Ph 2201 DEFINITIONS

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

(a) “Board investigator” means a pharmacist employed by the board of pharmacy to investigate violations of the pharmacy laws or the rules of the board by a person licensed at the time the alleged violation occurred.

(b) “Confidential letter of concern” means a warning letter issued by the board to a licensee as a type of outcome to an investigation conducted by the 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, and veterinarian clinic that have medication on their premises and are inspected by the Board of Pharmacy.

(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 board of pharmacy 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 may 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) “Naturopath” means the practitioner of a system of alternative medicine based on the theory that diseases can be successfully treated or prevented without the use of drugs, by techniques such as control of diet, exercise, and massage. “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
diseases that uses education, natural medicines and therapies to support and stimulate the individual’s intrinsic self-healing processes.

(i)(j) "Nurse practitioner" or "Advanced Practice Registered Nurse (APRN)" means a registered nurse currently licensed by the board under RSA 326-B:18.

(j)(k) "Professional misconduct" means behavior by a professional that implies an intentional compromise of ethical standards: As defined in RSA 318:29 II;

(k)(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

(l)(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.

Ph 2202 PURPOSE AND SCOPE

Ph 2202.01 Purpose. This section shall describe how the board conducts investigations as authorized by RSA318:8(a), RSA318:14(a), RSA318:30, and RSA318:42.

Ph2202.02 Scope. This section shall apply to any party licensed by the board or party licensed by another regulatory board that has given investigatory authority to the board of pharmacy under RSA 318:30.

Ph 2203 CONSUMER COMPLAINTS

Ph 2203.01 Consumer Complaints.


(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 board’s jurisdiction shall be addressed by the board compliance staff. A report of investigation shall be issued to the board for review and further action if required.

(c) Investigations shall be assigned by the Board Administrator/Chief of Compliance.
(d) The board shall have the discretion to 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.

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 11/1/2018 3/19, available on the board’s website at https://www.o plc.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.

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); and

(b) Other medical providers pursuant to RSA 318:30 including:

(1) Physicians;

(2) Nurse practitioners;

(3) Physician assistants;

(4) Naturopaths;

(5) Podiatrists;

(6) Optometrists;

(7) Dentists; and

(8) Veterinarians with prescriptive authority; and

(c) Other medical providers shall be subject to the pharmacy laws under RSA 318 for the labeling, storage, distribution, and destruction of drugs, and shall be subject to the laws under RSA 318-B for issues of controlled drugs and the prescription drug monitoring program.

Ph 2205.02 Investigations of a Complaint.

(a) Investigations into complaints shall be done by pharmacy board commissioners and board investigators in conjunction with board counsel and the New Hampshire Attorney General's 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 board;

(5) FDA recalls;
(6) Noncompliance with the prescription drug monitoring program;

(7) Unsanitary conditions, as per Ph 400404.03 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 board to:

(1) Obtain factual evidence to gain an understanding of the complaint allegations;

(2) Conduct interviews of 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 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 board administrator/chief of compliance shall follow up with a complainant as to the outcome of the investigation.
(b) Unfounded investigation reports and board actions shall be kept on file by the board for 5 years. Founded 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)(II)

(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 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 board.

Ph 2206 INVESTIGATION REPORTS.

Ph 2206.01 Reports of Investigation.

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

Ph 2207 DISCIPLINARY ACTION

Ph 2207.01 Board Action.

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

(b) After review, the board shall take action in one or more of the following ways:

(1) Refer to the board investigator for further investigation; or

(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) (V).

(c) In cases where the individual investigated is a licensee of another board, the board of 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 2207.01(b)(3) above, the 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 board;

(7) The cost to the 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 board and other persons subject to administrative fines or penalties under RSA 318:29, IV shall, at the discretion of the board and after notice and an opportunity to be heard, be assessed fines and penalties as authorized under RSA 318:29, IV.

(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 violation fines as defined on form ph543 “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 ph710.02.

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

(e) When no violation of the same type has occurred within the 5 years preceding the board’s notice to the respondent, the fine assessed shall not exceed $1,000 per violation upon the licensee and/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 board’s notice to the licensee, the fine assessed shall not exceed $2,000 per violation upon the licensee and/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 board’s notice to the licensee, the fine assessed shall not exceed $3,000 per violation upon the licensee and/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 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 board;
   (7) The cost to the 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.
## Appendix

<table>
<thead>
<tr>
<th>Rule</th>
<th>State Statute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ph 2201.01</td>
<td>RSA 318:30; RSA 318-B:24</td>
</tr>
<tr>
<td>Ph 2202.01</td>
<td>RSA 318:30; RSA 318-B:24</td>
</tr>
<tr>
<td>Ph 2202.02</td>
<td>RSA 318:30; RSA 318-B:24</td>
</tr>
<tr>
<td>Ph 2203.01</td>
<td>RSA 318:30; RSA 318-B:24; RSA 318:47-h</td>
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<td>Ph 2204.01</td>
<td>RSA 318:30; RSA 318-B:24</td>
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<tr>
<td>Ph 2205.01</td>
<td>RSA 318:30; RSA 318-B:24</td>
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<tr>
<td>Ph 2205.02</td>
<td>RSA 318:30; RSA 318-B:24</td>
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<tr>
<td>Ph 2205.03</td>
<td>RSA 318:30; RSA 318-B:24</td>
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<td>Ph 2206.03</td>
<td>RSA 318:30; RSA 318-B:24</td>
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<tr>
<td>Ph 2207.01</td>
<td>RSA 318:30; RSA 318-B:24; RSA 318:29; RSA 318-B:26; RSA 318-B:36</td>
</tr>
<tr>
<td>Ph 2207.02</td>
<td>RSA 318:30; RSA 318-B:24; RSA 318:29; RSA 318-B:26; RSA 318-B:36</td>
</tr>
</tbody>
</table>
New Hampshire Board of Pharmacy  
Compliance Major Violation Notice

Name of Pharmacy: ___________________________ NH Pharmacy Permit #: ___________________________
Pharmacist-In-Charge: ___________________________ Pharmacist on Duty: ___________________________
Date: ___________________________ C.I.: ___________________________

For an explanation of specific violations noted, refer to remarks section of Violation Notice

<table>
<thead>
<tr>
<th>Violation</th>
<th>Type of Violation</th>
<th>Statute / Rule</th>
<th>Fine Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Equipment Failure - Medication / Vaccine Refrigerator or Freezer, Hot or Cold Water, Heat or A/C Failure Causing Pharmacy to Be Outside of Appropriate Temperature Range for Proper Drug Storage per Manufacturer</td>
<td>Ph 404.03 &amp; Ph 704.11</td>
<td>$ 100.00</td>
</tr>
<tr>
<td>2</td>
<td>Failure to Maintain Temperature Logs</td>
<td>Ph 702.02</td>
<td>$ 100.00</td>
</tr>
<tr>
<td>3</td>
<td>No Signature on Hardcopy of C/S Rx</td>
<td>RSA 318-B:9</td>
<td>$ 100.00</td>
</tr>
<tr>
<td>4</td>
<td>Printed C/S Rx Not Marked Copy Only - Not Valid for Dispensing</td>
<td></td>
<td>$ 100.00</td>
</tr>
<tr>
<td>5</td>
<td>Immunizing Pharmacist or Immunizing Intern with Expired CPR Certification or Liability Insurance Policy</td>
<td>RSA 318:16-b, II &amp; Ph 1303.01(b)</td>
<td>$ 100.00</td>
</tr>
<tr>
<td>6</td>
<td>CII Inventory Missing or Incomplete</td>
<td>Ph 703.03</td>
<td>$ 100.00</td>
</tr>
<tr>
<td>7</td>
<td>Failure to Report Changes within 15 Days (Name, Address, Work Location)</td>
<td>RSA 318:26-a</td>
<td>$ 100.00</td>
</tr>
<tr>
<td>8</td>
<td>Pharmacy Technician or Intern Working in Pharmacy While Unregistered or With an Expired Registration</td>
<td>RSA 318:15-a &amp; b</td>
<td>$ 100.00</td>
</tr>
<tr>
<td>9</td>
<td>DEA 222 Forms Not Sent to DEA</td>
<td>Ph 703.05</td>
<td>$ 250.00</td>
</tr>
<tr>
<td>10</td>
<td>Registered Tech Performing Certified Tech Duties</td>
<td>Ph 801.01(e)</td>
<td>$ 250.00</td>
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<tr>
<td>11</td>
<td>Biennial Inventory Missing or Not Done</td>
<td>RSA 318-B:12, III</td>
<td>$ 500.00</td>
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<tr>
<td>12</td>
<td>CS Losses - Failure to Report</td>
<td>Ph 703.03</td>
<td>$ 500.00</td>
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<td>13</td>
<td>Pharmacist Working in Pharmacy While Unlicensed or With an Expired License</td>
<td>RSA 318:25</td>
<td>$ 500.00</td>
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<tr>
<td>14</td>
<td>Unfit Place To Work</td>
<td>RSA 318:38</td>
<td>$ 500.00</td>
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<td>15</td>
<td>Failure to Report PIC Change in Timely Manner</td>
<td>Ph 306.02</td>
<td>$ 500.00</td>
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<td>16</td>
<td>No PIC Change Inventory Done</td>
<td>Ph 704.13</td>
<td>$ 500.00</td>
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<tr>
<td>17</td>
<td>Operating Pharmacy Without a PIC</td>
<td>Ph 304.01</td>
<td>$ 500.00</td>
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<tr>
<td>18</td>
<td>Pharmacy Access / Security</td>
<td>Ph 702.04</td>
<td>$ 500.00</td>
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<tr>
<td>19</td>
<td>PDMP - Pharmacy Not Registered</td>
<td>Ph 1503.01</td>
<td>$ 1,000.00</td>
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<tr>
<td>20</td>
<td>Failure to Respond to Violation Notice or Report of Investigation</td>
<td></td>
<td>$ 5,000.00</td>
</tr>
</tbody>
</table>

