Drugs with special handling or storage requirements that will be administered by the practitioner, such as but not limited to radio pharmaceuticals or frozen immunizations, may be delivered directly to the practitioner's office

(g) A signature, or electronic signature, log must be maintained by the pharmacy. A signature or electronic signature is not required to be obtained for delivered prescriptions.

Ph 703.07 Dispensing Adulterated or Misbranded Drugs. A pharmacist shall not dispense or sell to the public any drug which is adulterated, misbranded, or has been previously sold and returned to stock. 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, misbranded drug, or previously sold drug, shall be subject to disciplinary action according to RSA 318:29.

Repeal Ph 704.10 through Ph 704.13, effective 8-5-15 (Document #10903), as follows:

~~[Ph 704.10 Out-of-State Prescriptions. Prescriptions written by providers in a state other than New Hampshire may be dispensed to a patient only when a traditional physician-pharmacist-patient relationship exists.~~

~~Ph 704.11 Pharmacist in-Charge/Corporate Entity Requirements/Duties.~~

~~(a) Pharmacists looking to serve as a Pharmacist-in-Charge (PIC) shall:~~

~~(1) Have worked as a pharmacist for a minimum of 2 years post-graduation;~~

~~(2) Complete and pass with a minimum of 80% an exam designed by the board to assess the knowledge of the candidate in regard to their responsibilities as PIC; and~~

~~(3) Work a minimum of 20 hours per week at the location where he/she serves as PIC except when absent due to scheduled vacation or other authorized leave.~~

~~(b) Pharmacist in charge duties shall include:~~

~~(1) Responsibility for the control of all drugs issued or dispensed in the pharmacy where he/she practices;~~

~~(2) Ensuring written policies and procedures for the procurement, storage, compounding and dispensing of drugs are in place;~~

~~(3) Ensuring that all staff pharmacists are familiar with and in compliance with the established policies and procedures;~~

~~(4) Establishing and supervising the recordkeeping system for the purchase, sale, possession, storage, and repackaging of drugs;~~

~~(5) Maintaining the security of the prescription department and its contents;~~

~~(6) Determining who will have keys and access to the pharmacy with the exception of security personnel;~~

~~(7) Establishing quality assurance guidelines to ensure the medication dispensed is in conformance with the prescription received;~~

~~(8) Prohibiting the presence of adulterated or misbranded drugs in the pharmacy;~~

~~(9) Ensuring compliance with the provisions of RSA 318 and RSA 318-B and any other state or federal pharmacy-related laws or rules;~~

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

~~(11) Ensuring all personnel involved in the preparation and dispensing of prescriptions are properly licensed or registered with the board.~~

~~(c) Pharmacists may serve as a pharmacist-in-charge for a maximum of 2 pharmacies, providing that one of these pharmacies shall be in an institution requiring the services of a pharmacist only on a part-time basis.~~

~~(d) The corporate entity or permit holder shall be responsible for the following:~~

~~(1) Written policies and procedures for the procurement, storage, compounding and dispensing of drugs;~~

Unclear/Legis. Intent. Ph 703.01 above requires the regulated pharmacy to develop policies and procedures for breaks; however, RSA 318:5-a, XIV requires the Board to adopt rules relative to the policy and procedures for when the pharmacist is temporarily away from the facility. Also, RSA 318:5-a, XI-a requires rules for the supervision of pharmacy interns by the pharmacist. It is unclear whether there are rules for intern supervision elsewhere.

~~(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~~

~~Ph 704.12 Termination of Pharmacist-in-Charge Notice. Whenever a pharmacist-in-charge shall cease performing that function, that pharmacist-in-charge shall notify the board in writing of the date upon which the cessation of that function is effective. That pharmacist-in-charge shall remain responsible for compliance, in the pharmacy in which he or she was the pharmacist-in-charge, with all pharmacy related statutes and rules until the effective date of termination.~~

~~Ph 704.13 Termination of Pharmacist-in-Charge - Inventory. Whenever a pharmacist-in-charge shall cease performing that function in a pharmacy, the new pharmacist-in-charge shall, within 3 days, cause to be completed a written inventory of all controlled substances located in that pharmacy. The record of that inventory shall be retained in the pharmacy for a minimum of 2 years.~~]

Readopt with amendment and renumber Ph 704.14, effective 8-5-15 (Document #10903), as Ph 703.08 to read as follows:

Ph 703.08 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 703.09.

