

Adopt Ph 2200 to read as follows:

CHAPTER Ph 2200 PHARMACY BOARD INVESTIGATIONS

PART Ph 2201 DEFINITIONS

Ph 2201.01 Definitions. In addition to RSA 318:1, the following definitions shall apply to this chapter:

- (a) “Board investigator” means a pharmacist employed by the pharmacy board to investigate violations of the pharmacy laws or the rules of the pharmacy board by a person licensed at the time the alleged violation occurred;
- (b) “Confidential letter of concern” means a warning letter issued by the pharmacy board to a licensee as a type of outcome to an investigation conducted by the pharmacy board investigators;
- (c) “Drug diversion” means the illegal distribution of prescription controlled drugs, or transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use;
- (d) “Facility” means any pharmacy, hospital, clinic, practitioner offices, methadone clinic, or veterinarian clinic that have medication on their premises and are inspected by the pharmacy board;
- (e) “Infusion center” means a place, usually outpatient, where patients can receive intravenous infusions and therapeutic injections in a safe, professional, and comfortable environment;
- (f) “Licensee” means any entity or individual which is licensed, certified, registered, or regulated by the pharmacy board or a board whose licensees are subject to investigation under RSA 318:30;
- (g) “Medication error” means any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional or patient. Such events can be related to professional practice, healthcare products, procedures, and systems including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.
- (h) “Methadone clinic” means a clinic which has been established for the dispensing of methadone, a schedule II drug under the Controlled Substance Act, for the purpose of treating addiction disorder;
- (i) “Naturopathic medicine” means “naturopathic medicine” as defined in RSA 328-E:2, IX, namely, “a system of primary health care practiced by doctors of naturopathic medicine for the prevention, diagnosis, and treatment of human health conditions, injuries, and disease that uses education, natural medicines, and therapies to support and stimulate the individual’s intrinsic self-healing processes;”
- (j) “Nurse practitioner” means a registered nurse currently licensed by the board under RSA 326-B:18. The term includes “advanced practice registered nurse (APRN).;”
- (k) “Professional misconduct” means behavior by a professional that implies an intentional compromise of ethical standards, including the acts specified in RSA 318:29, II;

(l) “Quality related event (QRE)” means the incorrect dispensing of a prescribed medication that is received by a patient, including a variation from the prescriber’s prescription order, or failure to identify and manage errors identified during a drug utilization review; and

(m) “Tele-pharmacy service” means the delivery of pharmaceutical care via telecommunications to patients in locations where they may not have direct contact with a pharmacist.

PART Ph 2202 PURPOSE AND SCOPE

Ph 2202.01 Purpose. This part describes how the pharmacy board conducts investigations as authorized by RSA 318:8-a, RSA 318:14-a, RSA 318:30, and RSA 318:42.

Ph 2202.02 Scope. This section shall apply to any party licensed by the pharmacy board or party licensed by another regulatory board that has given investigatory authority to the pharmacy board of pharmacy under RSA 318:30.

PART Ph 2203 CONSUMER COMPLAINTS

Ph 2203.01 Consumer Complaints.

(a) Consumer complaints shall be filed using the administrative complaints packet Ph532, revised 11/1/18, containing “Complaint cover sheet form Ph533,” revised 11/1/18, “Pharmacy/Pharmacist Complaint Form” (Ph 534), revised 11/1/2018, and “Release of Medical Information form Ph535,” revised 11/1/18, available on the pharmacy board website at <https://www.oplc.nh.gov/pharmacy/complaints.htm>.

(b) All complaints that meet the minimum technical requirements by identifying a licensee and facts, which, if true, could be a violation subject to the pharmacy board’s jurisdiction, shall be addressed by the pharmacy board compliance staff. A report of investigation shall be issued to the pharmacy board for review and further action if required.

(c) Investigations shall be assigned by the pharmacy board administrator/chief of compliance.

(d) The pharmacy board shall dismiss any complaint that is not filed in accordance with this chapter or that fails to state a cause of action pursuant to RSA 318:30, VII.

PART Ph 2204 RESPONSES

Ph 2204.01 Quality Related Event Reports.

(a) The board investigator shall issue “Quality Related Event (QRE) Report” forms (Ph 530), revised 3/19, available on the pharmacy board’s website at <https://www.oplc.nh.gov/pharmacy/compliance.htm>, to licensees for information concerning the allegations of a complaint.

(b) A licensee who received a “QRE Report” shall:

(1) If a pharmacist, pharmacy technician, or person directly involved in the complaint, complete a “QRE Report” form;

(2) If a permit holder or corporate entity, complete a separate “QRE Report”; and

(3) Sign and return the completed form to the board investigator within 15 days of receipt pursuant to RSA 318:30 VIII.

