

Adopt Ph 2100 to read as follows:

CHAPTER Ph 2100 INSPECTIONS

PART Ph 2101 AUTHORITY AND SCOPE

Ph 2101.01 Board Authority for Inspections. All inspections shall be conducted as stated in Ph 2104, as part of an investigation process, and at the request of the various regulatory boards listed in RSA 318:8-a and RSA 318:9-a.

Ph 2101.02 Scope. Registrants and licensees, including all pharmacists, pharmacies, and practitioners pursuant to RSA 318:8-a and RSA 318:9-a, shall permit the board investigators, board inspectors, and board commissioners to enter and inspect the premises and audit the records and operations for compliance with the statutes and rules enforced by or under the board's jurisdiction.

PART Ph 2102 DEFINITIONS

Ph 2101.02 Definitions. In addition to the definitions in RSA 318:1, the following definitions shall apply to this chapter:

(a) "Clinics" means an institution, building, or part of a building devoted to the diagnosis and care of outpatient ambulatory patients. The term also includes public health clinics and methadone clinics;

(b) "Compounding pharmacy" means a pharmacy licensed to perform the preparation, mixing, assembling, packaging or labeling of a drug or device as a result of a practitioner's prescription drug order;

(c) "Facility" means any pharmacy, hospital, medical clinic, practitioner office, methadone clinic, or veterinarian clinic that has prescription drugs on its premises and is inspected by the pharmacy board;

(d) "High risk compounding" means compounding that requires the use of non-sterile ingredients or non-sterile devices, which usually creates a high-risk condition. Exposing sterile ingredients and devices to air quality below ISO Class 5, an International Organization for Standardization metric for environmental management, will create a high-risk compounding situation, as will the prolonged storage of opened or partially-used products that lack antimicrobial preservatives in an environment in less than ISO Class 5 conditions;

(e) "In-patient institution" means a facility where a patient is formally admitted or hospitalized for treatment or care and stays for a minimum of one night in the hospital or other institution providing in-patient care;

(f) "Inspector" means a pharmacist or certified pharmacy technician employed by the pharmacy board to inspect facilities, to ensure that they comply with federal and state law and the rules established by the board;

(g) "Institution" means an "institution" as defined in Ph 701.02(h), namely as "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; and
- (6) Correctional facilities.

(h) “Institutional pharmacy” means an “institutional pharmacy” as defined in Ph 701.02(i), namely “an area in an institution where drugs are stored, manufactured, compounded, dispensed, or issued to other areas or departments of the institution;”

(i) “Investigator” means a pharmacist employed by the pharmacy board to investigate consumer complaints of pharmacy law or rule violations by a person licensed at the time the alleged violation occurred;

(j) “Licensee” means any person or entity which is licensed, certified, registered, or regulated by the pharmacy board or a board listed in RSA 318:8-a and RSA 318:9-a;

(k) “Limited retail drug distributor” means a distributor of prescription devices or medical gases delivered directly to the consumer pursuant to a practitioner's prescription order, or federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored, or dispensed to patients pursuant to the order of an authorized practitioner;

(k) "Limited retail drug distributor" means a distributor of legend devices or medical gases delivered directly to the consumer pursuant to a practitioner's prescription order, or federally funded clinics operated under contract with the department of health and human services and drug abuse treatment centers, where legend and controlled drugs are held, stored, or dispensed to patients pursuant to the order of an authorized practitioner;

(l) “Methadone clinic” is a clinic which has been established for the dispensing of methadone and other medications to treat opioid addiction. In the United States, by law, patients must receive methadone under the supervision of a physician, and dispensed through an opioid treatment program certified by Substance Abuse and Mental Health Services Administration and registered with the Drug Enforcement Agency;

(m) “Practitioner” means any person who is lawfully entitled to prescribe, administer, dispense or distribute prescription drugs to patients;

(n) ”Public health clinics”, are private, nonprofit organizations that directly or indirectly, through contracts and cooperative agreements, provide primary health services and related services to residents of a defined geographic area that is medically underserved. The term includes “community health centers (CHCs); and

(o) “Retail pharmacy” means a pharmacy that dispenses and sells prescription drugs to patients with a valid prescription in an outpatient setting at retail prices.