Readopt with amendment and renumber Ph 704.15, effective 8-5-15 (Document #10903), as amended effective 3-20-20 (Document #13007, Emergency) and expired 9-16-20, and as amended effective 5-20-20 (Document #13016, Emergency) and expired 11-16-20, as Ph 703.09 to read as follows:

Ph 703.09 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) It is necessary to synchronize the patient's medications as referenced in RSA 415:27 and RSA 420-J:19;

(d) The quantity of prescription drug dispensed does not exceed a 90 days supply for maintenance medications, unless federal law states otherwise, excluding filling prescriptions for controlled substances listed in Schedule III, which [~~must~~] **shall** comply with NH RSA 318-B:9, IV;

(e) 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;

(f) The pharmacist shall inform the prescribing practitioner of the limited emergency supply, provided to the patient, at the earliest reasonable time; and

(g) The pharmacist exercises professional judgement in refilling the prescription drug order.

Readopt and renumber Ph 704.16, effective 8-5-15 (Document #10903), as Ph 703.10 to read as follows:

Ph 703.10 Acts Prohibited. Splitting fees, making rebates, or sharing money received for pharmaceutical services, or the donation of 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.

Repeal Ph 705, effective 8-5-15 (Document #10903), as follows:

[~~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.~~

~~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.~~

~~(c) "Automated medication dispensing system" means a computerized drug storage device or cabinet designed for use in long term care facilities and other health care institutions.~~

~~(d) The placement of controlled substances in emergency drug kits in non-federally registered long term care facilities/specialized care facilities shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:~~

~~(1) Controlled substances shall be stored in the emergency drug kit as deemed necessary and jointly approved by the pharmacist in charge and the consultant pharmacist, medical director and the director of nursing services;~~

~~(2) The source from which controlled substances for emergency drug kits are obtained shall be a DEA registered hospital, clinic, pharmacy or practitioner;~~

~~(3) Controlled substances in emergency drug kits shall be limited to a maximum of 16 separate drug entities with not more than 8 single use containers of each drug entity;~~

~~(4) The emergency drug kit containing controlled substances shall be closed with a tamper proof seal and kept in a locked medication room, cart or closet;~~

~~(5) Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist or practitioner shall have access to controlled substances stored in an emergency drug kit;~~

~~(6) Controlled substances in emergency drug kits shall be administered to patients only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21;~~

~~(7) A usage record shall be contained in the emergency drug kit for each separate drug included which shall be completed by the nursing staff when using any controlled substance or substances from the kit;~~
~~(8) The pharmacist shall receive and file for 2 years a copy of all completed usage records;~~

~~(9) When the emergency drug kit is opened:~~

~~a. The pharmacist shall be notified by the facility within 24 hours; and~~

~~b. Shift counts shall be done by the nursing staff on all controlled substances until resealed by the consultant pharmacist;~~

~~(10) Shift counts of the controlled substances contained in the emergency kit shall not be required when the kit is sealed;~~

~~(11) The pharmacist shall check the controlled substances in the emergency drug kit at least monthly and so document inside the kit; and~~

~~(12) The placement of controlled substances in emergency drug kits shall be only upon the written authorization of the board of pharmacy.~~]

~~(e) Automated electronic emergency drug kits shall meet the following conditions:~~

~~(1) Real time electronic communication to the provider pharmacy;~~

~~(2) For access, employ at least but not limited to:~~

~~a. Bio-Identification; and~~

~~b. Unique individualized password protections assigned by the provider pharmacy;~~

~~(3) Automatically generate notice to the provider pharmacy whenever the kit is accessed and provide at least the following information:~~

~~a. Name of individual accessing the kit;~~

~~b. Date and time the kit was accessed;~~

~~c. Name, strength and quantity of drug removed; and~~

~~d. Name of patient for whom the drug was administered; and~~

~~(4) Upon restocking the automated electronic emergency drug kit the following conditions shall be met:~~

~~a. The filling/restocking of an automated electronic emergency drug kit shall be performed by a licensed pharmacist, physician, physician assistant, advanced practice nurse, registered nurse and registered pharmacy technician.~~

