Adopt Ph 2300 to read as follows:

CHAPTER Ph 2300 INSTITUTIONAL PHARMACY PRACTICE

PART Ph 2301 PRACTICES

Ph 2301.01 Definitions.

(a) "Automated dispensing machines" (ADM) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

(b) " 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.

(c) "Auto-verification" means when a medication is entered and released, it is automatically verified in the electronic medical record, bypassing the pharmacist verification step.

(d) "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.

(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 of department of the institution.

(g) "Medication order" means a verbal, telephonic, written, facsimile, or electronically transmitted order provided by a prescribing practitioner for a specific drug to be administered to an individual.

(h) "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.

Ph 2301.02 Permitting.

(a) A pharmacy permit shall be required for each institution with an on-premise pharmacy. Such permit shall be issued to an institution, who shall be licensed in the state of New Hampshire.

(b) When an institution procures prescription drugs for its patients only on individual prescriptions for specific patients from an off-premises licensed pharmacy, the institution shall not be required to obtain a pharmacy permit.

(c) 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 2300. 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.

(d) The pharmacist-in-charge and the permit holder shall be responsible for compliance with federal, and state laws related to the practice of pharmacy.

Ph 2301.03 Practice Standards.

(a) An institutional permit shall permit the pharmacy to dispense medications to the following, but is not limited to:

(1) In-patients of the institution;

(2) Staff or employees and their dependents, of the institution;

(3) Interim supplies of medication to outpatients in emergency situations;

(4) Home infusion therapy to registered outpatients not requiring hospitalization; and

(5) Registered outpatients receiving treatment in a hospital-based clinic.

(b) 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.

(c) Members of the board and their agents shall inspect the pharmacy, drug room, or medication room and all areas or departments of the institution 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 institution is in compliance with all state and federal drug and pharmacy laws and rules.

(d) Those institutions obtaining prescription drugs only on individual prescriptions for specific patients from an off-premise licensed pharmacy shall not be exempt from inspection.

(e) 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 functions of this committee shall be to establish the written policies and procedures governing medication management, use of drugs, drug specifications, and drug distribution.

(f) The institutional pharmacy shall develop and implement clinical pharmacy practice policies and procedures which provide optimum comprehensive medication management for patients.

(g) An institutional pharmacy shall have the ability to dispense a generic or therapeutic equivalent or bio-similar, in accordance with RSA 318:47dd, that has been approved by the pharmacy and therapeutics committee or its equivalent per Ph 2301.03(a).

(h) Pharmacists shall have the ability to initiate or modify drug therapy by approved protocol according to the institution policy. Drug therapy initiated or modified by protocol shall be documented in the medical record in accordance with the institutional policy

(i) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage, preparation, and dispending of drugs in all areas or departments of the institution and shall be consistent with state and federal pharmacy laws and rules.

(j) Medication orders shall be reviewed by a pharmacist before the medication is initially dispensed or medication orders shall be reviewed by a pharmacist within 24 hours except when:

(1) A licensed independent practitioner controls the ordering, preparation, and administration of medications;

(2) In emergencies;

(3) When a pharmacist is temporarily unavailable;

(4) By auto-verification by policy;

(5) Those that are for distribution of drugs for floor stock; or

(6) When distributed by the ADC.

(k) The review of medication orders may include, but shall not limited to the following:

(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.

(l) Upon recognizing a clinical problem, the pharmacist shall take steps to avoid or correct the

problem.

Ph 2301.04 Environment. The institutional pharmacy environment shall be detailed in the institution's policies and procedures and shall include at the minimum the following:

(a) How the institution will be enclosed and lockable and how the alarm is to be engaged when not open 24 hours a day;

(b) How the institution shall have adequate space necessary for the storage, compounding, labeling, dispensing, and sterile preparation of drugs prepared in the pharmacy;

(c) How the institution is to be arranged and kept clean and in an orderly fashion;

(d) How the institution designates the sinks with hot and cold running water which are available to all pharmacy personnel;

(e) The institutions locked storage system used for all controlled substances;

(f) The institutions designated areas for the storage of flammable and caustic materials and how such areas shall meet the requirements set by local and state fire laws; and

(g) Describes designated areas for the preparation of sterile products if sterile products are prepared.