PART Ph 2103 PRE-INSPECTION REQUIREMENTS

Ph 2103.01 Licensee Pre-Inspection Duties for Pharmacies.

(a) All pharmacies shall be mailed, one to 3 months prior to inspection, a “Pre-Inspection Checklist”-advising the pharmacist-in-charge or designated representative that the items listed in (b) below must be readily available to pharmacy board inspectors at the beginning of the inspection.

(b) The following items must be available to board inspectors at the beginning of the inspection::

- (1) A printed list of the facility’s hours of operation;
- (2) The average daily and weekly volume of prescriptions processed;
- (3) The e-mail address of the pharmacist in charge or designated representative;
- (4) A list of all pharmacists employed at the pharmacy, with license number, if applicable;
- (5) A list of all certified pharmacy technicians employed at the pharmacy with registration number, if applicable;
- (6) A list of all registered pharmacy technicians employed at the pharmacy with registration number, if applicable;
- (7) A list of current pharmacy technician training data for technicians in certification training program, if applicable;
- (8) Date of most recent alarm test;
- (9) Policy for dispensing Narcan/naloxone
- (10) Copy of pharmacy’s break policy, if applicable;
- (11) Break counseling log book, if applicable;
- (12) Drug recall file;
- (13) Documentation of patient counseling, if applicable;
- (14) Protocol for vaccines;
- (15) Evidence of up to date pharmacist CPR certification, if applicable;
- (16) Pharmacist vaccination training information, if applicable;
- (17) Collaborative practice agreements, if applicable; and
- (18) Quality assurance information as stated in Ph 1700, if applicable;

(c) Pharmacies involved in sterile and non-sterile compounding shall have available for pharmacy board review a copy of their scheduled outsourced environmental monitoring report as required by Ph 405.05 relative to sterile quality requirements.

(d) Pharmacies shall make available all environmental monitoring reports upon request.

PART Ph 2104 INSPECTION FREQUENCY

Ph 2104.01 Scheduling. Inspections shall be:

(a) For any facility involved in sterile compounding, scheduled up to one month in advance;

(b) Unannounced for any other facility, notwithstanding the pre-inspection checklists sent to licensees in the quarter in which their inspection shall take place;

(c) Conducted upon the presentation of appropriate identification; and

(d) Investigators/inspectors shall present a “Notice of Inspection” form (#Ph510) upon arrival detailing the purpose of the inspection to the person of record on the day of the inspection. The form shall be signed underneath the following certification statement:

This is to acknowledge that NH Board of Pharmacy Inspector/Investigator, _____ has identified him/her self by presentation of official credentials pursuant to the provisions of NH RSA 318:8, RSA 318:8-a of the NH Pharmacy Act and RSA 318-B:25 of the NH Controlled Drug Act, and I hereby grant permission for the aforementioned Board agent to inspect any and all of the records relative to the receipt, distribution and security of prescription/legend drugs at this location. This also includes records which are required per the provisions of 21 CFR 1300 to end, of the Federal Controlled Substances Act. This inspection also addresses any other standards of practice issues outlined by other health care agencies, which these agents are charged to enforce. By my signature below, I hereby acknowledge the receipt of this Notice of Inspection and certify that:

1. I am the (title) _____, for the above described location;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have been provided with the purpose of this Notice of Inspection as noted above, but fully realize that the scope of this inspection may encompass ALL of the records required pursuant to the above mentioned State/Federal Statutes and Rules/Regulations; and
5. I have voluntarily consented to this inspection.

Ph 2104.02 Inspection Timeframes.

