

Readopt with amendment Ph 2106.01, effective 4/11/20 (Document #13028), to read as follows:

Ph 2106.01 Self-Inspection Requirements.

(a) Each pharmacy shall conduct a self-inspection at least 3 months before the date their license is set to expire but no sooner than 5 months before the license is set to expire.

(b) The self-inspection report shall be submitted to the board's office at least 2 months prior to the date the license is set to expire.

(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] **permit holder** either:

(1) A “Retail **Pharmacy – Self-Inspection [Survey] Report**” **completed by a designee of the permit holder who is licensed, as defined in RSA 541:A-18, by the board** [~~ph 538~~ revised 11/1/2018] **described in (c) below, or**

(2) An “Institutional Self-Inspection Survey” [~~ph 557~~ revised 11/1/2018] **completed by a designee of the permit holder who is licensed, as defined in RSA 541:A-18, by the board described in (d) below.**

(c) The “Retail Pharmacy – Self-Inspection Report” shall require the submission of the following information:

(1) Reason for self-inspection:

a. Annual audit; or

c. If other list;

(2) Date report completed;

(3) Name of pharmacy;

(4) Address of pharmacy;

(5) Pharmacy license number;

(6) DEA registration number and expiration date;

(7) Pharmacy phone number;

(8) Hours of operation including time of RPh lunch break;

(9) Name of the pharmacy's designee, license number, and primary contact e-mail address;

(10) Date the designee became employed at the pharmacy;

(11) Attached to this form a list of all staff employed in the pharmacy which includes all pharmacists, pharmacy interns, licensed advanced pharmacy technicians, certified pharmacy technicians, and registered pharmacy technicians. The list shall include their full name, NH board of pharmacy license or registration number, and expiration date;

(12) Yes, no, or not applicable to the following pharmacy personnel questions and if applicable any corrective action taken or general comments:

a. Do all certified pharmacy technicians perform only those tasks allowed under Ph 812.02?

(13) Yes, no, or not applicable to the following documents and records questions and if applicable any corrective action taken or general comments:

a. Is a copy of the most recent inspection report on file and readily retrievable within the pharmacy, Ph 2106.02 and Ph 2106.03?;

b. Is the most recent biennial controlled substance inventory on file and readily retrievable within the pharmacy and if yes list the date the most recent inventory was completed, 21 CFR 1304.04(a);

c. Are the schedule II-V invoices for the past 24 months inventory readily retrievable, 21 CFR 1304.04(a)?;

d. Are the completed CII order forms, DEA form 222, for the past 24 months readily retrievable, Ph 1304.04(a)?; and

e. Are completed CSOS order forms for the past 24 months readily retrievable, Ph 1304.04(a)?;

(14) Yes, no, or not applicable to the following licenses and permits questions and if applicable any corrective action taken or general comments:

a. Is the current state pharmacy permit posted, displayed, and plainly visible, RSA 318:39?;

b. Is the current DEA certificate posted, displayed, or in a location that is readily retrievable, 21 CFR 1301.35(c)?;

c. Does the pharmacy have a current combat methamphetamine certificate, 21 CFR 1314.40 and if yes provide the expiration date; and

d. Is the current license of all pharmacists practicing at this pharmacy posted, displayed, and plainly visible, RSA 318:28?;

(15) Yes, no, or not applicable to the following pharmacy policies and procedures questions and if applicable any corrective action taken or general comments:

a. Are policies and procedures available regarding non-sterile compounding, Ph 404.03(j)?;

b. Are policies and procedures available regarding vaccine, Ph 1304.01(c)?;

c. Are policies and procedures available regarding quality assurance, Ph 1703.01(c)?;

d. Are policies and procedures available regarding pharmacist break policy, Ph 703.01(b)?; and

e. Are policies and procedures available regarding initiating and dispensing or hormonal contraception, Ph 2403.01(c)?;

(16) Yes, no, or not applicable to the following pharmacy physical facility questions and if applicable any corrective action taken or general comments:

a. Are drugs that require refrigeration maintained between 36 and 46 degrees fahrenheit, RSA 146:4 and Ph 2107.02(b)(3)?;

b. Are drugs that are required to be frozen maintained at a temperature less than 5 degrees fahrenheit, RSA 146:4 and Ph 2107.02(b)(3)?;

c. Are drugs that require room temperature maintained between 66 and 78 degrees Fahrenheit, RSA 146:4 and Ph 2107.02(b)(3)?; and

d. For Pharmacy security does the pharmacy have a policy and procedure that prevents unauthorized access to the pharmacy, RSA 318:38, Ph 2107.02(b)(2)?;

