Adopt Ph 2500 to read as follows:

CHAPTER Ph 2500 AUTOMATED PHARMACY SYSTEMS

PART Ph 2501 PURPOSE AND SCOPE

Ph 2501.01 Purpose. The provisions of this chapter shall establish procedures for the use, documentation, security, maintenance, and monitoring of automated pharmacy systems.

Ph 2501.02 Scope. These rules shall apply to the placement of automated pharmacy systems in community remote sites, hospitals, and emergency drug kits, for the purpose of storage and dispensing of controlled and non-controlled prescription drugs.

PART Ph 2502 DEFINITIONS

Ph 2502.01 Definitions. Except where the context makes another meaning manifest, the following definitions shall apply:

(a) "Automated dispensing system" means an automated pharmacy system that is 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. These do not include prepackaging or repacking devices;

(b) "Provider pharmacy" means a pharmacy, licensed by the NH board of pharmacy, that provides pharmacy services by using an automated pharmacy system at a remote site or at the pharmacy site for use outside of pharmacy hours of operation in licensed pharmacy space;

(c) "Remote site" means a NH licensed long-term care facility, hospice facility, hospital, or state or county correctional facility, or other health care facilities that is not located at the same location as the provider pharmacy, at which pharmacy services are provided using an automated pharmacy system.

PART Ph 2503 REGISTRATION

Ph 2503.01 Application.

(a) Community pharmacies and provider pharmacies shall use application form "Automated Pharmacy System Registration Form", dated August 2022, to apply for placement of an automated pharmacy system at the desired location.

(b) The requirements on the form include:

(1) Name and address of the provider pharmacy;

(2) DEA number;

(3) If a remote location, the name and address of the remote site;

(4) Desired location in the facility where Automated Pharmacy System (APS) will be located; and

(5) Name of pharmacist in charge or consultant pharmacist.

(c) After receipt and review of the fully completed application the board shall approve or deny the location of the automated pharmacy system within 30 days.

PART Ph 2504 AUTOMATED PHARMACY SYSTEMS IN COMMUNITY SETTINGS

Ph 2504.01 Location, Access, and Other System Requirements.

(a) The automated pharmacy system shall be located within the prescription department, adjacent to the prescription department, or shall be located on the establishment of the licensed pharmacy, and the operation of the automated pharmacy system shall be under the supervision of a pharmacist.

(b) An automated pharmacy system that is not located within the prescription department shall be operated as an extension of the licensed pharmacy and the automated pharmacy system shall not require an independent and separate community pharmacy permit.

(c) Access to the automated pharmacy system shall be monitored and controlled as follows:

(1) Proper identification controls, including electronic passwords, biometrics, or other coded identification shall be utilized;

(2) Access control shall be limited and authorized by the pharmacist-in-charge or their authorized designee;

(3) The pharmacist-in-charge or their designee may have the authority to stop or change access at any time;

(4) The pharmacist-in-charge shall maintain a current and immediately retrievable list of all persons who have access and the limits of their access; and

(5) Review of user access reports shall be conducted periodically to ensure that access by persons no longer employed has been appropriately disabled.

(d) Access for maintenance or repair shall be pre-approved by the pharmacist-in-charge and shall be performed under the continuous supervision of a person with appropriate access authorization.

(e) A process of filling and stocking the system with drugs using an electronic or hard copy record of medication filled into the system shall include the product identification, lot number, and expiration date.

(f) The automated pharmacy system shall have adequate security and safeguards to prevent and detect unauthorized use or access, in order to protect patient privacy including the patients records and prescription drug orders.

(g) The system shall ensure that each finished, filled prescription is dispensed in compliance with all New Hampshire pharmacy laws including but not limited to an electronic or hard copy record of

prescription dispensing through the system, labelling requirements, and counselling.

(h) The system shall provide electronic identification or individual log in and passwords for patients to access the system.