Form # 532 (12/26/2018)
A Compliance Investigator/Inspector has inspected your pharmacy and noted any major violations of New Hampshire laws/rules as noted above. All violation notices are reviewed by the Board of Pharmacy at their next scheduled meeting. Upon further review additional disciplinary action may be taken. Issues cited on this violation notice must be corrected within 15 days and returned to the Board office at 121 South Fruit Street, Suite 401, Concord NH 03301 or faxed to the board at 603-271-2856, or scanned/emailed to pharmacy.compliance@oplc.nh.gov.

I acknowledge that the noted violations, which are not in Compliance, have been explained to me and I have received a copy of this report.

Investigator/Inspector for Board of Pharmacy  

Signature of Authorized Individual for the Pharmacy

Date

Printed Name and Title of Authorized Individual

Corrective Action Taken By Pharmacy:

Date:  

Print Name

Signature

Mail Completed Form with Fine Payment due within 15 days
(Make Check Payable to: Treasurer, State of NH)

NH BOARD OF PHARMACY
121 SOUTH FRUIT ST, STE 401
CONCORD, NH 03301-2412

Form # 532  (12/26/2018)
New Hampshire Board of Pharmacy  
Compliance Division - Minor Violation Notice

Name of Pharmacy _______________________________ Pharmacist-In-Charge _______________________________

Pharmacist on Duty _______________________________ Date __________________ C.I. __________________

* V Column = Violation - $25.00 fine for each offense, maximum of $250.00
* W/N Column = Warning Notice / Needs Improvement

For an explanation of specific violations noted, refer to Inspector’s Remarks section of this Violation Notice

<table>
<thead>
<tr>
<th>A. GENERAL</th>
<th>V</th>
<th>W/N</th>
<th>B. RETAIL</th>
<th>V</th>
<th>W/N</th>
<th>C. HOSPITAL</th>
<th>V</th>
<th>W/N</th>
<th>D. CONTROLLED SUBSTANCES</th>
<th>V</th>
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<tr>
<td>Pharmacist Licenses Not Posted</td>
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<td>Rx Lacks Proper Information</td>
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<td>C/S Vendor Return Confirmation</td>
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<td>2</td>
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<td>Insufficient Equipment</td>
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<td>Counseling Area Inadequate</td>
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<td>C/O Locked or Dispersed</td>
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<tr>
<td>Work Area Orderly/Clear</td>
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<td>No Counseling by RPh</td>
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<td>No Power of Attorney</td>
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<td>Equipment Inspection/Calibration</td>
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<td>Allergies Not Properly Noted</td>
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<td>Improper Security</td>
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<td>No CPR Certification for Vaccines</td>
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<td>Rx 222 Form Records Not in Numerical Order</td>
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<td>Out of Date/Mislabeled Drug</td>
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<td>No Vaccine Provider Notification</td>
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<td>Non-Compliant NH Controlled Drug Loss / DEA 106 Forms</td>
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<td>V</td>
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<td>Improper Drug Storage</td>
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<td>Vaccination Standing Order</td>
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<td>Improper Drug Destruction</td>
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<td>No C/I Monthly Perpetual Inventory</td>
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<td>10</td>
<td>W/N</td>
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<td>11</td>
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<tr>
<td>Improper Supervision of Support Personnel</td>
<td>W/N</td>
<td></td>
<td>No Lunch Break Signage</td>
<td></td>
<td></td>
<td>No Daily/Nightly C/S Log</td>
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<td>11</td>
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<tr>
<td>Improper Registration Procedures</td>
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<td>Improper Automated Dispensing Procedures</td>
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<td></td>
<td>C/S Returns Procedure Inadequate</td>
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<td>12</td>
<td>W/N</td>
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<tr>
<td>Nametags</td>
<td>W/N</td>
<td></td>
<td>Improper Telephone/Voicemail Order Intake</td>
<td></td>
<td></td>
<td>Patient Care Guidelines Incomplete</td>
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<td>13</td>
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<td>Improper Documentation of Training</td>
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<td>Improper Return to Stock Procedures</td>
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<td>Improper Dispensing/Labeling</td>
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<td>No P &amp; P Manual</td>
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<tr>
<td>Food in Rx Refrigerator</td>
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<td>Shelving Not Clean &amp; Orderly</td>
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<td>Outdated Drugs Separate from Active Inventory</td>
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<td>Quality Assurance Info Unavailable</td>
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<td>Quality Assurance Meeting Held Quarterly</td>
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<td>Purified Water System Inadequate</td>
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<td>No Hot/Cold Running Water</td>
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<td>No CMEA Certificate</td>
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</table>

E. PDMP  
1. Failure to Verify Rx's with PDMP  
2. PDMP Provider Verification

Total Number of Violations  
@ $25/Each X 25

Total Fine Amount ($250 Max)  
$
Inspector's Remarks:

A Compliance Investigator/Inspector has inspected your pharmacy and noted any violations of New Hampshire rules. All violation notices are reviewed by the Board of Pharmacy at their next scheduled meeting. Upon further review additional disciplinary action may be taken. Issues cited on this violation notice must be corrected within 15 days and returned to the Board office at 121 South Fruit Street, Suite 401, Concord N.H. 03301 or faxed to the board at 603-271-2856. I acknowledge that the noted violations, which are not in Compliance, have been explained to me and I have received a copy of this report.

Investigator/Inspector for Board of Pharmacy

Signature of Authorized Individual for the Pharmacy

Date

Printed Name and Title of Authorized Individual

Corrective Action Taken By Pharmacy:


Date: Print Name

Signature

Mail Completed Form with Fine Payment due within 15 days
(Make Check Payable to: Treasurer, State of NH)

NH BOARD OF PHARMACY
121 SOUTH FRUIT ST, STE 401
CONCORD, NH 03301-2412
Administrative Complaints

Purpose:

The purpose of the licensing system is to protect the public against:

1. Dishonest or unethical practitioners;
2. Practitioners who have fallen below minimum standards of competence in the practice of their profession; and/or
3. Dispensing System that may be prone to error.

Licensees or registrants may be subject to disciplinary action that can range from a formal warning to revocation of license, registration or permit. Disciplinary action is handled by the Board of Pharmacy ("Board") in response to a complaint received from a member of the public, another health care provider, or as a result of observations of the Board's compliance officers.