~~(5) "Automated medication dispensing system" means a computerized drug storage device or cabinet designed for use in long term care facilities and other health care institutions. An automated medication dispensing system may be used as an electronic emergency drug kit provided the system performs operations or activities relative to~~

~~the storage, packaging, dispensing and distribution of medications, and which tracks and maintains a record of transaction information;~~

~~(6) Automated emergency drug kits shall be allowed as set forth in rules adopted under RSA 151;~~

~~(7) Non-controlled legend drugs may be stored in the emergency drug kit in quantities deemed necessary and jointly approved by the pharmacist in charge of the provider pharmacy, consultant pharmacist, medical directorand the director of nursing services; and~~

~~(8) The placement of controlled substances in automated electronic emergency drug kits in non-federally registered long term care facilities and other health care institutions shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:~~

~~a. Controlled substances shall be selected and stored in the automated electronic emergency drug kits in quantities deemed necessary and jointly approved by the pharmacist in charge and the consultant pharmacist, medical director and the director of nursing services;~~

~~b. Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist, registered pharmacy technician or practitioner shall have access to controlled substances stored in an automated electronic emergency drug kit;~~

~~c. Controlled substances in automated electronic emergency drug kits shall be administered to patients only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 1306.21; and~~

~~d. When an automated electronic emergency drug kit is utilized, notification of usage shall be reported in accordance with Ph705.02 (e) (3).~~]

Readopt with amendment and renumber Ph 706, effective 8-5-15 (Document #10903), as Ph 704 to read as follows:

PART Ph 704 PHARMACEUTICAL CARE STANDARDS

Ph 704.01 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) A reasonable effort shall be made to obtain, record, and maintain the following information:

(1) The full name of the patient for whom the drug is intended;

(2) The address and telephone number of the patient;

(3) The patient's date of birth;

(4) The patient's gender;

(5) A list of all prescription drug orders;

(6) Documentation relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) The pharmacist or support personnel shall make a reasonable effort to obtain from the patient or the patient's agent, and record, any known:

(1) Allergies;

(2) Drug reactions; and

(3) Usage of other drugs, including over-the-counter drugs, currently being used by the patient.

Ph 704.02 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.

Ph 704.03 Patient Counseling.

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

(b) 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.

Readopt and renumber Ph 707.01 and Ph 707.02, effective 8-5-15 (Document #10903), as Ph 705.01 and Ph 705.02 to read as follows:

PART Ph 705 DISPOSAL AND DESTRUCTION OF CONTROLLED DRUGS

Ph 705.01 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.

Ph 705.02 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 or 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.

Readopt and renumber Ph 707.03 and Ph 707.04, effective 8-5-15 (Document #10903, as amended effective 4-7-20 (Document #13016, Emergency) and expired 10-4-20, as Ph 705.03 and Ph 705.04 to read as follows:

Ph 705.03 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:

Edit. Use upper case.

(1) A record of the controlled drugs destroyed shall be made on [~~form # Ph 558 (revised 7/2015)~~] **the "consultant's Record of Drugs Destroyed" revised 5/2022 and** obtained at the board office, identified in Ph 103.03; and

(2) Copies of form [~~# Ph 558 (revised 7/2015)~~] **the "Consultant's Record of Drugs Destroyed"** 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 or agent making the destruction.

Ph 705.04 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) 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.

Readopt and renumber Ph 707.05, effective 8-5-15 (Document #10903), as Ph 705.05 to read as follows:

Ph 705.05 Record of Controlled Drug Destruction.

(a) A record of the drugs destroyed shall be made on federal form DEA-4l, "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 required under federal law 21CFR, 317, 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 2 years.

Readopt with amendment and renumber Ph 707.06, effective 8-5-15 (Document #10903, as Ph 705.06 to read as follows:

Ph 705.06 Exemption. Nothing contained in part Ph 705 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.