PART Ph 2205 INVESTIGATIONS

Ph 2205.01 Licensees Subject to Investigations. The following licensees and medical providers shall be subject to investigations:

(a) Licensees of the pharmacy board including:

(1) Pharmacies, pharmacists, and pharmacy technicians;

(2) Permit holders including:

a. Tele-pharmacy service providers;

b. Methadone clinics;

c. Infusion centers; and

d. All other facilities where medications are administered, stored, or dispensed;

(3) Wholesalers, manufacturers, and distributors of pharmaceuticals and pharmaceutical devices;

(4) Medical gas providers; and

(5) Out of state permit holders under RSA 318:37 II(d);

(b) Other medical providers pursuant to RSA 318:8-a and RSA 318-B, including:

(1) Physicians;

(2) Nurse practitioners;

(3) Physician assistants;

(4) Naturopaths;

(5) Podiatrists;

(6) Optometrists;

(7) Dentists; and

(8) Veterinarians with prescriptive authority.

Ph 2205.02 Investigations of a Complaint.

(a) Investigations into complaints shall be done by pharmacy board commissioners and pharmacy board investigators in conjunction with pharmacy board counsel and the administrative prosecution unit (APU) of the NH department of justice.

(b) Investigations shall focus on evidence of:

- (1) Professional misconduct;
- (2) Medication errors;
- (3) Drug diversion;
- (4) Violation of federal or state law and the rules of the pharmacy board;
- (5) FDA recalls;
- (6) Noncompliance with the prescription drug monitoring program;
- (7) Unsanitary conditions, as per Ph 404.03 and United States Pharmacopia (USP) 797; and
- (8) Any condition, issue, or event related to the practice of pharmacy, pharmaceutical product, or prescriptive device that jeopardizes patient safety.

(c) Investigators shall be authorized by the pharmacy board to:

- (1) Obtain factual evidence to gain an understanding of the complaint allegations;
- (2) Conduct interviews with complainant, respondent, or any other person thought to have knowledge of the incident which gave rise to the complaint;
- (3) Issue a “QRE Report” form to a party to the complaint;
- (4) Request information from outside sources needed to investigate the complaint or issue identified for investigation;
- (5) Consult with pharmacy board counsel or the APU; and
- (6) Obtain any relevant information or data regarding external variables that negatively impact the safe practice of pharmacy including but not limited to:
 - a. Working conditions;
 - b. Staffing;
 - c. Training;
 - d. Facility conditions;

- e. Equipment;
- f. Power; and
- g. The weather.

Ph 2205.03 Follow Up to Investigations.

(a) The pharmacy board administrator/chief of compliance shall follow up with a complainant as to the outcome of the investigation.

(b) Unfounded investigation reports and pharmacy board actions shall be kept on file by the pharmacy board for 5 years. Founded pharmacy board actions shall be attached to the license of the pharmacist or pharmacist-in-charge and the pharmacy permit holder.

Ph 2205.04 Cost of the Investigation.

(a) All costs associated with an investigation shall be reported to the respective regulatory board of the licensee for tracking and potential assessing of investigation cost under RSA 332-G:11.

(b) Costs involved with an investigation shall include:

- (1) The cost of the investigator at a cost per hour rate;
- (2) The cost of the office staff timed at a cost per hour rate;
- (3) The cost of the pharmacy board counsel or APU at cost per hour rate;
- (4) Costs associated with travel of the above persons; and
- (5) Other costs as deemed necessary by the pharmacy board.

PART Ph 2206 INVESTIGATION REPORTS

Ph 2206.01 Reports of Investigation.

(a) Pharmacy board investigators shall review all information concerning technically sufficient complaints and prepare a report of investigation for pharmacy board review.

(b) The report of investigation shall include, but need not be limited to:

- (1) The name and license number or permit number of all accused;
- (2) The origin or nature of the allegations;
- (3) All background information gathered during the investigation;
- (4) The sources of all information gathered in the investigation;
- (5) The results of the investigation;

- (6) A summary of the investigation, when relevant;
- (7) The relevant laws and rules for consideration of the complaint; and
- (8) The investigator's recommendation to the pharmacy board for further action or for dismissal.

Ph 2206.02 Notification of Violations. If, in the course of their investigation, a board investigator finds a violation of an administrative rule in plain sight, then the investigator shall issue a violation notice pursuant to the rules in Ph 2100.

Ph 2206.03 Prescription Drug Monitoring Program Investigations. All pharmacy board investigations concerning the prescription drug monitoring program shall be referred to the respective board of the licensee upon completion.

PART Ph 2207 DISCIPLINARY ACTION

Ph 2207.01 Pharmacy Board Action.

(a) The pharmacy board shall review the completed reports of investigation at their next scheduled pharmacy board meeting.