(a) Unless otherwise specified in this chapter, pharmacy board inspections shall be conducted at a minimum:

(1) Annually for:

a. Retail pharmacies;

b. Institutional pharmacies;

- c. Compounding pharmacies;
- d. Public health clinics; and
- e. Methadone clinics;

(2) Every 3 years for:

- a. Veterinarians and veterinary clinics without controlled substances;
- b. Drug manufacturers;
- c. Drug wholesalers;
- d. Limited retail drug distributors; and
- e. Naturopaths without controlled substances.

(3) Every 5 years for:

- a. Practitioners in private practice without controlled substances; and
- b. Medical and hospital clinic-based practitioner without controlled substances.

(b) The following entities possessing controlled substances shall be inspected at a minimum every 2 years;

- (1) Practitioners in private practice;
- (2) Clinic-based practitioners;
- (3) Veterinarians or veterinary clinics; and
- (4) Naturopaths.

PART Ph 2105 RISK LEVEL INSPECTIONS

Ph 2105.01 Risk Level Assignment

(a) Pharmacy inspections shall be conducted based on risk level as assigned by pharmacy board staff.

(b) Risk level shall be assigned by the pharmacy board compliance staff following inspection and shall be reevaluated on a yearly basis or upon:

- (1) A review of previous inspections;
- (2) A review of minor violations if applicable;
- (3) A review of control loss information;

(4) A major violation as set forward in this chapter; or

(5) Investigatory discipline as set forward in Ph 2200.

(c) A pharmacy's prescription volume level shall be evaluated by the pharmacy board compliance staff and assigned as:

(1) Low, for a prescription volume of less than 1,250 prescriptions per week;

(2) Medium, for a prescription volume of 1,250 or more and less than 2,000 prescriptions per week; and

(3) High, for a prescription volume of 2,000 or more prescriptions per week.

(d) Risk level assignments and inspections, in addition to the self-inspection requirements in Ph 2106, shall be as follows:

(1) For low risk inspections:

a. Pharmacy board inspections shall occur biennially; and

b. Low risk facilities shall include:

1. Retail pharmacies with a proven record of compliance for a period of 3 years;

2. Facilities with a low to medium prescription volume; and

3. Facilities with a pharmacist-in-charge with no violations in the previous 2 years and previous satisfactory inspection and stability of at least 2 years at the site;

(2) For medium risk inspections:

a. Board inspections shall occur annually; and

b. Medium risk facilities shall include:

1. Institution pharmacies not involved in sterile or non-sterile compounding;

2. In-patient institutions involved in sterile or non-sterile compounding as defined by United States Pharmacopeia Chapter 797 (USP 797);

3. High prescription volume pharmacies with a pharmacist-in-charge stability of at least 2 years at site as identified by pharmacy board staff;

4. Pharmacies with 6 minor violations or warnings, such as for temperature variations of refrigerated storage;

5. Non-sterile compounding pharmacies; and

6. Outpatient pharmacies involved in low to medium risk compounding as defined by USP 797; and

(3) For high risk inspections:

a. Pharmacy board inspections shall occur up to 2 times a year; and

b. High risk facilities shall include:

1. Outpatient pharmacies involved in high risk sterile and complex nonsterile compounding as defined by USP 797;

2. Retail pharmacies with any previous violation of federal law, including previous cases of drug diversion, or a record of non-compliance with state law or administrative rule by pharmacy staff or permit holders over a 3-year period;

3. Pharmacies with a pharmacist-in-charge change 3 or more times in one calendar year;

4. Pharmacies with any unresolved control drug loss forms pursuant to Ph 700; and

5. Practitioners, clinics, veterinarians, veterinary clinics, naturopaths, and non-institutional pharmacies involved in sterile and non-sterile compounding.

PART Ph 2106 SELF-INSPECTIONS

Ph 2106.01 Self-Inspection Requirements.

(a) A self-inspection shall be conducted in accordance with, and documented upon, the self-inspection survey provided by the pharmacy board.