Filing a Complaint:

To file a complaint against a licensee, registrant, or permit holder, contact the Board, at the address listed above, and request a complaint form. Complete the form, sign it and mail it back to the board office, "ATTN: Compliance.

License Status of Person Complained Against:

The Board can only act against a person who is actually licensed, registered by, or who seeks to be licensed or registered by the board. If the person complained against does not bold and has not applied for a license or registration, the Board has no administrative authority to consider the complaint itself. If the complaint alleges a violation of the Board's
statutes or rules, the Board may investigate the matter for possible referral to the NH Attorney General or local prosecutor for civil action or criminal prosecution. If the person complained against is indeed licensed or registered by the board, the complaint is assigned a complaint number and assigned to a Compliance Investigator.

Who is a "Compliance Investigator". A Compliance Investigator is a member of the board staff. Part of his/her duties is to investigate complaints. After investigating the complaint, the Compliance Investigator submits a report to the Chief Compliance Investigator who reviews the complaint and the report. Upon completion of the review, he presents the mailer to the Board for it to decide how the matter should be handled. If the Board decides to proceed with a formal hearing, the Chief Compliance Investigator assists the Administrative Prosecution's Unit of the Attorney General's Office in presenting the case to the Board. The Chief Compliance Investigator does not participate in the Board's deliberations or vote in any manner.

Notice to Complainant:

The Compliance Investigator sends the complainant a written acknowledgement of the complaint.

Notice to Licensee:

The Chief Compliance Investigator “may” ¹ immediately forward a copy of the complaint to the licensee, registrant or permit holder, along with notification that the licensee is under investigation. If so, the licensee, registrant or permit holder shall be asked to respond to the complaint.

Additional Investigation:

The Board employs compliance investigators, who report to the Chief Compliance Investigator. On occasion, federal and state law enforcement officials may work with the Board’s investigators, depending upon the nature of the complaint. Any of these investigators may personally contact the complainant and/or the licensee, registrant or permit holder, as part of an expanded investigation.

Presentation to the Board:

The complaint will be presented to the Board when the investigation is complete. How quickly the presentation is made depends on the complexity of the investigation, the Board's overall workload, the number of other pending investigations, and the frequency with which the Board meets.
Confidentiality:

All complaints, information regarding the complaint, and investigative records are confidential during the pendency of an investigation. If the Board initiates a formal adjudicatory proceeding, some or all of the information collected during the investigation may become public.

Penalties:

The Board may impose sanctions against a licensee, registrant or permit holder including those listed below. The penalties may be subject to limitations set out in the governing law:

1. Issue a reprimand to a licensee, registrant or permit holder
2. Suspend or revoke a license, registration or permit
3. Impose a civil fine
4. Impose conditions of probation upon a licensee, registrant or permit holder

1 This action depends upon the “nature” of the complaint. It may not be in the best interest of the Board to notify the licensee prior to initiation of the investigation.
COMPLAINT COVER SHEET

Enclosed is a complaint form, a brief outline of the administrative complaint procedures, and if applicable, a release of information.

In the event that you need to be contacted regarding your complaint, please provide the following information and return this page with your complaint form.

PLEASE NOTE

This complaint cannot go forward unless the enclosed medical release form is signed, dated, witnessed and returned with the complaint.

COMPLAINANT INFORMATION:
Please PRINT

Your Name: ________________________________

Your Complete Mailing Address:

________________________________________

________________________________________

Daytime Telephone Number: ( ) ____________________________

Evening Telephone Number: ( ) ____________________________

FOR OFFICE USE ONLY:

File Number: ________________________________

Date Assigned: ______________________________

Investigator: ________________________________ Acknowledgement Sent: ______________________________

Date Investigation Complete: ______________________________

Resolution:

Form # Ph 533 (Rev. 11/1/18)  Policy #2-12-17-96
PHARMACY/PHARMACIST COMPLAINT FORM

PLEASE PRINT:

Today’s Date: ___________ Your Name (Complainant): _________________________

Your Signature: ____________________________________________________________

Pharmacy Name: __________________________________________________________

Pharmacy Address __________________________________________________________

Name of Pharmacist **: _____________________________________________________

Date of incident: ___________________________________________________________

Prescription number(s) of prescription(s) involved in this complaint:

_________________________   __________________________

Patients Name: _____________________________________________________________

Relationship to complainant: ______________________ (self, husband, wife etc.)

Was this a NEW [ ] or REFILL [ ] prescription order?

Was the “offer to counsel” given? Yes [ ] No [ ]

Was counseling GIVEN [ ] or REFUSED [ ]

**If “unknown” please look at the prescription bottle and record the initials of the dispensing pharmacist, which are printed on the label.
Did this involve any other pharmacy personnel other than the pharmacist on duty?
   Yes [ ]       No [ ]

If “yes” individual(s) name AND title (clerk, technician, store manager etc.)

______________________________________________________________
______________________________________________________________

Have you contacted the pharmacy regarding this incident?
   Yes [ ]       No [ ]

If “yes” to whom did you speak (name & title, if possible)?

______________________________________________________________
______________________________________________________________

Have you spoken with anyone at the corporate level (supervisor, company main office etc.,)?
   Yes [ ]       No [ ]

If “yes”, to who did you speak (name & title, if known)?

______________________________________________________________
______________________________________________________________

Please PRINT (or attach a typewritten statement)
Clearly explain your complaint. It is important to list the facts and details in the order in which they occurred, including names, dates, places and times. Include “copies” of any documents, which support your complaint. If you require more space, include extra sheets. Return this form, the “cover sheet”, along with documentation, to the address at the top of page 1 of this form. ATTN: COMPLIANCE. (please sign and date the bottom of each page used.)

______________________________________________________________
______________________________________________________________
______________________________________________________________
______________________________________________________________

Signed: ____________________________________________________ Date: ______________________
Health Insurance Portability and Accountability Act ("HIPPA")

RELEASE OF MEDICAL INFORMATION FORM

I ________________________________________________ hereby grant authority to agents of the New Hampshire Board of Pharmacy to access my pharmacy, medical, hospital, and insurance records for the purpose of investigating the complaint I have filed with the Board of Pharmacy office on ____________________________.

Signed: _______________________________ Date: __________________

Witness: _______________________________ Date: __________________

Witness: _______________________________ (print name)
Quality Related Event (QRE) Report

<table>
<thead>
<tr>
<th>Date of Report:</th>
<th>Date of Incident:</th>
<th>Time of Incident:</th>
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</thead>
<tbody>
<tr>
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</tbody>
</table>

- Type of Prescription Involved:
  - New
  - Refill

- How Received:
  - Hard Copy Rx
  - Telephoned In
  - Fax or E-Prescription

- If Telephoned In, Order Was Taken By:
  - Pharmacist
  - Certified Pharmacy Technician
  - Not Applicable

- At What Level Was the Event Discovered?
  - Patient
  - Prescriber
  - Pharmacist
  - Pharmacy Staff
  - Other

- Was the Patient Harmed?
  - Yes
  - No

- Describe Incident Type (Check All That Apply)
  - Wrong Medication
  - Transcription Error
  - Incorrect Dosage
  - Labels Switched
  - Mislabeled/Misread
  - Allergy Not Listed in Profile
  - Communication Error
  - Incorrect Directions or Usage
  - Other:

Describe in detail what happened – be specific using facts only – no opinions. Do not include names or any other patient, prescriber or pharmacy staff identifiers. Attach additional sheet if required.