(17) Yes, no, or not applicable to the following patient counseling questions and if applicable any corrective action taken or general comments:

a. Is the patient counseling area within the licensed and alarmed pharmacy area, Ph 303.02(n)?; and

b. Is the patient's refusal or acceptance of counseling documented and if yes provide a description of how the record is kept?;

(18) Yes, no, or not applicable to the following compounding in pharmacy questions and if applicable any corrective action taken or general comments:

a. Is all non-sterile compounding, not including reconstituting antibiotics, performed only by the pharmacists, intern, licensed advanced pharmacy technician, or certified pharmacy technician, Ph 812.02(a)(8), Ph 1606.01(d), and Ph 1807.02(a)?;

b. Are all sources of ingredients for compounding USP, NF, or FCC approved Ph 404.03(f)(1)?;

c. Is a master formulary record available and readily retrievable, Ph 404.03(i)(4)?; and

d. Is adequate hand and equipment washing facilities easily accessible to the compounding areas, Ph 404.03(d)(3)?;

(19) Yes, no, or not applicable to the following pharmacy dispensing questions and if applicable any corrective action taken or general comments;

a. Do Rx profiles include allergy information, Ph 704.01(c)(1)?;

b. Are all telephoned prescriptions dated, initialed, and documented with the name of the person who called in the prescription when transcribed to paper, RSA 318:47-c, I(a)?; and

g. Does the pharmacy dispense drugs that are not outdated, mislabeled, or adulterated, Ph 703.07?;

(20) Yes, no, or not applicable to the following continuous quality improvement (CQI) questions and if applicable any corrective action taken or general comments:

a. Does the pharmacy maintain a written copy of its CQI program description in the pharmacy or is it readily retrievable, Ph 1703.01?; and

b. Does the pharmacy have a current log of mandatory CQI meetings and proper documentation, Ph 1706.01 and if yes list the dates of the last 4 CQI meetings, Ph 1705.01?;

(21) Yes, no, or not applicable to the following immunizations questions and if applicable any corrective action taken or general comments:

a. Are immunizations administered at the pharmacy, RSA 318:16-b?;

b. Is proof available onsite that each immunizing pharmacist meets the education requirements, including having current CPR certification, Ph 1303.01?;

c. Are all of the pharmacy's immunizing pharmacists registered with the board as immunizing pharmacists, Ph 1303.02?;

d. Are signed copies of the patient immunization consent forms retained and are they readily retrievable, Ph 1304.02?;

e. When a patient so authorizes are providers notified when a patient is given an immunization, Ph 1304.01(f)?;

f. Does the documentation of each injection include the name of the medication administered, lot number, and expiration date, Ph 1304.02(b)?; and

g. Does the documentation of each injection include the name of the pharmacist administering the injection, Ph 1304.02(f)?;

(22) Yes, no, or not applicable to the following controlled substances questions and if applicable any corrective action taken or general comments:

- a. Do you order schedule II controlled substance with a paper DEA 222 form, 21CFR 1305.03? If the answer is no the board assumes the pharmacy uses CSOS;
 - b. Are schedule II order forms and invoices filed separately, 21 CFR 1305.17(c)?;
 - c. Are controlled drugs returned for disposal via a reverse distributor, 21 CFR 1317.05(b)(2), and if yes name the reverse distributor under comments;
 - d. Has there been any loss of controlled substances since the last inspection and if yes provide the number of drug loss reports filed and did you complete and submit a report of all theft's/losses to the board within 1 business day, Ph 702.03(a);
 - e. Do prescriptions for controlled substances contain the prescriber's name, address, and DEA number, 21 CFR 1306.05(a)?;
 - f. Do prescriptions for controlled substances contain the date of issue, 21 CFR 1306.05(a)?;
 - g. Do prescriptions for controlled substances contain the date of filling, RSA 318-B:9, I?;
 - h. Are all schedule II prescriptions dispensed from the pharmacy the appropriate day supply based on diagnosis, RSA 318-B:9, IV?;
 - i. Are "Do not fill until _____" notations in compliance and not filled prematurely, 21 CFR 1306.12(b)(1)(ii)?;
 - j. Are schedule II prescriptions accepted electronically, RSA 318:47, III?;
 - k. was the NH prescription drug monitoring program checked and verified before filling all schedule II prescriptions?;
 - l. Are schedule II prescriptions accepted electronically?;
 - m. Are electronically ordered schedule II prescriptions kept on file if they are printed out and if yes are they marked "Copy only – not valid for dispensing. Enter the phrase or wording printed or stamped on the print outs, 21 DFR 1311.170(c);
 - o. Are hard copies of schedule II prescriptions cancelled signed and dated by the filling pharmacist, RSA 318-B:9, I?;
 - p. Are hard copies of schedule II prescriptions cancelled, signed, and dated by the filling pharmacist, RSA 318-B:9, I?; and
 - q. Is monthly perpetual inventory of all schedule II drugs available for inspection, Ph 702.03(d)?;
- (23) Controlled substance audit shall be completed by providing the following information for 3 separate schedule II controlled substances in stock at the pharmacy