(b) Upon a required self-inspection, the pharmacy board shall email to each licensee either:

(1) A “Retail Self-Inspection Survey,# ph538” revised 11/1/2018, or

(2) An “Institutional Self-Inspection Survey, #ph 557” revised 11/1/2018.

(c) Licensees shall complete all self-inspection surveys within 7 days of receipt.

(d) A self-inspection shall include environmental monitoring reports, if applicable under Ph 404.05, for board review.

(e) The original self-inspection form shall be printed, signed, dated, and kept on file in a readily available format upon pharmacy board inspection for 4 years.

Ph 2106.02 Required Self-Inspections by Risk Level.

(a) A low risk facility shall conduct a self-inspection each year in which it is not inspected by the pharmacy board.

(b) A medium risk facility shall conduct a self-inspection upon request by the pharmacy board.

(c) The pharmacy board shall request a self-inspection under (b) above upon receipt of a complaint involving the facility, upon receipt of a controlled drug loss form, or as a follow-up self-inspection after a regular board inspection.

Ph 2106.03 Self-Inspection for Change of the Pharmacist-in-Charge.

(a) A self-inspection shall be required within 7 days of a pharmacy board-approved change in a pharmacist-in-charge.

(b) A copy of the “change in pharmacist-in-charge” application, outlined in Ph 700, shall be on file and readily retrievable upon pharmacy board inspection or on request of the pharmacy board.

PART Ph 2107 INSPECTION PROCESS FOR PRACTITIONERS

Ph 2107.01 Inspection Practices. The pharmacy board shall develop inspection practices related to the practice of pharmacy for the following regulatory boards as stated in RSA 318:8-a and RSA 318:9-a:

- (a) Board of medicine;
- (b) Board of nursing;
- (c) Board of dental examiners;
- (d) Board of veterinary medicine;
- (e) Board of podiatry;
- (f) Board of registration in optometry; and
- (g) Naturopathic board of examiners.

Ph 2107.02 Performance of Inspections.

(a) Inspections shall be performed, after presentation of proper identification, by pharmacy board investigators, inspectors, or commissioners, and he or she shall have access to all records concerning the purchase, storage, labeling, distribution, compounding, reconstitution, and disposal of prescription drugs.

(b) Inspections for licensees of the boards included in RSA 318:8-a and RSA 318:9-a, shall include:

- (1) Verification of active DEA number and prescription monitoring program registration and all delegates;
- (2) General facility and security related to the practice of pharmacy;
- (3) Proper storage of medications;
- (4) Proper labeling of medications;

- (5) Complete record keeping of distribution of control drug medications;
- (6) Proper disposal of medications; and
- (7) Purchasing information of medications.

(c) Inspections for licensees involved with non-hazardous sterile and non-sterile compounding of medications as stated in 318:14-a shall include:

- (1) Verification of patient specific medications;
- (2) Purchasing information from pharmacy board-licensed wholesaler/manufacturer;
- (3) Training of personnel in aseptic technique and available for review;
- (4) Standards of practice policy and procedure for injectable or intravenous medications; and
- (5) Policy and procedure to ensure environment meets minimum requirements related to the practice of pharmacy.

(d) Inspections for licensees involved with hazardous sterile compounding of medications as stated in 318:14-a shall include:

- (1) Demonstrated adherence with Ph 404 standards concerning sterile compounding;
- (2) Be licensed with the pharmacy board as an institutional pharmacy/infusion center;
- (3) Policies and procedures for hazardous spills related to the practice of pharmacy; and
- (4) The spill kit in the facility.

2107.03 Inspection Frequency for Practitioners. Practitioner inspections shall occur based on a risk assessment level assigned by pharmacy board compliance staff based on the factors in Ph 2107.04 through 2107.06.

Ph 2107.04 Category I: High Risk. The following providers' offices that dispense or administer prescription medications shall be inspected biennially:

- (a) Veterinarians in private practice offering intravenous services for non-sterile and sterile compounding of medications;
- (b) Animal hospitals/clinics;
- (c) Oral surgeons;
- (d) Ambulatory surgical units (ASUs);
- (e) Provider offices offering intravenous services for sterile compounding; and

(f) Naturopath providers offering intravenous services.