<table>
<thead>
<tr>
<th>Medication Ordered</th>
<th>Medication Actually Dispensed</th>
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<tbody>
<tr>
<td>Name</td>
<td>Name</td>
</tr>
<tr>
<td>Strength</td>
<td>Strength</td>
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<tr>
<td>Quantity</td>
<td>Quantity</td>
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<tr>
<td>Directions</td>
<td>Directions</td>
</tr>
</tbody>
</table>

Using the description of the six stages of filling a prescription (explained at end of this form), at what stage of the process does it appear that the problem originated:

- Stage One
- Stage Two
- Stage Three
- Stage Four
- Stage Five
- Stage Six

- Whom was the initial cause of the error related to:
  - Pharmacist
  - Intern
  - Technician
  - Prescriber
  - Patient
  - Prescriber’s Office Staff

- Did the error reach the patient?
  - Yes
  - No

- Did the patient use / ingest the medication?
  - Yes
  - No

- If yes, did this result in an adverse reaction to the patient?
  - Yes
  - No

- Was a “Prospective Drug Review” completed?
  - Yes
  - No

- Where in the process was the “Prospective Drug Review” Completed?
  - During Rx data entry
  - During Rx final verification

- Was this a “Central Fill Processing” Prescription?
  - Yes
  - No

* If Yes, name and location of pharmacist?
### Initial data entry of prescription information was performed by:

<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Intern</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Certified Technician</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Registered Technician</td>
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</tbody>
</table>

#### *If registered technician has been trained on data entry?*

<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>☐ Yes</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>☐ No</td>
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</table>

#### *Is there documentation available that the registered technician completed Board approved data entry training?*

<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>☐ Yes</td>
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<td>☐</td>
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<tr>
<td>☐ No</td>
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</table>

#### Upon completing the data entry, did the computer identify any problem with drug interaction, dosage alert, etc.?

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<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>☐ Yes</td>
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<td>☐</td>
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<tr>
<td>☐ No</td>
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</table>

Did the computer require the pharmacist or technician to do a “manual over-ride”?

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<thead>
<tr>
<th>Option</th>
<th>Yes</th>
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<tbody>
<tr>
<td>☐ Yes</td>
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<tr>
<td>☐ No</td>
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</table>

#### During the dispensing process, did the “stock” bottle accompany the finished product up to the time of final verification?

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<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>☐ Yes</td>
<td>☐</td>
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<tr>
<td>☐ No</td>
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</table>

Did the “original” hard copy prescription physically follow the order through the process to the point of verification?

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<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>☐ Yes</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>☐ No</td>
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</table>

#### Was the “original” prescription “scanned” into the system?

<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
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<tbody>
<tr>
<td>☐ Yes</td>
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<tr>
<td>☐ No</td>
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</table>

Was the dosage ordered (for administration) different than the commercially available form of the medication? (Example: Zantac @ 75mg/5ml sig: 25 mg once daily.)

<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>☐ Yes</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>☐ No</td>
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</table>

#### How many hours was the pharmacy open the day the incident occurred?

<table>
<thead>
<tr>
<th>Staffing level at pharmacy on the day of the incident?</th>
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</thead>
<tbody>
<tr>
<td>☐ Usual staffing level</td>
</tr>
<tr>
<td>☐ Reduced staffing level *</td>
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</tbody>
</table>

#### If staffing was reduced / lower than usual, please explain why (i.e. vacation, sick, etc.)

<table>
<thead>
<tr>
<th>Number of pharmacists on duty at the time of incident?</th>
<th>Total number of pharmacist hours that day?</th>
<th>Total time in hours of pharmacist “overlap” on day of incident? (i.e. more than 1 RPI on duty at same time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>☐ No</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

#### Number of pharmacy technicians on duty at the time of incident?

<table>
<thead>
<tr>
<th>Does the PIC (Pharmacist-In-Charge) or staff pharmacist have the ability to regulate the scheduling of pharmacists and/or technicians?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>

Scheduling is done by? (title only)

<table>
<thead>
<tr>
<th>Total number of prescriptions (new &amp; refill) that were filled at the pharmacy on the date of the incident?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 0 - 50</td>
</tr>
<tr>
<td>☐ 51 - 100</td>
</tr>
<tr>
<td>☐ 101 - 150</td>
</tr>
<tr>
<td>☐ 151 - 200</td>
</tr>
<tr>
<td>☐ 201 - 250</td>
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<tr>
<td>☐ 251 - 300</td>
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<tr>
<td>☐ 301 - 350</td>
</tr>
<tr>
<td>☐ 351 - 400</td>
</tr>
<tr>
<td>☐ 401 - 500</td>
</tr>
<tr>
<td>☐ 501 - 600</td>
</tr>
<tr>
<td>☐ Over 600</td>
</tr>
</tbody>
</table>

#### Any unusual distractions on the date of the Incident? (If so, explain)

Any other issues that might have contributed to the incident? (Be brief and specific)
Stages of filling a Prescription

- **Stage 1:** Receiving the Prescription
- **Stage 2:** Data Entry
- **Stage 3:** Prescription Assembly
- **Stage 4:** Pharmacist Final Check
- **Stage 5:** Addressing the Issues
- **Stage 6:** Delivery to the Patient

**Stage One:**
Receiving the prescription. This is when phone-in, electronic, faxed, or physically delivered prescriptions start their journey culminating with the ingestion of the drug by the patient. At this stage it is important to find out everything that reasonably can be known about the patient. Is this a child or an older adult? Are there significant allergies? If it is a refill request, has the drug been working? What other medications are being used? Later on in the chain of events, the responses to these questions may take on greater importance.

**Stage Two:**
The second stage usually involves data entry. A person trained to do so will input information into the computer, and that information will become the electronic record upon which everyone within the pharmacy will subsequently rely. Inaccurate data entry could result in serious consequences to the patient. It is much easier to get this step right than it is to later recognize that an error has occurred.

**Stage Three:**
The third stage centers on prescription assembly. A correct vial or other container must be chosen. The correct label must affixed to the correct container, with the correct medication inside the container. All of this must be done as a singular process in order to avoid confusing one prescription with another. At the end of this stage, there should be a prescription, a stock container of medication from which the medication was obtained, and a labeled container of medication for the patient. These things should be kept together for each patient, perhaps in a basket that separates them from medications for other patients.

**Stage Four:**
The fourth stage requires a final review of the prescription-filling process by the pharmacist. At this point, everything previously done by a pharmacy technician, another pharmacist, or the pharmacist who filled the prescription, is reviewed to ensure accuracy. There is no single “gold standard” for how this is done. Some pharmacists use the NDC number as a way to compare what is in the stock bottle with what is listed on the computer printout. Others shake out and visualize on the cap, a supply of the medication. It is probably important to vary the approach to this final review from time-to-time to prevent bias that leads people to see what they expect to see rather than what is really there. Pharmacists frequently address soft edits at this stage, resolving problems identified by the computer.

**Stage Five:**
The fifth stage addresses any issues that may arise. These may include queries emanating from the prescription software program, denials by third-party payers, the need for communication with the prescriber or patient, and ambiguities related to the intended course of therapy. It is important to place aside these issues until they are able to be resolved in order to avoid time-consuming backlogs. Other patients should not have to wait unnecessarily for their prescription to be filled while another patient’s prescription is awaiting resolution of an issue.

**Stage Six:**
The sixth and final stage is the delivery of the medication, with counseling if necessary or requested, to the patient. This is the time to make sure that auxiliary labeling, if appropriate, has been affixed to the container, that the computer information leaflet has been included, and that the patient being given the drug is the one for whom it has been prescribed. Any particularly critical pieces of information should be emphasized to the patient, and any questions answered.
COMPLAINT ACKNOWLEDGEMENT

This is to acknowledge that the written complaint against:

Subject of Complaint: ____________________________

Address: _______________________________________

_______________________________________________

City: _______________ Zip: _______________

Was received in the Board office on ________________ and has been assigned to

Compliance Investigator ________________________

During the course of the investigation, you may be contacted about your complaint. Please provide your cooperation in the investigation.

Upon Completion of the investigation complaint and the details of the investigation will be presented to the Board for action. Please understand that the Compliance Investigator cannot share information learned during the course of the investigation with you. You will be notified of the disposition and outcome of your complaint by the Administrator/Chief of Compliance after the Board rules on your complaint.