(b) After review and after considering the factors set forth in (e) below, the pharmacy board shall take action in one or more of the following ways:

- (1) Refer to the board investigator for further investigation;
- (2) Dismiss the complaint;
- (3) Issue a confidential letter of concern; or
- (4) Impose disciplinary action in the form of fines, public reprimands, additional education, suspension or revocation of license, or other corrective action following notice and an opportunity for a hearing or other action as stated in RSA 318:29, (IV) and (V). In considering which form of disciplinary action to take, the pharmacy board shall consider the factors set forth in (e) below.

(c) In cases where the individual investigated is a licensee of another board, the pharmacy board shall refer the report of investigation to that respective board with recommendations.

(d) Disciplinary action concerning a reprimand, fine, additional continuing education, the suspension or revocation of a license, or any action resulting in a restriction on a pharmacy or pharmacist license, shall be reported to the National Board of Pharmacy and National Provider databases.

(e) In all cases of disciplinary action under Ph 2207.01(b) above, the pharmacy board shall consider:

- (1) The nature of the offense;
- (2) The purpose of the rule or statute violated;

- (3) The licensee's state of mind at the time the offense occurred;
- (4) The potential harm to the public health;
- (5) The deterrent effect upon other practitioners;
- (6) The licensee's willingness to cooperate with the pharmacy board;
- (7) The cost to the pharmacy board of any formal disciplinary hearings which were necessary;
- (8) The licensee's acknowledgment of his or her wrongdoing; and
- (9) The nature of any other disciplinary sanctions imposed as a result of the offense in question.

Ph 2207.02 Administrative and Disciplinary Fines.

(a) Persons subject to the disciplinary authority of the pharmacy board and other persons subject to administrative fines or penalties under RSA 318:29, IV or RSA 318:55, II shall after notice and an opportunity to be heard, be assessed fines and penalties as authorized under RSA 318:29, IV. In considering the amount of fines and penalties to assess, the pharmacy board shall consider the factors set forth in (b) through (i) below.

(b) The decision to impose a fine and the amount of such fine shall depend on:

- (1) The severity of harm to the public posed by the violation;
- (2) The number of concurrent or repeated violations; and
- (3) The frequency of violations committed by the particular licensee, permit holder, or other person.

(c) Minor violations as listed in Ph 2109.02(d) and on form ph 543 "Minor Violation Notice" shall be subject to a fine of \$25.00 for each offense with a maximum of \$250.00 per Ph 710.01 and Ph 710.02.

(d) Fines shall be paid within 15 days, or a hearing shall be requested in front of the pharmacy board.

(e) When no violation of the same type has occurred within the 5 years preceding the pharmacy board's notice to the respondent, the fine assessed shall not exceed \$1,000 per violation upon the licensee or \$2,000 per violation upon the permit holder.

(f) When a single disciplinary infraction of the same type has occurred within the 5 years preceding the pharmacy board's notice to the licensee, the fine assessed shall not exceed \$2,000 per violation upon the licensee or \$3,000 per violation upon the permit holder.

(g) When more than one disciplinary infraction of the same type has occurred within the 5 years preceding the pharmacy board's notice to the licensee, the fine assessed shall not exceed \$3,000 per violation upon the licensee or \$5,000 per violation upon the permit holder.

(h) In the case of continuing violations, a separate fine shall be assessed for each day the violation continues, but the total amount of the fine and the licensee's promptness and cooperativeness in ceasing the prohibited conduct in question shall be considered in assessing the daily fines.

(i) In all cases, the pharmacy board shall consider:

- (1) The nature of the offense;
- (2) The purpose of the rule or statute violated;
- (3) The licensee's state of mind at the time the offense occurred;
- (4) The potential harm to the public health;
- (5) The deterrent effect upon other practitioners;
- (6) The licensee's willingness to cooperate with the pharmacy board;
- (7) The cost to the pharmacy board of any formal disciplinary hearing which were necessary;
- (8) The licensee's acknowledgement of his or her wrongdoing; and
- (9) The nature of any other disciplinary sanctions imposed as a result of the offense in question.

Appendix

Rule	State Statute
Ph 2201.01	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2202.01	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2202.02	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2203.01	RSA 318:30; RSA 318-B:24; RSA 318:47-h; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2204.01	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2205.01	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2205.02	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2205.03	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2206.01	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2206.02	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2206.03	RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2207.01	RSA 318:30; RSA 318-B:24; RSA 318:29; RSA 318-B:26; RSA 318-B:36; RSA 318:8-a; RSA 318:14-a; RSA 318:42
Ph 2207.02	RSA 318:30; RSA 318-B:24; RSA 318:29; RSA 318-B:26; RSA 318-B:36; RSA 318:8-a; RSA 318:14-a; RSA 318:42