Ph 2107.05 Category II: Medium Risk. For the following providers without controlled substances who dispense or administer prescription medications, inspections shall be every 3 years:

(a) Private practice providers without a hospital/HMO affiliation, also known as independent private practice providers; and

(b) Veterinarians in private practice.

Ph 2107.06 Category III: Low Risk. For the following providers without controlled substances who dispense or administer prescription medications, inspections shall be upon request of the provider's board or provider:

(a) Private practice physicians with a hospital/HMO affiliation;

(b) Providers who are always affiliated with a hospital/HMO;

(c) Naturopath providers with no prescription legend medications; and

(d) Other health care providers with no prescription legend medications.

PART Ph 2108 INSPECTION REPORTS

Ph 2108.01 Inspections.

(a) Inspections for pharmacy licensees, and licensees of the boards included in RSA 318:9-a and 318:8-a, shall include the certification listed in (d) and inspectors shall use the following forms:

(1) For retail pharmacies, all matter included in the "Retail Pharmacy-Inspection Form, #ph 511" revised 11/1/2018, available on the pharmacy board's website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(2) For institutional pharmacies, all matter included in the "Institutional Pharmacy-Inspection Form, #ph 519" revised 11/1/2018, available on the pharmacy board's website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(3) For long term care pharmacies, all matter included in the "Long Term Care Pharmacy-Inspection Form, #ph 516" revised 11/1/2018, available on the pharmacy board's website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(4) For methadone clinics, all matter included in the "Methadone Clinic-Inspection Form, #ph 517" revised 11/1/2018, available on the pharmacy board's website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(5) For manufacturers and wholesalers, all matter included in the "Manufacturer/Wholesaler-Inspection Form, #ph 518" revised 11/1/2018, available on the pharmacy board's website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(6) For practitioners and clinics, all matter included in the “Practitioner/Clinic-Inspection Form, #ph 554” revised 11/1/2018, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(7) For public health clinics, all matter included in the “Public Health Clinic-Inspection Form, #ph 520” revised 11/1/2018, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(8) For naturopathic practitioners and clinics, all matter included in the “Naturopathic Practitioner/Clinic Inspection Form, #ph 560” revised 11/1/2018, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(9) For facilities which maintain controlled substances, all matter included in the “Controlled Substance-Inspection Form, #ph 512” revised 11/1/2018 available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(10) For home infusion and sterile compounding facilities, all matter included in the “Home Infusion/Sterile Compounder-Inspection Form, #ph 513” revised 11/1/2018, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(11) For prescription device and medical gas distributors, all matter included in the “Inspection Form Prescription Device/Medical Gas Distributors, form # ph 515,” revised 11/1/2018, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>;

(12) For break policies involving pharmacists, all matter included in the “Pharmacist Break Policy Supplemental Inspection Form ph 553,” revised 11/1/2018, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>. and;

(13) For practitioners offices, all matter included in the “Facilities performing IV infusion according to Manufacturer Labeling or Aseptic Technique Form # ph 559” revised 11/1/2018, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>.

(14) For compounding and dispensing parenterals in an institutional setting USP 795/797 inspection form Ph 514 revised 11/1/18, available on the board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>.

(15) For compounding and dispensing non-sterile preparations, compounding audit inspection form Ph 563 revised 11/1/19, available on the board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>.

(16) For compounding and dispensing sterile preparations, compounding audit inspection form Ph 564, revised 11/1/19, available on the board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>.

(b) Upon inspection, all prescription and medication files requested by the investigator or inspector shall be available on demand.

(c) If, during the course of an inspection, the inspector identifies a violation of an administrative rule, the inspector shall issue a minor or major violation notice to the licensee as stated in Ph 2200 and Ph 2109.