Thank you for bringing your concerns to the Board’s attention.
APPENDIX II-C
RULEMAKING NOTICE FORM

<table>
<thead>
<tr>
<th>Notice Number</th>
<th>2019-72</th>
<th>Rule Number</th>
<th>Ph 2200</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Agency Name &amp; Address:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Board of Pharmacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c/o Office of Professional Licensure &amp; Certification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>121 S. Fruit Street</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concord, NH 03301</td>
<td></td>
<td></td>
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</tbody>
</table>

2. RSA Authority: RSA 541-A:16, I(b) intro.
3. Federal Authority: n/a
4. Type of Action: Adoption X

5. Short Title: Investigations

6. (a) Summary of what the rule says and of any proposed amendments:

The intended action is to adopt rules to govern the Board of Pharmacy's investigation procedures under RSA 318:8-a for inspection and regulation of certain users of prescription drugs, RSA 318:14-a on drug compounding, RSA 318:30 on complaints relative to misconduct by licensees and others, and RSA 318:42 on dealing in or possessing prescription drugs.

6. (b) Brief description of the groups affected:

This proposal will affect all those licensed by the Board of Pharmacy, as well as physicians, nurse practitioners, physician assistants, naturopaths, podiatrists, optometrists, dentists, and veterinarians with prescriptive authority.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

<table>
<thead>
<tr>
<th>Rule</th>
<th>Statute</th>
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</thead>
<tbody>
<tr>
<td>Ph 2201.01</td>
<td>RSA 318:30; RSA 318-B:24; RSA 318:8-a; RSA 318:14-a; RSA 318:42</td>
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<td>Ph 2203.01</td>
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</tr>
</tbody>
</table>
7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name: Tom Broderick  
Address: 121 S. Fruit Street  
Concord, NH 03301  
Title: Attorney III  
Phone #: (603) 271-3103  
Fax#: (603) 271-0597  
E-mail: Thomas.Broderick@OPLE.NH.GOV  
TTY/TDD Access: Relay NH 1-800-735-2964  
or dial 711 (in NH)

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: May 28, 2019 at the conclusion of the public hearing.

☐ Fax  ☑ E-mail  ☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: May 28, 2019 at 9:00 a.m.  
Place: Office of Professional Licensure & Certification, 121 S. Fruit St., Concord, NH 03301

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # 19:067, dated April 19, 2019

1. Comparison of the costs of the proposed rule(s) to the existing rule(s): Not applicable as these are new rules.

2. Cite the Federal mandate. Identify the impact on state funds: No federal mandate, no impact on state funds.

3. Cost and benefits of the proposed rule(s): There is no cost to proposed Ph 2201-Ph 2206.

Proposed Ph 2207.01 and Ph 2207.02 contain administrative fines and subjective criteria to be considered by the board in levying these fines, after notice and an opportunity for a hearing, that are substantively similar to existing Ph 710.01 and Ph 710.02. The only difference in cost is contained in proposed 2207.02(c), which provides that "minor violation fines shall be subject to a fine of $25 for each offense with a maximum of $250 per Ph 710.01 and 710.02." Note: Ph 710.01 and Ph 710.02 do not contain this provision. This fine may be more or less than what any licensee may pay under the current subjective fine structure, so the cost or benefit of this new fine is indeterminable.

A. To State general or State special funds: The board licenses 3 state pharmacies: at the Department of Corrections, New Hampshire Hospital and the State Veteran’s Home. Fines may be assessed and collected from these agencies, with a potential de minimis general fund impact. Additional fine revenue will be deposited into the Office of Professional Licensure and Certification Fund pursuant to RSA 310-A:1-e, I(b).

B. To State citizens and political subdivisions:  
See 3. Above.

C. To independently owned businesses:  
See 3. Above.
11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

These rules do not violate Part I, Article 28-a of the New Hampshire Constitution. These rules do not mandate or assign this program to any political subdivision in any way.
Adopt Ph 2200 to read as follows:

CHAPTER Ph 2200 BOARD INVESTIGATIONS

PART Ph 2201 DEFINITIONS

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

(a) "Board investigator" means a pharmacist employed by the board of pharmacy to investigate violations of the pharmacy laws or the rules of the board by a person licensed at the time the alleged violation occurred.

(b) "Confidential letter of concern" means a warning letter issued by the board to a licensee as a type of outcome to an investigation conducted by the 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, and veterinarian clinic that have medication on their premises and are inspected by the Board of Pharmacy.

(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 board of pharmacy 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 may 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) "Naturopath" means the practitioner of a system of alternative medicine based on the theory that diseases can be successfully treated or prevented without the use of drugs, by techniques such as control of diet, exercise, and massage.

(j) "Nurse practitioner" or "Advanced Practice Registered Nurse (APRN)" means a registered nurse currently licensed by the board under RSA 326-B:18.

(k) "Professional misconduct" means behavior by a professional that implies an intentional compromise of ethical standards.

(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.

(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 section shall describe how the board conducts investigations as authorized by RSA 318:3-a, 318:14-a, 318:30, and 318:42.

Ph 2202.02 Scope. This section shall apply to any party licensed by the board or party licensed by another regulatory board that has given investigatory authority to the 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 "Pharmacy/Pharmacist Complaint Form" (Ph 531), revised 11/1/2018, available on the 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 board’s jurisdiction, shall be addressed by the board compliance staff. A report of investigation shall be issued to the board for review and further action if required.

(c) Investigations shall be assigned by the Board Administrator/Chief of Compliance.

(d) The board shall have the discretion to 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 11/1/2018, available on the 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 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;
   (5) Out of state permit holders under RSA 318:37 II(d); and

(b) Other medical providers pursuant to RSA 318:30 including:
   (1) Physicians;
   (2) Nurse practitioners;
   (3) Physician assistants;
   (4) Naturopaths;
   (5) Podiatrists;
   (6) Optometrists;
   (7) Dentists; and
   (8) Veterinarians with prescriptive authority;

(c) Other medical providers shall be subject to the pharmacy laws under RSA 318 for the labeling, storage, distribution, and destruction of drugs, and shall be subject to the laws under RSA 318-B for issues of controlled drugs and the Prescription Drug Monitoring Program.
Ph 2205.02 Investigations of a Complaint.

(a) Investigations into complaints shall be done by pharmacy board commissioners and board investigators in conjunction with board counsel and the New Hampshire Attorney General's Administrative Prosecution Unit (APU).

(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 board;
5. FDA recalls;
6. Noncompliance with the Prescription Drug Monitoring Program;
7. Unsanitary conditions, as per Ph 400 and 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 board to:

1. Obtain factual evidence to gain an understanding of the complaint allegations;
2. Conduct interviews of 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 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 [board administrator/chief of compliance] shall follow up with a complainant as to the outcome of the investigation.

(b) Unfounded investigation reports and board actions shall be kept on file by the board for 5 years. Founded 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 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 board.

PART Ph 2206 INVESTIGATION REPORTS

Ph 2206.01 Reports of Investigation.

(a) Board investigators shall review all information concerning technically sufficient complaints and prepare a report of investigation for 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;

(7) The relevant laws and rules for consideration of the complaint; and

(8) The investigator's recommendation to the 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 Board Action.

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

(b) The board shall take action in one or more of the following ways:

(1) Refer to the board investigator for further investigation; or

(2) Dismiss the complaint;

(3) Issue a confidential letter of concern;

(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)(V).

(c) In cases where the individual investigated is a licensee of another board, the board of pharmacy 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 2207.01(b)(3) above, the 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 board;

(7) The cost to the 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 board and other persons subject to administrative fines or penalties under RSA 318:29, IV shall, at the discretion of the board and after notice and an opportunity to be heard, be assessed fines and penalties as authorized under RSA 318:29, IV.

(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.

(d) Minor violation fines shall be subject to a fine of $25.00 for each offense with a maximum of $250.00 per Ph 710.01 and 710.02.

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

(e) When no violation of the same type has occurred within the 5 years preceding the board's notice to the respondent, the fine assessed shall not exceed $1,000 per violation upon the licensee and/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 board's notice to the licensee, the fine assessed shall not exceed $2,000 per violation upon the licensee and/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 board's notice to the licensee, the fine assessed shall not exceed $3,000 per violation upon the licensee and/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.