(i) The system shall include a mechanism to ensure that the patient or an authorized agent of the patient has a means to communicate with a pharmacist regarding the medical drug product.

(j) The means of communication shall include at least one of the following:

(1) In person;

(2) Telephone; or

(3) Interactive face to face electronic communication.

(k) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, licensed advanced pharmacy technicians, certified pharmacy technicians, and registered pharmacy technicians involved in the dispensing of a prescription.

(l) After-hours access by the patient shall permitted provided all the criteria in (f) and (g) are followed.

(m) No automated pharmacy system shall be installed in compliance with the board's rules.

PART Ph 2505 AUTOMATED PHARMACY SYSTEMS IN REMOTE SITES

Ph 2505.01 Requirements for the Automated Systems in Remote Sites.

(a) A provider pharmacy may provide pharmacy services to remote sites properly licensed in New Hampshire through the use of an automated pharmacy system.

(b) An automated dispensing system shall only be used to provide pharmacy services to an inpatient or a resident of the remote site.

(c) The pharmacy shall have security to prevent unauthorized access. Such method shall include at least one of the following:

(1) Electronic password(s);

(2) Biometric identification (optic scanning or fingerprint); or

(3) Other coded identification.

(d) All the drug inventory stored in the automated pharmacy system shall be owned by the provider pharmacy.

(e) An automated dispensing system shall be under the supervision of a licensed pharmacist or licensed advanced pharmacy technician employed by the provider pharmacy who does not need to be the individual need not be physically present at the remote site if the system is supervised electronically.

(f) The pharmacist in charge and permit holder shall ensure that the automated dispensing system complies with RSA 318-B and 21 C.F.R., relating to the regulation of controlled substances, for each automated pharmacy system that contains a controlled substance.

(g) The pharmacist in charge shall ensure that the use of an automated dispensing system does not compromise patient confidentiality.

(h) A medicinal drug may be removed from an automated dispensing system for administration to a patient only after a prescription or order has been received and approved by a pharmacist at the provider pharmacy.

(i) A pharmacist at the provider pharmacy shall control all operations of the automated dispensing system and approve release of the initial dose of a prescription or order.

(j) A subsequent dose from an approved prescription or order may be released without additional approval of a pharmacist except that any change made in a prescription or order shall require a new approval by a pharmacist to release the drug.

(k) A pharmacist at the provider pharmacy shall comply with the patient record requirements and prospective drug use review requirements in the Ph 700 rules for every drug delivered through an automated pharmacy system.

(l) The stocking or restocking of a medicinal drug in an automated dispensing system at the remote site shall be completed by a pharmacist, licensed advanced pharmacy technician, certified pharmacy technician, registered pharmacy technician, or designated health care professional except as provided in (n) below.

(m) If the automated dispensing system uses removable cartridges or containers to store the drug, the stocking or restocking of the cartridges or containers may occur at the provider pharmacy and be sent to the remote site to be loaded by personnel designated by the pharmacist if:

(1) A pharmacist or licensed advanced pharmacy technician verifies the cartridge or container has been properly filled and labeled;

(2) The individual cartridge or container is transported to the remote site in a secure, tamper-evident container; and

(3) The automated pharmacy system uses bar code verification, electronic verification, or similar process to assure that the cartridge or container is accurately loaded into the automated dispensing system by pharmacist, a certified pharmacy technician, registered technician, licensed advanced pharmacy technician, or designated health care professional.

(n) A medicinal drug that has been removed from the automated dispensing system shall not be replaced into the system unless a pharmacist or licensed advanced pharmacy technician has examined the medication, packaging, and labeling and has determined that reuse of the medication is appropriate.

(o) If a provider pharmacy intends to store a controlled substance in an automated dispensing system:

(1) No additional DEA registration shall be required outside of the dispensing pharmacy if

used as an e-kit only in accordance with Federal Register 24128; and

(2) It may utilize one DEA registration to include multiple automated pharmacy systems located at a single address.