(d) The inspection forms listed in (a) above shall require a representative's signature on the following certification:

My signature acknowledges my awareness and understanding of all entries and notations made on this report and my receipt of a copy thereof. I also understand my responsibilities for corrective action as outlined above.

Ph 2108.02 Inspection Report Requirements.

(a) Inspectors or investigators shall have all inspection reports, that is, forms as described in Ph 2108.01, reviewed and signed by the pharmacist on duty or designated representative at the completion of an inspection.

(b) A copy of the inspection report shall be provided to the licensee or registrant and shall be made available, in a readily retrievable manner, on request of the pharmacy board.

(c) Inspection report results shall be:

- (1) Satisfactory, indicating no issues or violations;
- (2) Unsatisfactory, indicating the finding of a violation; and
- (3) Not applicable.

(d) If an "unsatisfactory" result on a pharmacy inspection occurs, the pharmacist-in-charge shall be required to do the following:

- (1) Immediately fix the issues noted by the investigator or inspector and respond in writing to the pharmacy board within 10 days with a detailed report on the actions taken;
- (2) If an immediate fix is not possible, then a detailed action plan shall be developed with a timeline that shall be approved by the investigator or inspector; or
- (3) Schedule an immediate follow up inspection, if applicable.

(e) If an "unsatisfactory" result on a provider inspection occurs, the report shall be forwarded to the respective board for review.

(e) The current compliance inspection report of the licensed location, conducted by the board, shall be kept on file in the facility per Ph 703.06.

(f) Inspection reports shall be stored by the pharmacy board in a licensing data base by name of the permit holder and the pharmacist-in-charge.

PART Ph 2109 VIOLATION AND VIOLATION NOTICES

Ph 2109.01 Violation Notices.

(a) The board inspector shall issue a violation notice to a licensee should the inspector find, during the course of an inspection, noncompliance with an administrative rule or federal, state, or local law related to the practice of pharmacy. A licensee or practitioner may contest any notice of violation as provided in Ph 2207.02.

(b) All violation notices shall be forwarded to the respective regulatory board of the licensee for review and appropriate action.

(c) Violations of rules under RSA 318-B shall result in a fine by the pharmacy board.

(d) Violation notices that are not appealed, or that are determined to be founded after appeal, shall be kept on file in an appropriate licensing data base of the pharmacist-in-charge and permit holder. All violation notices shall be readily retrievable upon inspection, investigation, or request of the pharmacy board for a period of 2 years.

Ph 2109.02 Minor Violations.

(a) The minor violations shall be as listed in Ph 2109.07.

(b) Remediating any minor violations shall be the responsibility of the pharmacist-in-charge and the permit holder. All corrective action taken shall be documented and mailed to the pharmacy board office with 15 days of notification.

(c) The investigator/inspector shall review remediation and respond if not satisfactory.

(d) All minor violation notices shall be made available to the pharmacy board at next scheduled meeting.

(e) Repeat minor violations shall result in board review with a consideration for further disciplinary action under RSA 318:29.

Ph 2109.03 Major Violations.

(a) Major violations shall as listed in Ph 2109.08.

(b) All major violations for those regulated by the board of pharmacy shall be the responsibility of the pharmacist-in-charge and the permit holder. The pharmacist-in-charge and the pharmacist on duty at the time of violation shall be responsible for correcting the violation. This corrected action shall be recorded on the violation notice and returned to the inspector or investigator within 15 days of receiving the notification.

(c) Major violations shall be reviewed by the pharmacy board at the next scheduled meeting for possible further disciplinary action.

(d) Major violations for practitioners shall be referred to the respective regulatory board for review.

Ph 2109.04 Prescription Drug Monitoring Program Violation Notifications.

(a) Any person or entity who fails to submit the information required in RSA 318-B:33, or knowingly submits incorrect information, shall be subject to a warning letter and provided with an opportunity to correct the failure.

(b) Any person or entity who subsequently fails to correct such failure, or who fails to resubmit the information, shall be subject to discipline by the board in reference to RSA 318-B:36.