Unclear: This means the same as "may." See § 3.8 of Ch. 4 of the Manual. Under what circumstances shall the board assess fines and penalties?
### Appendix

<table>
<thead>
<tr>
<th>Rule</th>
<th>State Statute</th>
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Administrative Complaints

Purpose:

The purpose of the licensing system is to protect the public against:

1. Dishonest or unethical practitioners;
2. Practitioners who have fallen below minimum standards of competence in the practice of their profession; and/or
3. Dispensing System that may be prone to error.

Licensees or registrants may be subject to disciplinary action that can range from a formal warning to revocation of license, registration or permit. Disciplinary action is handled by the Board of Pharmacy ("Board") in response to a complaint received from a member of the public, another health care provider, or as a result of observations of the Board's compliance officers.

Filing a Complaint:

To file a complaint against a licensee, registrant, or permit holder, contact the Board, at the address listed above, and request a complaint form. Complete the form, sign it and mail it back to the board office, "ATTN: Compliance."

License Status of Person Complained Against:

The Board can only act against a person who is actually licensed, registered by, or who seeks to be licensed or registered by the board. If the person complained against does not hold and has not applied for a license or registration, the Board has no administrative authority to consider the complaint itself. If the complaint alleges a violation of the Board's
statutes or rules, the Board may investigate the matter for possible referral to the NH Attorney General or local prosecutor for civil action or criminal prosecution. If the person complained against is indeed licensed or registered by the board, the complaint is assigned a complaint number and assigned to a Compliance Investigator.

Who is a "Compliance Investigator". A Compliance Investigator is a member of the board staff. Part of his/her duties is to investigate complaints. After investigating the complaint, the Compliance Investigator submits a report to the Chief Compliance Investigator who reviews the complaint and the report. Upon completion of the review, he presents the matter to the Board for it to decide how the matter should be handled. If the Board decides to proceed with a formal hearing, the Chief Compliance Investigator assists the Administrative Prosecution's Unit of the Attorney General's Office in presenting the case to the Board. The Chief Compliance Investigator does not participate in the Board's deliberations or vote in any manner.

Notice to Complainant:

The Compliance Investigator sends the complainant a written acknowledgement of the complaint.

Notice to Licensee:

The Chief Compliance Investigator "may" immediately forward a copy of the complaint to the licensee, registrant or permit holder, along with notification that the licensee is under investigation. If so, the licensee, registrant or permit holder shall be asked to respond to the complaint.

Additional Investigation:

The Board employs compliance investigators, who report to the Chief Compliance Investigator. On occasion, federal and state law enforcement officials may work with the Board's investigators, depending upon the nature of the complaint. Any of these investigators may personally contact the complainant and/or the licensee, registrant or permit holder, as part of an expanded investigation.

Presentation to the Board:

The complaint will be presented to the Board when the investigation is complete. How quickly the presentation is made depends on the complexity of the investigation, the Board's overall workload, the number of other pending investigations, and the frequency with which the Board meets.
Confidentiality:

All complaints, information regarding the complaint, and investigative records are confidential during the pendency of an investigation. If the Board initiates a formal adjudicatory proceeding, some or all of the information collected during the investigation may become public.

Penalties:

The Board may impose sanctions against a licensee, registrant or permit holder including those listed below. The penalties may be subject to limitations set out in the governing law:

1. Issue a reprimand to a licensee, registrant or permit holder
2. Suspend or revoke a license, registration or permit
3. Impose a civil fine
4. Impose conditions of probation upon a licensee, registrant or permit holder

[Comment on p. 2 of Form Instructions, Attachment p. a.]

This action depends upon the "nature" of the complaint. It may not be in the best interest of the Board to notify the licensee prior to initiation of the investigation.
Enclosed is a complaint form, a brief outline of the administrative complaint procedures, and if applicable, a release of information.

In the event that you need to be contacted regarding your complaint, please provide the following information and return this page with your complaint form.

**PLEASE NOTE**

This complaint **cannot** go forward unless the enclosed medical release form is signed, dated, witnessed and returned with the complaint.

**COMPLAINANT INFORMATION:**
Please PRINT

Your Name: ________________________________

Your Complete Mailing Address:

________________________________________

______________

Daytime Telephone Number: ( ___ )

Evening Telephone Number: ( ___ )

FOR OFFICE USE ONLY:

File Number: ______________________________

Date Assigned: ___________________________

Investigator: _____________________________ Acknowledgement Sent: ____________________________

Date Investigation Complete: ________________

Resolution: _________________________________

Form # Ph 533 (Rev. 11/1/18) Policy #2-12-17-96
PHARMACY/PHARMACIST COMPLAINT FORM

PLEASE PRINT:

Today's Date: ______________ Your Name (Complainant): ______________

Your SIGNATURE: ______________________________________________________

Pharmacy Name: ______________________________________________________

Pharmacy Address: ____________________________________________________

Name of Pharmacist **: ________________________________

Date of incident: ________________________________

Prescription number(s) of prescription(s) involved in this complaint:
____________________________________________________________________

Patients Name: ______________________________________________________

Relationship to complainant: ________________________(self, husband, wife etc.)

Was this a NEW [ ] or REFILL [ ] prescription order?

Was the "offer to counsel" given? Yes [ ] No [ ]

Was counseling GIVEN [ ] or REFUSED [ ]

**If "unknown" please look at the prescription bottle and record the initials of the dispensing pharmacist, which are printed on the label.

Form #Ph 534 (Rev. 11/1/18)       Policy # 2-12-17-97       Page 1 of 3
Did this involve any other pharmacy personnel other than the pharmacist on duty?
   Yes [ ]        No [ ]

If "yes" individual(s) name AND title (clerk, technician, store manager etc.)

__________________________________________________________________________

Have you contacted the pharmacy regarding this incident?
   Yes [ ]        No [ ]

If "yes" to whom did you speak (name & title, if possible)?

__________________________________________________________________________

Have you spoken with anyone at the corporate level (supervisor, company main office etc.)?
   Yes [ ]        No [ ]

If "yes", to who did you speak (name & title, if known)?

__________________________________________________________________________

Please PRINT (or attach a typewritten statement)
Clearly explain your complaint. It is important to list the facts and details in the order in which they occurred, including names, dates, places and times. Include "copies" of any documents, which support your complaint. If you require more space, include extra sheets. Return this form, the "cover sheet", along with documentation, to the address at the top of page 1 of this form. ATTN: COMPLIANCE. (please sign and date the bottom of each page used.)

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

Signed: __________________________   Date: __________________________

Form #Ph 534 (Rev. 11/1/18)   Policy # 2-12-17-97   Page 2 of 3
STATE OF NEW HAMPSHIRE  
OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION  
DIVISION OF HEALTH PROFESSIONS  
BOARD OF PHARMACY  
121 South Fruit Street, Suite 401  
Concord, NH 03301-2412  
Phone 603-271-2350 • Fax 603-271-2856  
www.plpc.nh.gov/pharmacy

Health Insurance Portability and Accountability Act ("HIPPA")

RELEASE OF MEDICAL INFORMATION FORM

I __________________________ hereby grant authority to agents of the New Hampshire Board of Pharmacy to access my pharmacy, medical, hospital, and insurance records for the purpose of investigating the complaint I have filed with the Board of Pharmacy office on (date) _____________________.

Signed: ______________________ Date: ______________________

Witness: ______________________ Date: ______________________  
(Signature)

Witness: ______________________ (Print Name)

Form #Ph 535 (Rev. 11/1/18)  
Policy # 2-12-17-98
**Quality Related Event (QRE) Report**

<table>
<thead>
<tr>
<th>Date of Report:</th>
<th>Date of Incident:</th>
<th>Time of Incident:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>A.M.</strong></td>
<td><strong>P.M.</strong></td>
</tr>
</tbody>
</table>

**Type of Prescription Involved:**
- [ ] New
- [ ] Refill
- [ ] How Received:
  - [ ] Hard Copy Rx
  - [ ] Telephoned In
  - [ ] Fax or E-Prescription

**If Telephoned in, Order Was Taken By:**
- [ ] Pharmacist
- [ ] Certified Pharmacy Technician
- [ ] Not Applicable

**At What Level Was the Event Discovered?**
- [ ] Patient
- [ ] Prescriber
- [ ] Pharmacist
- [ ] Pharmacy Staff
- [ ] Other:

**Was the Patient Harmful?**
- [ ] Yes
- [ ] No

**Describe Incident Type (Check All That Apply):**
- [ ] Wrong Medication
- [ ] Transcription Error
- [ ] Incorrect Dosage
- [ ] Labels Switched
- [ ] Mislabeled/Misread
- [ ] Allergy Not Listed in Profile
- [ ] Communication Error
- [ ] Incorrect Directions or Usage
- [ ] Other:

Describe in detail what happened — be specific using facts only — no opinions. Do not include names or any other patient, prescriber or pharmacy staff identifiers. Attach additional sheet if required.