Repeal Ph 708 through Ph 710, effective 8-5-15 (Document #10903), and renumber Ph 710 as Ph 708 as follows:

[~~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.~~

~~Ph 708.02 Disposition of Drugs/Records.~~

~~(a) Security of the pharmacy shall be maintained while there is a supply of legend drugs including controlled substances on the pharmacy premises. Stable, unopened containers of legend drugs including controlled drugs may be returned by the pharmacy to the wholesaler/manufacturer.~~

~~(b) At the time of closing, the remaining supply of controlled substances may be sold or given to another pharmacy provided that:~~

~~(1) The transfer of schedule II substances shall comply with 21 CFR 1307.14 and 21 CFR 1305.06 by means of a properly executed federal DEA #222 Form;~~

~~(2) The transfer of schedules III, IV, and V are made by invoice with copies to each party and the board; and~~

~~(3) Prescription files, executed DEA #222 forms, biennial DEA inventories, applicable invoices, the balance of stock of all controlled substances, and the final printouts required by Ph 703.05(r)(2), shall be transferred as a package.~~

~~(c) At the time of closing, in addition to the electronic file transfer of the prescription records the closing pharmacy shall:~~

~~(1) Provide an up-to-date hard-copy printout of all non-controlled drug prescriptions stored in the automated system and a printout of all controlled drug prescriptions for the current 2 year period as part of the final records of that pharmacy;~~

~~(2) In lieu of such printout, an electronic back-up of the prescription records for the last 2 year may be provided on electronic media; and~~

~~(3) In the event that the pharmacy files are not sold to another pharmacy, the closing pharmacy shall make provision for these records to be available to any nearby pharmacy.~~

~~(d) If, in the interest of public health and safety, the board determines that after closure of the pharmacy a lack in the security, according to Ph 702.04, of the prescription drugs including controlled substances exists, the licensee shall immediately surrender to the board all prescription drugs including controlled substances and forms and invoices thereof. The drugs so held shall be inventoried, packaged, sealed and stored at the expense of the licensee in a place determined by the board to be appropriately secure. The licensee shall have 60 days after the effective date of the closing to make arrangements for the lawful sale or other disposition of these drugs. Lawful sale and/or disposition of these drugs shall be to a duly licensed person authorized to possess and store prescription drugs including controlled substances. Failing compliance within this 60-day period, such drugs shall then be surrendered to the board for destruction.~~

~~(e) Before disposing of any merchandise in the pharmacy, the owner and pharmacist in-charge shall submit the licensed premises to an inspection by a representative of the board to certify that all prescription drugs including controlled substances have been secured.~~

~~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.~~]

[~~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.~~

~~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.~~

~~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.~~

~~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.~~

~~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.~~

~~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.~~

~~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.~~

~~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.~~

~~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.~~]

PART Ph 710 ADMINISTRATIVE FINES

Ph 710.01 Liability for Administrative Fines. Persons subject to the disciplinary authority of the board and other persons subject to administrative fines or penalties under RSA 318:29, IV shall, at the discretion of the board, after notice and an opportunity to be heard, be assessed fines and/or penalties as authorized under RSA 318:29, IV.

Ph 710.02 Severity of Fine.

(a) The decision to impose a fine and the amount of such fine shall depend on:

(1) The severity of harm to the public posed by the violation(s);

(2) The number of concurrent and/or repeated violations; and

(3) The frequency of violations committed by the particular licensee, permit holder, or other person.

(b) When no violation of the same type has occurred within the 5 years preceding the board's notice to the respondent, the fine assessed shall not exceed $1,000 per violation upon the licensee and/or $2,000 per violation upon the permit holder.

(c) When a single disciplinary infraction of the same type has occurred within the 5 years preceding the board's notice to the licensee, the fine assessed shall not exceed $2,000 per violation upon the licensee and/or $3,000 per violation upon the permit holder.

(d) When more than one disciplinary infraction of the same type has occurred within the 5 years preceding the board's notice to the licensee, the fine assessed shall not exceed $3,000 per violation upon the licensee and/or $5,000 per violation upon the permit holder.

(e) In the case of continuing violations, a separate fine shall be assessed for each day the violation continues, but the total amount of the fine and the licensee's promptness and cooperativeness in ceasing the prohibited conduct in question shall be considered in assessing the daily fines.

(f) In all cases, the board shall consider:

(1) The nature of the offense;

(2) The purpose of the rule or statute violated;

(3) The licensee's state of mind at the time the offense occurred;

(4) The potential harm to the public health;

(5) The deterrent effect upon other practitioners;

(6) The licensee's willingness to cooperate with the board;

(7) The cost to the board of any formal disciplinary hearings which were necessary;

(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.