Ph 2109.05 Administrative Fines. Violations found in the course of an inspection shall be subject to administrative fines pursuant to Ph 2207.02.

Ph 2109.06 Prescription Monitoring Program Audit.

(a) Pharmacy board investigators/inspectors shall audit prescriptions at the request of the PMP auditor during normal inspection;

1. Auditor shall request from pharmacy/provider 8 prescriptions from random sampling a minimum of 2 weeks prior to inspection;

2. Pharmacy board investigators/inspectors shall verify data per audit procedure and return copied information to auditor; and

3. Pharmacy board investigators/inspectors shall select 2 additional prescriptions for audit per audit procedure.

(b) Failure to provide or correct data per RSA 318-B:36, I shall be subject to pharmacy board review and possible disciplinary action under RSA 318:29.

Ph 2109.07 Minor Violation Schedule. The following violations shall be considered minor violations for which licensees shall be subject to a \$25.00 fine:

(a) General Violations:

(1) Pharmacist license is not posted;

(2) Pharmacy has insufficient equipment;

(3) The work area is not orderly and clear of obstructions;

(4) Equipment inspection/calibration issues;

(5) Pharmacy permit not posted;

(6) Improper security;

(7) Out of date or mislabeled drug;

(8) Improper drug storage;

- (9) Improper drug destruction;
 - (10) Improper supervision of support personnel;
 - (11) Improper registration procedures;
 - (12) Nametags;
 - (13) Improper documentation of training;
 - (14) Improper return to stock procedures;
 - (15) Improper dispensing/labeling;
 - (16) No drug regimen review;
 - (17) No P&P manual;
 - (18) Food in Rx refrigerator;
 - (19) Shelving not clean and orderly;
 - (20) Outdated drugs separate from active inventory;
 - (21) Quality Assurance Info Unavailable;
 - (22) Quality Assurance Meeting Held Quarterly;
 - (23) Purified Water System Inadequate;
 - (24) No hot/cold running water;
 - (25) No CMEA certificate;
- (b) Retail Violations:
- (1) Prescription lacks proper information;
 - (2) Counseling area inadequate;
 - (3) No counseling by RPh;
 - (4) Do not fill date followed;
 - (5) Allergies not properly noted;
 - (6) No CPR certification for vaccines;
 - (7) No vaccine provider information;

- (8) Vaccination standing order;
 - (9) No lunch break;
 - (10) No lunch break signage;
 - (11) Improper automated dispensing procedures;
 - (12) Improper telephone/voicemail order intake;
 - (13) Patient care guidelines incomplete;
- (c) Hospital violations:
- (1) Area for non-sterile compounding inadequate;
 - (2) Records for non-sterile compounding;
 - (3) Master compounding formulary;
 - (4) Improper procedures for IV preparation;
 - (5) Area for preparation of sterile products;
 - (6) Improper packaging procedures;
 - (7) Cytotoxic/biohazardous procedures;
 - (8) Open multi-dose vials expiration dates;
- (d) Controlled Substances:
- (1) Controlled substance vendor return confirmation;
 - (2) CII locked or dispersed;
 - (3) No power of attorney;
 - (4) Dispensing record not available;
 - (5) Improper transfer of prescription controlled substances;
 - (6) Controlled substance prescription pharmacist sign/date;
 - (7) Prescription 222 form records not in numerical order;
 - (8) Non-compliant NH controlled drug loss/DEA 106 forms;
 - (9) Controlled substances invoices not separated;
 - (10) No CII monthly perpetual inventory;

- (11) No daily/nightly controlled substances log;
 - (12) Controlled substances returns procedure inadequate;
- (e) PDMP:
- (1) Failure to verify prescriptions with the PDMP; and
 - (2) PDMP provider verification.