Ph 2301.05 Drug Security. The institution drug security protocols shall be detailed in the institution's policies and procedures and shall include, but not be limited to, the following:

(a) Drugs stored in any area or department of the facility shall be labeled and kept secure 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, a secure system shall be developed to assign, discontinue, or change personnel access codes;

(d) The institution shall have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications shall not be available for patient use. Inspections by the institutional pharmacy shall be periodically performed but, at a minimum, no less than every 90 days; and

(e) A retrievable record of each 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) Significant controlled drug losses shall be reported to the pharmacy within 24 hours and resolved within 72 hours. If the drug is determined to be missing or unaccounted for, it shall be reported to the board and DEA as specified by 21 CFR § 1301.76-b.

(g) 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.

(h) The written report referenced in (a) shall contain at least the following:

(1) Date of discovery;

(2) Identity of the person making the discovery;

(3) 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) Cause of the controlled drug loss as determined by the investigation.

Ph 2301.06 Access to the Pharmacy.

(a) Only a pharmacist shall open and close the pharmacy for dispensing. The pharmacist-in-charge of each institutional pharmacy shall establish written policies identifying specific situations when authorized personnel 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, registered 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, as follows:

(1) The authorized nurse may enter the pharmacy area and remove the following:

a. A drug in its original container or a drug prepackaged for use within the facility subject to these rules; or

b. An emergency supply of a drug from the original container to be administered to a specific patient.

(2) The authorized nurse shall document the physician's medication order using a suitable form recording the following:

a. Name and strength of the drug taken;

b. Dosage form taken;

c. Quantity taken;

d. Time and date of withdrawal;

e. Patient name and location, where applicable; and

f. Nurse's signature.

(3) The nurse shall identify the bulk container from which the medication was taken or a representative sample of the unit-dose medication. In the event that a representative sample of a medication is not available to be left, then a photocopy of the label of the medication shall be acceptable.

Ph 2301.07 Drug Control In Ambulatory Patient Treatment Areas.

(a) In the ambulatory patient treatment areas, a practitioner authorized under under any other law of the state of New Hampshire may dispense drugs for the immediate needs of the patient, with no more than a maximum of a 72-hour supply, except:

(1) For Schedule II-IV controlled substances, a maximum of 48-hour supply; or

(2) Multi-dose forms of drugs such as, but not limited to, inhalers or epi-pens.

(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 dispensing of controlled drugs in the ambulatory patient area ambulatory patient area and contain the following:

(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 2301.0l(b), of the agent removing the drug(s) from the inventory.

Ph 2301.08 Investigational Drugs. lnvestigationa1 drugs for research shall be used only under the authority of the principal investigator. Such drugs shall be controlled by the pharmacy and shall be labeled according to the research protocols. The principal investigator shall provide essential information on such drugs to the current treatment team.

Ph 2301.09 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) Drugs including, but not limited to, radiopharmaceuticals, blood products, radiopaque media, biologicals, pharmaceutical chemicals, intravenous and irrigation drugs, and medical devices may be exempted from the approval and control of the pharmacist-in-charge by the institution's pharmacy and therapeutics committee or a comparable committee.

APPENDIX

Rule	Statute Implemented
Ph 2301.01	RSA 318:5-a, XII; RSA 318:5-a, XIII
Ph 2301.02	RSA 318:5-a, IV-a
Ph 2301.03	RSA 318:5-a, XIII
Ph 2301.04	RSA 318:5-a, XII
Ph 2301.05	RSA 318:5-a, XII
Ph 2301.06	RSA 318:5-a, XII
Ph 2301.07	RSA 318:5-a, XIII
Ph 2301.08	RSA 318:5-a, XII
Ph 2301.09	RSA 318:5-a, XII