APPENDIX

Rule	Specific State Statute the Rule Implements
Ph 701.02 and Ph 701.03	RSA 318:5-a, IV-a
Ph 702.01 – 702.04 (Repealed)	RSA 318:5-a, II, IV-a
Ph 702.01 (b)(3) (Repealed)	RSA 318:5-a, II
Ph 702.05 (Repealed)	RSA 318:5-a, XIV
Ph 702.06 – 702.07 (Repealed)	RSA 318:5-a, IV-a
Ph 702.01 – 702.03 (Formerly Ph 703.01 – 703.03)	RSA 318:5-a, III, IV-a, IX
Ph 703.04 (Deleted)	RSA 318:5-a, III, IV-a, IX
Ph 702.04 (Formerly Ph 703.05)	RSA 318:5-a, II, IV-a
Ph 703.06 (Deleted)	RSA 318:5-a, IV-a
Ph 703.01 (Formerly Ph 704.01)	RSA 318:5-a, XIV, IV-a
Ph 703.02	RSA 318:5-a, XIV, IV-a
Ph 704.02 and Ph 704.03 (Repealed)	RSA 318:5-a, II, III, IV-a, XV
Ph 703.03 (Formerly Ph 704.04)	RSA 318:5-a, II, III, IV-a, XV
Ph 704.05 (Repealed)	RSA 318:5-a, XIV, IV-a
Ph 703.04 (Formerly Ph 704.06)	RSA 318:5-a, II, III, IV-a, XV
Ph 703.05 (Formerly Ph 704.07)	RSA 318:38, I; RSA 91-A
Ph 703.06 (Formerly Ph 704.08)	RSA 318:47-c
Ph 703.07 (Formerly Ph 704.09)	RSA 318:47-c
Ph 704.10 – Ph 704.13 (Repealed)	RSA 318:47-c
Ph 703.08 (Formerly Ph 704.14)	RSA 318:52-a
Ph 703.09 (Formerly Ph 704.15)	RSA 318-B:9, I, III, IV
Ph 703.10 (Formerly Ph 704.16)	RSA 318:29, V, (g)(h)
Ph 705.01 and Ph 705.02 (Repealed)	RSA 318:5-a, IV-a, RSA 318:38, I
Ph 705.03 (a) – (d) (Repealed)	RSA 318:38, I
Ph 704 (Formerly 706)	RSA 318:5-a, IV-a
Ph 705.01 (Formerly Ph 707.01)	RSA 318:5-a, IV-a
Ph 705.02 (Formerly Ph 707.02)	RSA 318:5-a, , II, III, IV-a
Ph 705.02(a) (Formerly Ph 707.02 (a))	RSA 318:5-a, III, IV-a
Ph 705.02(b)(1) (Formerly Ph 707.02 (b)(1))	RSA 318:5-a, II
Ph 705.02 (b)(7) (Formerly Ph 707.02 (b) (7))	RSA 318:5-a, III
Ph 705.03 (Formerly Ph 707.03)	RSA 318:5-a, IV-a
Ph 705.04 (Formerly Ph 707.04)	RSA 318-B:17-a, RSA 318:5-a, IV-a
Ph 705.05 and Ph 705.06 (Formerly Ph 707.05 and Ph 707.06)	RSA 318:5-a, IV-a
Ph 708.01 (Repealed)	RSA 318:5-a, III, IV-a, IX
Ph 708.02 (Repealed)	RSA 318:47
Ph 708.03 (Repealed)	RSA 318-B:9, II
Ph 709.01 (Repealed)	RSA 318:5-a, IV-a and XV
Ph 709.02 (Repealed)	RSA 318:5-a, IV-a
Ph 709.03 – 709.06 (Repealed)	RSA 318:5-a, IV-a, and XII
Ph 709.05 (Repealed)	RSA 318:5-a, IV-a; RSA 318:42
Ph 709.07 - 709.09 (Repealed)	RSA 318:5-a, IV-a
Ph 710.01 and Ph 710.02 (Repealed)	RSA 318:5-a, IV-a, VII; RSA 318:29, IV