(p) Controlled substances shall only be released from the automated dispensing system to authorized personnel by a supervising pharmacist in compliance with provisions in 21 CFR 1306.11 and 21 CFR 1306.21.

(q) A provider pharmacy shall only store a medicinal drug at a remote site within an automated dispensing system which is locked by a mechanism that prevents access to a drug or to data by unauthorized personnel.

(r) Access to the drugs shall be limited to a pharmacist, certified pharmacy technician, registered pharmacy technician, licensed advanced pharmacy technician employed by the provider pharmacy, or licensed personnel in the facility or institution who are authorized to administer medications.

(s) An automated dispensing system that contains a controlled substance shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances.

(t) If an automated dispensing system is utilized for both a medication order for a specific patient and a non-controlled emergency medication for which the review of a pharmacist is not required the record shall include:

(1) The name of the medication;

(2) The patient's name;

(3) The name of the prescriber;

(4) The name of the person who accessed the automated dispensing system; and

(5) The date and time of the release.

(u) The record of transactions with the automated dispensing system shall be maintained in a readily retrievable manner.

(v) The record shall be available to a compliance investigator from the office of professional licensure and certification or the board of pharmacy.

(w) The record shall include:

(1) Name or identification of the patient or resident;

(2) Name, strength**,** and dosage form of the drug product released;

(3) Quantity of drug released;

(4) Date and time of each release of a drug;

(5) Prescription number or order number;

(6) Name of prescribing practitioner;

(7) Identity of the pharmacist who approved the prescription or order; and

(8) Identity of the person to whom the drug was released.

(x) Records of all transaction with the automated dispensing system shall be maintained for 4 years.

PART Ph 2506 AUTOMATED PHARMACY SYSTEMS FOR EMERGENCY KIT USE

Ph 2506.01 Definitions.

(a) "Automated electronic emergency drug kit" means an automated pharmacy system used for the immediate administration to patients or residents upon the order of a practitioner as set forth in rules adopted under RSA 151:2.

Ph 2506.02 Automated Pharmacy Systems Emergency Kit Use Requirements.

(a) Automated electronic emergency drug kits located in remote sites shall:

(1) Provide real time electronic communication to the provider pharmacy;

(2) Have a method to ensure security of the system to prevent unauthorized access. Such method shall include the use of electronic passwords, biometric identification or other coded identification;

(3) Be supervised by a New Hampshire licensed pharmacist or licensed advanced pharmacy technician employed by the provider pharmacy;

(4) Have all the drug inventory stored in the automated dispensing system shall be owned by the provider pharmacy;

(5) When placed in non-federally registered long term care facilities and other health care institutions be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:

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

b. Controlled substances in emergency drug kits are limited to a maximum of 250 total dosage units per kit;

c. Only the director of nursing services, registered nurse on duty, licensed practical nurse on duty, pharmacist, registered pharmacy technician, or New Hampshire licensed health care professionals authorized under regulations associated with their scope of practice shall have access to controlled substances stored in an automated electronic emergency

drug kit; and

d. Controlled substances are only released from the automated electronic emergency drug kit to authorized personnel by a supervising pharmacist in compliance with provisions in 21 CFR 1306.11 and 21 CFR 1306.21;

(6) Be able to 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 the drug removed; and

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

(7) Be restocked by a licensed pharmacist, licensed pharmacist assistant, physician, physician assistant, advanced practice nurse, registered nurse, certified pharmacy technician, or an advanced practice technician;

(8) Have a system to allow for records to be retrievable and in a readily available manner; and

(9) Allow for the storage of records of all transaction**s** with the automated pharmacy system for at least 4 years.