Ph 2109.08 Major Violation Schedule. The following shall be considered major violations:

(a) For which licensees be subject to a \$100.00 fine:

- (1) The failure of equipment such as the medication/vaccine refrigerator or freezer, hot or cold water, heat of air conditioning failure causing the pharmacy to be outside the appropriate temperature range for proper drug storage per the manufacturer;
- (2) Failure to Maintain Temperature Logs;
- (3) No Signage on Hardcopy of C/S Rx;
- (4) Printed C/S Rx Not Marked Copy Only- Not Valid for Dispensing
- (5) Immunizing Pharmacist or Immunizing Intern with Expired CPR Certification or Liability Insurance Policy;
- (6) CII Inventory Missing or Incomplete;
- (7) Failure to Report Changes of Name, Address, or Work Location within 15 Days; and
- (8) Pharmacist technician or intern working in the pharmacy while unregistered or with an expired registration.

(b) For which licensees shall be subject to a \$250.00 fine:

- (1) DEA 222 forms were not sent to the DEA; and
- (2) A registered pharmacy technician has been performing certified pharmacy technician duties.

(c) For which the licensee shall be subject to a \$500.00 fine:

- (1) The biennial inventory is missing or not done;
- (2) A failure to report a controlled substance loss;
- (3) A pharmacist has been working in the pharmacy while unlicensed or with an expired license;

- (4) The pharmacy is an unfit place to work;
 - (5) The pharmacy failed to report a change of its pharmacist-in-charge in a timely manner;
 - (6) No pharmacist-in-charge change inventory was done;
 - (7) The pharmacy has been operating without a pharmacist-in-charge; and
 - (8) Issues with pharmacy access or security.
- (d) The licensee shall be subject to a \$1,000.00 fine if the pharmacy is not registered with the PDMP.
- (e) The licensee shall be subject to a \$5,000.00 fine if the licensee has failed to respond to a violation notice or report of investigation.

Appendix

Rule	State Statute
Ph 2101.01	RSA 318:5-a, IX; RSA 541-A:16, I(b)
Ph 2102.01	RSA 318:5-a, IX; RSA 318:8-a; RSA 318:9-a; RSA 318-B:25; RSA 541-A:16, I(b)
Ph 2102.02	RSA 318:5-a, IX; RSA 318:8-a; RSA 318:9-a; RSA 318-B:25; RSA 541-A:16, I(b)
Ph 2103.01	RSA 318:5-a, IX; RSA 541-A:16, I(b)
Ph 2104.01	RSA 318:5-a, IX; RSA 541-A:16, I(b); RSA 318-B:25
Ph 2104.02	RSA 318:5-a, IX; RSA 318:8-a; RSA 318:9-a; RSA 318-B:25
Ph 2105.01	RSA 318:5-a, IX; RSA 541-A:16, I(b); RSA 318-B:25
Ph 2106.01	RSA 318:5-a, IX; RSA 541-A:16, I(b)
Ph 2106.02	RSA 318:5-a, IX; RSA 541-A:16, I(b)
Ph 2106.03	RSA 318:5-a, IX; RSA 541-A:16, I(b)
Ph 2108.01	RSA 318:5-a, IX; RSA 318-B:25; RSA 318:8-a; RSA 318:9-a; RSA 541-A:16, I(b)
Ph 2108.02	RSA 318:5-a, IX; RSA 318-B:25; RSA 541-A:16, I(b)
Ph 2109.01	RSA 318:5-a, IX; RSA 318-B:25; RSA 318:29; RSA 541-A:16, I(b)
Ph 2109.02	RSA 318:5-a, IX; RSA 318-B:25; RSA 318:29; RSA 541-A:16, I(b)
Ph 2109.03	RSA 318:5-a, IX; RSA 318-B:25; RSA 318:29; RSA 541-A:16, I(b)
Ph 2109.04	RSA 318:5-a, IX; RSA 318-B:25; RSA 318:29; RSA 541-A:16, I(b)
Ph 2109.05	RSA 318:5-a, IX; RSA 318-B:25; RSA 318:29; RSA 541-A:16, I(b)