Adopt Ph 2300 to read as follows:

PART 2300 INSTITUTIONAL PHARMACY PRACTICE

Ph 2301 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.

(c) "ADM" Automatic dispensing machines (ADM) or (automated drug cabinets) means a computerized drug storage and dispensing device used in the health care settings.

Ph 2302 Licensing.

(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. 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 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.

(c) 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.

Ph 2303 Practice Standards.

(a) An institutional permit 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.

(b) Members of the board and/or 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 facility is in compliance with all local, state, and federal drug and pharmacy laws and rules.

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

(d) 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 medication management, use of drugs, drug specifications, and drug distribution.

(e) The Institutional Pharmacy has the authority to develop and implement clinical pharmacy practice policies and procedures which provide optimum pharmaceutical care for patients.

(f) An institutional pharmacy may dispense a generic or therapeutic equivalent or bio-similar 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.

(g) Pharmacists may initiate or modify drug therapy by approved protocol according to institution policy. Drug therapy initiated or modified by protocol shall be documented in the medical record per hospital policy. The Pharmacist shall document in the medical record and this documentation shall be reviewed and signed by the provider per hospital institutional policies and procedures. Examples of protocols include but not limited to the following:

(1) Renal dosing;

(2) Antibiotic per Pharmacy;

(3) Medication Reconciliationp; and

(4) Outpatient IV.

(h) Drugs shall be dispensed in compliance with state and federal pharmacy-related laws and rules.

(i) 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.

(j) Orders shall be reviewed by a pharmacist before the medication is initially dispensed except in emergencies or when a pharmacist is unavailable. Medication orders shall be reviewed by a pharmacist within 24 hours. This regulation shall not be construed to prevent the distribution of drugs for floor stock or systems that perform auto-verification, which will be established in policy. Review may include, but is 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.

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

Ph 2304 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 all controlled substances based on institutional policies and procedures.

(e) 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.

(f) The institutional pharmacy shall have a designated area for the preparation of sterile products if sterile products are prepared. The pharmacy shall be in compliance with all board rules and regulations as they pertain to sterile compounding.

Ph 2305 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 or ADM or automated systems 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 based on institutional policies and procedures.

(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, registered pharmacy technician, or a designee 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 designed to prevent the illicit diversion of drugs.

(h) Controlled drug discrepancies 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 will be reported to the board and DEA as specified by 21 CFR § 1301.76-b.

Ph 2306 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 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 318:38,1 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

(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. 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 2307 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 dispensing of controlled drugs in the ambulatory patient area. 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 2301.0l(b), of the agent removing the drug(s) from the inventory.

Ph 2308 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 2309 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.