<table>
<thead>
<tr>
<th>Medication Ordered</th>
<th>Medication Actually Dispensed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Name</td>
</tr>
<tr>
<td>Strength</td>
<td>Strength</td>
</tr>
<tr>
<td>Quantity</td>
<td>Quantity</td>
</tr>
<tr>
<td>Directions</td>
<td>Directions</td>
</tr>
</tbody>
</table>

Using the description of the six stages of filling a prescription (explained at end of this form), at what stage of the process does it appear that the problem originated:
- [ ] Stage One
- [ ] Stage Two
- [ ] Stage Three
- [ ] Stage Four
- [ ] Stage Five
- [ ] Stage Six

**Whom was the initial cause of the error related to:**
- [ ] Pharmacist
- [ ] Intern
- [ ] Technician
- [ ] Prescriber
- [ ] Patient
- [ ] Prescriber's Office Staff
- [ ] Other:

**Did the error reach the patient?**
- [ ] Yes
- [ ] No

**Did the patient use / Ingest the medication?**
- [ ] Yes
- [ ] No

**If yes, did this result in an adverse reaction to the patient?**
- [ ] Yes
- [ ] No

**Was a “Prospective Drug Review” completed?**
- [ ] Yes
- [ ] No

**Where in the process was the “Prospective Drug Review” Completed?**
- [ ] During Rx data entry
- [ ] During Rx final verification

**Patient’s Age:**
- [ ] During Rx data entry
- [ ] During Rx final verification

*If Yes, name and location of pharmacist?*
<table>
<thead>
<tr>
<th>Initial data entry of prescription information was performed by:</th>
<th>Pharmacist</th>
<th>Intern</th>
<th>Certified Technician</th>
<th>Registered Technician</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;If registered technician, has technician been trained on data entry?&quot;</td>
<td>Yes</td>
<td>No</td>
<td>*Is there documentation available that the registered technician completed Board approved data entry training?</td>
<td>Yes</td>
</tr>
<tr>
<td>Upon completing the data entry, did the computer identify any problem with drug interaction, dosage alert, etc.?</td>
<td>Yes</td>
<td>No</td>
<td>Did the computer require the pharmacist or technician to do a &quot;manual over-ride&quot;?</td>
<td>Yes</td>
</tr>
<tr>
<td>During the dispensing process, did the &quot;stock&quot; bottle accompany the finished product up to the time of final verification?</td>
<td>Yes</td>
<td>No</td>
<td>Did the &quot;original&quot; hard copy prescription physically follow the order through the process to the point of verification?</td>
<td>Yes</td>
</tr>
<tr>
<td>Was the &quot;original&quot; prescription &quot;scanned&quot; into the system?</td>
<td>Yes</td>
<td>No</td>
<td>Was the dosage ordered (for administration) different than the commercially available form of the medication? (example: Zantac® 75mg/5ml Sig: 25 mg once daily.)</td>
<td>Yes</td>
</tr>
<tr>
<td>How many hours was the pharmacy open the day the incident occurred?</td>
<td></td>
<td></td>
<td>Staffing level at pharmacy on the day of the incident?</td>
<td>Usual staffing level</td>
</tr>
<tr>
<td>Number of pharmacists on duty at the time of incident?</td>
<td>Total number of pharmacist hours that day?</td>
<td>Total time in hours of pharmacist &quot;overlap&quot; on day of incident? (i.e. more than 1 RPh on duty at same time)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of pharmacy technicians on duty at the time of incident?</td>
<td>Does the PIC (Pharmacist-In-Charge) or staff pharmacist have the ability to regulate the scheduling of pharmacists and/or technicians?</td>
<td>Scheduling is done by? (title only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the PIC (Pharmacist-In-Charge) have any input into the scheduling?</td>
<td>Yes</td>
<td>No</td>
<td>Did any other store personnel become involved in the incident? (i.e. front store manager, PDM, etc.)</td>
<td>Yes</td>
</tr>
<tr>
<td>Total number of prescriptions (new &amp; refill) that were filled at the pharmacy on the date of the incident?</td>
<td>0 - 50</td>
<td>51 - 100</td>
<td>101 - 150</td>
<td>151 - 200</td>
</tr>
<tr>
<td></td>
<td>301 - 350</td>
<td>351 - 400</td>
<td>401 - 500</td>
<td>501 - 600</td>
</tr>
</tbody>
</table>

Any unusual distractions on the date of the incident? (If so, explain)

Any other issues that might have contributed to the incident? (Be brief and specific)
<table>
<thead>
<tr>
<th>Submitter's Printed Name</th>
<th>Submitter's Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Submitter's Title</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Pharmacist-In-Charge</td>
<td>☐ Staff Pharmacist</td>
<td>☐ Pharmacy Intern</td>
</tr>
</tbody>
</table>

Form # 530 (Rev. 8/13)
Stages of filling a Prescription

- **Stage 1:** Receiving the Prescription
- **Stage 2:** Data Entry
- **Stage 3:** Prescription Assembly
- **Stage 4:** Pharmacist Final Check
- **Stage 5:** Addressing the Issues
- **Stage 6:** Delivery to the Patient

**Stage One:**
Receiving the prescription. This is when phone-in, electronic, faxed, or physically delivered prescriptions start their journey culminating with the ingestion of the drug by the patient. At this stage it is important to find out everything that reasonably can be known about the patient. Is this a child or an older adult? Are there significant allergies? If it is a refill request, has the drug been working? What other medications are being used? Later on in the chain of events, the responses to these questions may take on greater importance.

**Stage Two:**
The second stage usually involves data entry. A person trained to do so will input information into the computer, and that information will become the electronic record upon which everyone within the pharmacy will subsequently rely. Inaccurate data entry could result in serious consequences to the patient. It is much easier to get this step right than it is to later recognize that an error has occurred.

**Stage Three:**
The third stage centers on prescription assembly. A correct vial or other container must be chosen. The correct label must be affixed to the correct container, with the correct medication inside the container. All of this must be done as a singular process in order to avoid confusing one prescription with another. At the end of this stage, there should be a prescription, a stock container of medication from which the medication was obtained, and a labeled container of medication for the patient. These things should be kept together for each patient, perhaps in a basket that separates them from medications for other patients.

**Stage Four:**
The fourth stage requires a final review of the prescription-filling process by the pharmacist. At this point, everything previously done by a pharmacy technician, another pharmacist, or the pharmacist who filled the prescription, is reviewed to ensure accuracy. There is no single “gold standard” for how this is done. Some pharmacists use the NDC number as a way to compare what is in the stock bottle with what is listed on the computer printout. Others shake out and visualize on the cap, a supply of the medication. It is probably important to vary the approach to this final review from time-to-time to prevent bias that leads people to see what they expect to see rather than what is really there. Pharmacists frequently address soft edits at this stage, resolving problems identified by the computer.

**Stage Five:**
The fifth stage addresses any issues that may arise. These may include queries emanating from the prescription software program, denials by third-party payers, the need for communication with the prescriber or patient, and ambiguities related to the intended course of therapy. It is important to place aside these issues until they are able to be resolved in order to avoid time-consuming backlogs. Other patients should not have to wait unnecessarily for their prescription to be filled while another patient’s prescription is awaiting resolution of an issue.