which were dispensed during the audit period. It is not acceptable to choose drugs that were not dispensed during the audit period and then report “zero” sales:

a. Name of the pharmacy and NH pharmacy permit number;

b. Dates of audit period as follows:

1. From: date that is the date of the last biennial inventory; and

2. To date: which is the date the audit was done;

c. For each of the controlled substances chosen for audit the following information:

1. Name of CII drugs audited;

2. Amount on hand at last inventory;

3. Amount purchased and received since last inventory;

4. Amount sold or dispensed since last inventory;

5. Provide the number after completing the following calculation:

“Amount on hand at last inventory plus amount purchased and received since last inventory minus Amount sold or dispensed since last inventory”

6. Provide the current physical inventory count of the drug in the pharmacy;

7. Provided the number after completing the following calculation:

“Calculated amount from 5. above minus the current amount listed in 6. above;

(24) The permit holders designate who licensed by the board, as defined in RSA 541:A-18, their license number, signature, and date of signing below the following preprinted statement:

“I certify that I have performed the self-inspection of this pharmacy, as well as the controlled substance audit section of this form and affirm that is is an accurate and truthful assessment of the pharmacy as the date of this self inspection.”

(d) The “Institutional Pharmacy – Self-Inspection Report” shall require the submission of the following information:

(1) Reason for self-inspection:

a. Annual;

b. Audit; or

c. If other list;

(2) Date report completed;

(3) Name of pharmacy;

(4) Address of pharmacy;

(5) Pharmacy license number;

(6) DEA registration number and expiration date;

(7) Pharmacy phone number;

(8) Pharmacy e-mail address;

(9) List the pharmacists at the institutional pharmacy indicating their full name, NH license number, whether or not they are performing sterile compounding, and whether or not their sterile compounding training is on file at the pharmacy, Ph 404.05(a);

(10) List the pharmacy interns at the institutional pharmacy providing their full name, NH intern number, name of pharmacy school attending, month and year of anticipated graduation date, whether or not they are performing sterile compounding, and whether or not their sterile compounding training is on file at the pharmacy, Ph 404.05(a);

(11) List of licensed advanced pharmacy technicians at the institutional pharmacy providing their full name, NH license number, whether or not they are performing sterile compounding, and whether or not their sterile compounding training is on file at the pharmacy, Ph 404.05(a);

(12) List the certified pharmacy interns providing their full name, NH certification number, whether or not they are performing sterile compounding, and whether or not their sterile compounding training is on file at the pharmacy, Ph 404.05(a);

(13) List the registered pharmacy technicians including their full name and registration number;

(14) Answer the following questions regarding refrigeration and freezers:

a. How is the refrigerator temperature is monitored and logged, Ph 2301.03(c)(1)?;

b. How is the freezer temperature monitored and logged, Ph 2301.03(c)(1)?;

c. Yes or no to is there a policy and procedure for handling temperature excursions of the refrigerator, freezer, and room temperature, Ph 2301.03(c)(1)?; and

d. Yes or no to were there any temperature excursions in the last 30 days and if yes describe corrective action taken;

(15) Answer yes or no to the following questions regarding patient owned medications:

a. Are the medications admitted with patient properly stored and secured according to the hospital's or facility's policies?;

(16) Answer yes or no to the following questions regarding pharmacist remote order entry:

a. "Does the pharmacist do remote order entries and if yes provide the company used, list the pharmacists, and their NH license numbers, Ph 1203.01(d);