(b) In the instance where an automated system is unavailable the following criteria shall be met:

(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 250 dosage units per kit;

(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 a NH licensed healthcare professional authorized under regulations associated by their scope of practice shall have access to the 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 and shall be completed by the nursing staff when using any controlled substance or substances from the kit;

(8) The pharmacist shall receive a copy of all completed usage records and keep those records on file for a period not less than 2 years;

(9) When the emergency drug kit is opened a shift count shall be completed by the a member of the nursing staff on all controlled substances until the emergency drug kit is 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; and

(11) The pharmacist shall check the controlled substances in the emergency drug kit at least once a month and so document inside the kit.

Ph 2507 AUTOMATED PHARMACY SYSTEMS FOR HOSPITAL SETTINGS

Ph 2507.01 Automated Pharmacy Systems for Hospital Setting Requirements.

(a) Hospital permit holder**s** shall have policies in place to:

(1) Stop or change access to the system at any time;

(2) Maintain a current and immediately retrievable list of persons who have access and the limits of that access;

(3) Ensure the proper identification of controls, including electronic passwords or an electronic identifier shall be utilized and access control shall be limited and authorized by the pharmacist-in-charge, director, or their authorized designee;

(4) Review user access reports conducted periodically ensuring access by persons no longer employed have been appropriately disabled; and

(5) Allow for access for maintenance or repair to be pre-approved by the pharmacist-in-charge or director which is being performed under the continuous supervision of a person with appropriate access authorization.

(b) The automated dispensing system shall have adequate system security and safeguards to prevent and detect unauthorized access or use, maintain the integrity of patient records and prescription drug orders, and protect patient privacy.

(c) The filling, stocking, or replenishing of drugs into the automated dispensing system shall be accomplished by a pharmacist, certified technician, licensed advanced pharmacy technicians, registered technicians, or nurse and shall occur through bar coding or other electronic technology used for item identification.

(d) The automated medication supply system shall be able to generate a record on demand of drugs filled into the system that includes at least:

(1) Date;

(2) Drug name;

(3) Dosage form;

(4) Strength;

(5) Quantity;

(6) Drug expiration; and

(7) The name or initials of the authorized individual filling the system.

(e) If the automated medication supply system uses removable cartridges or containers to hold bulk drugs, the prepackaging of the cartridges or containers shall occur in the pharmacy where the original inventory is maintained.

(f) The prepackaged cartridges or containers may be sent to a remote dispensing site to be loaded into an automated dispensing system by a pharmacist or technician if:

(1) A pharmacist or licensed advanced pharmacy technician has verified the proper filling and labelling of the cartridge or container;

(2) The individual cartridges or containers are transported to the automated dispensing system in a secure, tamper-evident container; and

(3) The automated dispensing system utilizes technologies to ensure that the cartridges or containers are accurately loaded.

(g) Drugs stored in an automated dispensing system shall be contained in the manufacturers' sealed, original packages or in prepackaged unit-of use containers and shall be labelled as required.

(h) A pharmacist shall review the drug order prior to any removal from the system of a drug intended for immediate patient administration except if:

(1) The system is being used as an afterhours cabinet for drug dispensing in the absence of a pharmacist;

(2) The system is being used in place of an emergency kit;

(3) The drug is a subsequent dose from a previously reviewed drug order;

(4) The prescriber controls the drug administration process in procedural areas; or

(5) The drugs are approved for override by the pharmacy director, pharmacist in charge, or designee.

(i) The automated dispensing system shall provide a mechanism for securing and accounting for

drugs removed from and subsequently returned to the system.

(j) A drug removed from the system but not administered to a patient shall be returned as follows if unopened, sealed, intact and stored in compliance with the drug storage product rule to:

(1) The pharmacy immediately;

(2) The automated dispensing system for immediate reuse by authorized personnel in hospitals utilizing bar code scanning technology at the bedside or the automated pharmacy system;

(3) The automated dispensing system return bin; or

(4) An alternative, secure storage area until returned to the pharmacy.

Appendix

Rule	Specific State Statute the Rule Implements
Ph 2500	RSA 318:1, XXII; RSA 318:5-a, XII; RSA 318:42, XV; RSA 541-A:16, I(b)