**Stage Six:**
The sixth and final stage is the delivery of the medication, with counseling if necessary or requested, to the patient. This is the time to make sure that auxiliary labeling, if appropriate, has been affixed to the container, that the computer information leaflet has been included, and that the patient being given the drug is the one for whom it has been prescribed. Any particularly critical pieces of information should be emphasized to the patient, and any questions answered.
TITLE XXX
_OCCUPATIONS AND PROFESSIONS_

CHAPTER 318
_PHARMACISTS AND PHARMACIES_

Pharmacy Board

Section 318:8-a

318:8-a Inspection and Regulation of Certain Users of Prescription Drugs. – All physicians, veterinarians, dentists, advanced registered nurse practitioners, physician assistants, and clinics under contract to the department of health and human services and agricultural, technical, or industrial users of prescription drugs shall be subject to inspection and regulation by the board of pharmacy with regard to the storage, labeling, distribution, and disposal of prescription drugs.

318:14-a Compounding. –
I. Products that are not commercially available may be compounded for hospital or office use but shall not be resold or dispensed. Nonprescription items may be compounded upon order by a practitioner for sale as long as the labeling complies with RSA 318:47-a and the product is not a copy of, or similar to, prescription or nonprescription products. All compounding shall be done in compliance with the United States Pharmacopeia as defined by board of pharmacy rules.

II. The compound drug product shall bear the label of the pharmacy responsible for compounding and dispensing the product directly to the patient for administration, and the prescription shall be filed at that pharmacy. Compounded prescription labels shall include the phrase "compounded per subscriber request" or a similar statement on the prescription label or through the use of an auxiliary label attached to the prescription container.

III. A pharmacist shall offer a compounded drug product to a practitioner for administration to an individual patient, in limited quantities. The compounded drug products are for practitioner administration only and shall not be re-dispensed. The pharmacist shall maintain records to indicate what compounded drug products were provided to the medical office or practice. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services, in accordance with state law and rules of the board, as well as applicable federal laws.

IV. Where a commercial drug shortage exists because a manufacturer is the only entity currently manufacturing a drug product of a specific strength, dosage form, or route of administration for sale in the United States, and the manufacturer cannot supply the drug product to the public or to practitioners for use, a pharmacist may compound a limited quantity using the active pharmaceutical ingredient and sell to a patient with a valid prescription from a valid prescriber. When the compounded drug product is sold to a medical office or practice it is for the practitioner to administer to patients, and shall not be for resale.

V. The board shall adopt rules under RSA 541-A concerning the regulation of compounding.

VI. Labeling requirements pursuant to paragraph II shall not apply when medication is dispensed to institutionalized patients as provided under RSA 318:47-b.

318:29 Disciplinary Action. —
I. The board may undertake disciplinary action against any licensee, permittee, registrant, or certificate holder:
(a) Upon its own initiative; or
(b) Upon written complaint of any person which alleges that a licensee, permittee, registrant, or certificate holder has committed misconduct under paragraph II or V of this section or any other applicable provision of this chapter or RSA 318-B, and which specifies the grounds therefor.
II. Misconduct sufficient to support disciplinary proceedings under this section shall include:
(a) The practice of fraud or deceit in procuring or attempting to procure a license, permit, registration, or certificate to practice under this chapter;
(b) Conviction of a felony or any offense involving moral turpitude;
(c) Any dishonest or unprofessional conduct, or gross or repeated negligent conduct in the practice of pharmacy or in performing activities ancillary to the practice of pharmacy or any particular aspect or specialty thereof;
(d) Behavior which demonstrates a clear conflict with the basic knowledge and competence expected of licensed pharmacists or any particular aspect or specialty of the practice of pharmacy, or any intentional act which demonstrates a clear inconsistency with the health and safety of persons making use of the professional services of any person licensed under this chapter;
(e) Addiction to the use of alcohol or other habit-forming drugs to a degree which renders him or her unfit to practice under this chapter;
(f) Mental or physical incompetency to practice under this chapter; or
(g) Willful or repeated violation of any provision of this chapter, any substantive rule of the board, or any other federal, state, or local drug or pharmacy-related law, rule, or regulation.

III. [Repealed.]

IV. The board may take disciplinary action in any one or more of the following ways:
(a) By reprimand;
(b) By suspension, limitation or restriction of a license or probation for any period of time deemed reasonable by the board;
(c) By revocation of license;
(d) By assessing administrative fines in amounts established by the board;
(e) By requiring the person to participate in a program of continuing education in the area or areas in which he or she has been found deficient; or
(f) By requiring the licensee to submit to the care, observation or treatment of a physician, counseling service, health care facility, professional assistance program, or any comparable person or facility approved by the board.

V. The board may, after notice and hearing, suspend or revoke a pharmacy permit, license, or registration for grounds which include, but are not limited to:
(a) The suspension, revocation, or expiration of the pharmacist license of the pharmacist-in-charge.
(b) Termination of the employment of the pharmacist-in-charge with the pharmacy.
(c) Operation of the pharmacy in a manner that is in violation of federal, state, or local drug or pharmacy-related law, rule, or regulation.
(d) Conviction of the pharmacist-in-charge, an owner, a corporate officer, the corporation, or the pharmacy of a felony, a misdemeanor resulting from a violation of any federal, state, or local drug or pharmacy-related law, rule or regulation, or an act involving moral turpitude or gross immorality.
(e) Unsanitary conditions.
(f) Fraud, intentional misrepresentation or perjury in securing the permit, license, or registration or in any hearing before the board.
(g) Unprofessional conduct which includes, but is not limited to, violations of federal, state, or local drug or pharmacy-related laws, rules, or regulations, or other acts or omissions which, in the opinion of the board, pose a threat to the well-being or the safety of the public.
(h) Fee splitting for professional services. This does not prohibit rent payments under a rental or lease agreement for the operation of a pharmacy by a pharmacist or pharmacy to an individual licensed to prescribe medicine.
(i) Any ownership or control of an ownership interest of a pharmacy within the state by an individual licensed to prescribe medicine, or a corporation, professional association or partnership consisting of such prescriber or prescriber’s immediate family members, except such corporations as are expressly exempt from income taxation under section 501(c)(3) of the United States Internal Revenue Code. This shall not include ownership of investment securities purchased by the practitioner on terms available to the general public and which are publicly traded. This subparagraph shall not apply to the ownership or control of an ownership interest of an institutional pharmacy operated within the state by or for hospitals, as defined in RSA 151:2, I(a), licensed by the state pursuant to RSA 151.
(j) The sale, rental, trade, transfer, or release of patient identifiable medical information for the purpose of sales or marketing of services or products without written authorization.

Ph 709.08 Investigational Drugs. Investigational drugs for research shall be used only under the supervision of the principal investigator and shall be approved by an appropriate medical staff committee. Such drugs shall be controlled by the pharmacy and shall be properly labeled. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06 ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.09 Purchase of Drugs.

(a) The pharmacist-in-charge, with the consent of the institution's pharmacy and therapeutics committee or comparable committee of its medical staff shall be responsible for the quality of all drugs, biologicals and pharmaceutical chemicals.

(b) Purchasing of drugs, pharmaceuticals, biologicals, intravenous and irrigation fluids shall be subject to approval of the pharmacist-in-charge with the consent of the institution's pharmacy and therapeutic committee or comparable committee of its medical staff.

(c) Radiopharmaceuticals, blood products, radiopaque media and medical devices may be exempted from the approval and/or control of the pharmacist-in-charge by the institution's pharmacy and therapeutics committee.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

PART Ph 710 ADMINISTRATIVE FINES

Ph 710.01 Liability for Administrative Fines. Persons subject to the disciplinary authority of the board and other persons subject to administrative fines or penalties under RSA 318:29, IV shall, at the discretion of the board, after notice and an opportunity to be heard, be assessed fines and/or penalties as authorized under RSA 318:29, IV.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05, EXPIRED: 3-26-13; ss by #10903, eff 8-5-15

Ph 710.02 Severity of Fine.

(a) 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(s);
(2) The number of concurrent and/or repeated violations; and

(3) The frequency of violations committed by the particular licensee, permit holder, or other person.

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

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

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

(e) 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.

(f) In all cases, the 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 board;

(7) The cost to the 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.

Source.  #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New.  #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New.  #8316, eff 3-26-05, EXPIRED: 3-26-13

New.  #10903, eff 8-5-15