(17) Answer yes or no to the following questions regarding emergency medical services (EMS) medications, Ph 2301.03, I:

a. Does the pharmacy provide EMS with non-controlled medications?;

b. Does the pharmacy provide EMS with controlled medications and if yes the type of EMS medications Provided:

1. Kit exchange;

2. Item exchange; or

3. Other and speify;

c. Is there a written policy and procedure regarding EMS medications?;

d. Is proof-of-use forms utilized to adequately account for controlled substances used?;

e. Is controlled substance kit sealed upon delivery to ALS/EMT?; and

f. Is controlled substance kit sealed upon return from ALS/EMT?;

(18) Answer yes or no to the following question regarding the emergency room:

a. Are controlled substances dispensed from emergency room and if yes answer the following pertaining to the emergency room:

1. What type of ER controlled substance dispensing log is used, a ADM or manual, RSA 318-B:10, I;

2. Is ER dispensing of schedule II controlled drugs limited to no more than 2 day supply, RSA 318-B:10, I?;

3. Is the ER dispensing of schedule III-V controlled drugs limited to no more than a 7-day supply, RSA 318-B:10, II;

4. If yes is and dispensing greater than 48 supply of schedule III-IV being reported to PDMP, RSA 126-A:89, VI(a)

5. If yes are labels for ER dispensing meds adequate per RSA 318:47-a?; and

6. If yes are opioids dispensed with appropriate warning labels/information per RSA 318-B:16-a?;

(19) Answer the following questions regarding ancillary drug storage areas and automated dispensing machines:

a. What types of ancillary drug storage areas and automated dispensing machine (ADM) are used:

1. Med closet;

2. Medication room;

3. Pyxis;

4. Omnicell, or

5. Other and specify;

b. The total number of ADM's in use? If none enter 0; and

c. If scanning technology is used is resupply checked by a certified pharmacy technician, Ph 2507.01(c)?;

(20) Answer the following questions regarding controlled substances (CS):

a. Is the most recent CS biennial inventory available and readily retrievable, and if yes what is the date it was completed, RSA 318-B:12?;

b. Are the schedule II – V invoices for the past 24 months readily retrievable?

c. What is the number of CS loss reports filed with NH Board of Pharmacy within the last 12 months?;

d. Is the dose reconciliation performed by the pharmacy:

1. Daily;

2. Weekly;

3. Other; or

4. Not applicable;

3. Is the ADM cycle count discrepancy reviewed by the pharmacy:

1. Daily;

2. Weekly;

3. Other; or

4. Not applicable; and

4. Is the diversion specialist or diversion committees utilized on site or contracted?;

(21) Answer the following questions regarding compounded sterile products (CSP), RSA 318:14-a:

a. What type of sterile compounding is performed, checking all that apply?:

1. Immediate use;

2. Low risk;

3. Medium risk; or

4. High risk;

b. Does the pharmacy utilize a segregated compounding area?;

e. Is there an ante room adjacent to the buffer room, Ph 404.02(c) and Ph 404.05(af)?;

f. Did all HEPA filters pass inspection, Ph 404.07(c);

g. Is hazardous compounding performed?

h. What is the type of primary engineering control, checking all that apply?:

1. CAI;

2. LAWF;

3. CACI;

4. BSC;

i. Since the last board inspection, has any primary engineering control (PEC) equipment been relocated or has there been a remodel, Ph 306.02 and Ph 306.04?;

(22) Answer the following questions or provide information regarding sterile area(s):

a. Is there a classified buffer room, Ph 404.01(q) and:

1. If yes provide all information required by the section; or

2. If no skip this section;

b. Provide the air exchange number per hour for each of the following applicable rooms:

1. Ante room;

2. Non-HD buffer room;

3. HD buffer room”;

c. Provide the date of last ISO certification for each of the following applicable rooms:

1. Primary Engineering Control (PEC) (Non-HD);

2. Primary Engineering Control (Pec)(HD

3. Ante room;

4. Non-HD buffer room;

5. HD buffer room;

d. Provide the date of last air pressure test for each of the following applicable adjacent rooms:

1. Primary Engineering Control (PEC) (Non-HD);

2. Primary Engineering Control (Pec)(HD

3. Ante room;

4. Non-HD buffer room;

5. HD buffer room;

6. HD storage area;

e. Do you have documentation of uni-directional air flow for the following hoods:

1. Primary engineering control (PEC) non-HD; and

2. Primary engineering control (PEC) HD;

f. Is the primary engineering control (PEC) HD and HD buffer room vented to the outside of the building;

g. Is a temperature log maintained for the following areas:

1. Primary Engineering Control (PEC) (Non-HD);

2. Primary Engineering Control (Pec)(HD

3. Ante room;

4. Non-HD buffer room;

5. HD buffer room;

6. HD storage area;

h. Is a cleaning log maintained for the following areas:

1. Primary Engineering Control (PEC) (Non-HD);

2. Primary Engineering Control (Pec)(HD

3. Ante room;

4. Non-HD buffer room;

5. HD buffer room;

i. Is the viable air exceeding the action limit for the following areas:

1. Primary Engineering Control (PEC) (Non-HD);

2. Primary Engineering Control (Pec)(HD

3. Ante room;

4. Non-HD buffer room;

5. HD buffer room;

j. If the answer to any of the areas listed in i. above is yes attach a corrective action plan;

k. Is the viable surface sampling exceeding the action limit for the following areas:

1. Primary Engineering Control (PEC) (Non-HD);

2. Primary Engineering Control (Pec)(HD

3. Ante room;

4. Non-HD buffer room;

5. HD buffer room;

l. If the answer to any of the areas listed in k. above is yes attach a corrective action plan;

m. Is there bacterial growth in the sterile area since the last inspection in any of the following areas;

1. Primary Engineering Control (PEC) (Non-HD);

2. Primary Engineering Control (Pec)(HD

3. Ante room;

4. Non-HD buffer room;

5. HD buffer room;

n. If the answer to any of the areas listed in m. above is yes attach a corrective action plan;

(23) The pharmacist in charge shall fill in the blanks on the following statement:

“I certify that I have performed a self-inspection of: Name of Pharmacy _____ NH Pharmacy Permit #: _____ on the following date: _____ and affirm that it is an accurate and truthful assessment of the pharmacy as of the date of this self-inspection.”

(24) The pharmacy’s designee, who has completed the form, shall print their full name, sign the form, and date the form at the time of signature after the statement described in (23) above.

~~[(e)]~~**(e)** Licensees shall complete all self-inspection surveys within 7 days of receipt.

~~[(d)]~~**(f)** A self-inspection shall include environmental monitoring reports, if applicable under Ph 404, for board review.

~~[(e)]~~**(g)** 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.

Repeal Ph 2108.01, effective 4/11/20 (Document #13028), to read as follows:

~~[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.]~~

Readopt with amendment Ph 2108.02, effective 4/11/20 (Document #13028) and renumber as Ph 2108.01, to read as follows:

Ph 2108.0[2]**1** **Inspection Report Requirements.**

(a) 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.

~~[(a)]~~**(b)** 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 under the following attestation[-]:

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.

~~[(b)]~~**(c)** 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)]~~**(d)** 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)]~~**(e)** If an “unsatisfactory” result on a pharmacy inspection occurs, ~~[the pharmacist in charge]~~ **permit holder** 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)]~~**(f)** If an “unsatisfactory” result on a provider inspection occurs, the report shall be forwarded to the respective board for review.

~~[(e)]~~**(g)** The current compliance inspection report of the licensed location, conducted by the board, shall be kept on file in the facility per Ph 702.05.

~~[(f)]~~**(h)** Inspection reports shall be ~~[stored]~~ **retained** by the pharmacy board ~~[in a licensing data base by]~~ **under the** name of the permit holder and the ~~[pharmacist in charge]~~.

Adopt Ph 2108.02 to read as follows:

Ph 2108.02 Inspection of Medication Files.

(a) All prescription and medication files requested by the investigator or inspector shall be available as follows:

- (1) Prescription and medication files dated 2 years or less from the inspection or investigation occurred shall be available on demand; and
- (2) Prescription and medication files dated more than 2 years from the date the inspection or investigation occurred shall be available within 7 days of the date of the inspection or investigation.

APPENDIX

Rule	Specific State Statute the Rule Implements
Ph 2106.01	RSA 318:5-a, IX, RSA 318:37, I(c), RSA 318:41, RSA 318:47-c; RSA 318:51-c, VI
Ph 2108.01 (repealed)	RSA 318:47-c;
Ph 2108.01 (formerly Ph 2108.02)	RSA 318:47-c;
Ph 2108.02	RSA 318:42, VII (a), RSA 318:47-c, I (a), RSA 318:51-f, IV (f)