

Readopt with amendment Ph 1500, effective 2-26-14 (Document #10526), to read as follows:

CHAPTER Ph 1500 NEW HAMPSHIRE CONTROLLED DRUG PRESCRIPTION HEALTH AND SAFETY PROGRAM

PART Ph 1501 PURPOSE

Ph 1501.01 Purpose. This rule implements the New Hampshire Controlled Drug Prescription Health and Safety Program created by RSA 318-B:31–38, which authorizes the pharmacy board to establish and contract with a third party for the implementation and operation of an electronic system to facilitate the confidential sharing of information relating to the prescribing and dispensing of schedule II–IV controlled substances by prescribers and dispensers within the state to promote public health and safety through the prevention of and treatment for misuse and abuse of controlled substances and the reduction of the diversion of such substances, without interfering with the legal medical use of these substances.

PART Ph 1502 DEFINITIONS

Ph 1502.01 Definitions.

- (a) “Authorized representative” means a parent or guardian of a minor child, or a person who has been authorized in the manner required by law to make health care decisions, or gain access to health care records, on behalf of another.
- (b) “Board” means “board” as defined in RSA 318-B:31, I, namely, “the pharmacy board, established in RSA 318:2.”
- (c) “Controlled substance” means “controlled substance” as defined in RSA 318-B:31, II, namely, “controlled drugs as defined in RSA 318-B:1, VI.”
- (d) “Credential” means information or a device provided by the program to a registered dispenser or prescriber that allows the dispenser or prescriber to electronically submit or access prescription monitoring information. Credentials include, but are not limited to, a user name and password, or an identification device that generates a user name and password.
- (e) “Dispense” means “dispense” as defined in RSA 318-B:31, III, namely, “to deliver a controlled substance by lawful means and includes the packaging, labeling, or compounding necessary to prepare the substance for such delivery.”
- (f) “Dispenser” means “dispenser” as defined in RSA 318-B:31, IV, namely, “a person lawfully authorized to deliver a schedule II-IV controlled substance, but does not include:
 - (a) A licensed hospital pharmacy that dispenses less than a 48 hour supply of a schedule II-IV controlled substance from a hospital emergency department, or that dispenses for administration in the hospital;
 - (b) A practitioner, or other authorized person who administers such a substance;
 - (c) A wholesale distributor of a schedule II–IV controlled substance or its analog;

- (d) A prescriber who dispenses less than a 48 hour supply of a schedule II – IV controlled substance from a hospital emergency department to a patient; or
- (e) A veterinarian who dispenses less than a 48 hour supply of a schedule II-IV controlled substance to a patient.”
- (g) “Patient” means “patient” as defined in RSA 318-B:31, V, namely, “the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance or other such drug is lawfully dispensed.”
- (h) “Person” means “person” as defined in RSA 318-B:1, XXI, namely, “any corporation, association or partnership, or one or more individuals.”
- (i) “Practitioner” means “practitioner” as defined in RSA 318-B:31, VI, namely, “a physician, dentist, podiatrist, veterinarian, pharmacist, APRN, physician assistant, naturopath, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance in the course of licensed professional practice.”
- (j) “Prescribe” means “prescribe” as defined in RSA 318-B:31, VII, namely, “to issue a direction or authorization, by prescription, permitting a patient to lawfully obtain controlled substances.”
- (k) “Prescriber” means “prescriber” as defined in RSA 318-B:31, VIII, namely, “a practitioner or other authorized person who prescribes a schedule II, III, and/or IV controlled substance.”
- (l) “Program” means “program” as defined in RSA 318-B:31, IX, namely, “the controlled drug prescription health and safety program that electronically facilitates the confidential sharing of information relating to the prescribing and dispensing of controlled substances listed in schedules II-IV, established by the board pursuant to RSA 318-B:32.”
- (m) “Program manager” means the person designated by the board to oversee the implementation and operation of the program by the program vendor.
- (n) “Program vendor” means a third party with which the board contracts for the implementation and operation of the program.
- (o) “Regulatory board” means the New Hampshire board of dentistry, board of medicine, board of nursing, board of registration in optometry, board of podiatry, board of veterinary medicine, and pharmacy board.

PART Ph 1503 REGISTRATION OF PRESCRIBERS AND DISPENSERS

Ph 1503.01 Registration of Prescribers and Dispensers.

- (a) All practitioners authorized to prescribe or dispense schedule II–IV controlled substances within the state of New Hampshire shall register with the program [~~no later than June 30, 2015~~], as follows:
- (1) Practitioners who prescribe but do not dispense schedule II-IV controlled substances shall register with the program as a prescriber;

- (2) Practitioners who dispense but do not prescribe schedule II-IV controlled substances shall register with the program as a dispenser if they fall under the definition of “dispenser” in RSA 318-B:31, IV; and
 - (3) Practitioners who prescribe and dispense schedule II-IV controlled substances shall register with the program as both a prescriber and a dispenser unless exempted pursuant to RSA 318-B:31, IV.
- (b) Program registration shall be by one of the following methods:
- (1) Automatic registration at the time of the program go-live date or at the time of initial licensure or license renewal, if permitted by the prescriber’s or dispenser’s regulatory board; or
 - (2) Completing and submitting to the program vendor a registration form provided by the program vendor.
- (c) Before a program credential is issued, the registrant shall be verified as having a current and valid license, as follows:
- (1) Those prescribers and dispensers who register in accordance with (b)(1) above shall be automatically verified; and
 - (2) Those prescribers and dispensers who register in accordance with (b)(2) above shall be verified by the program manager by confirming that the registrant has a valid license.
- (d) On a monthly basis, each regulatory board shall submit to the program manager or program vendor a list of prescribers and dispensers:
- (1) Who have been issued a new license;
 - (2) Whose license has been renewed; and
 - (3) Who have had their license revoked, suspended, restricted, or not renewed.
- (e) If the credentials issued by the program vendor are lost or missing, or if the security of the credentials is compromised, the prescriber or dispenser shall cause the program manager to be notified by telephone and in writing as soon as possible.
- (f) Those dispensers licensed under RSA 318 who have not registered shall be subject to disciplinary action as established pursuant to RSA 318:29.
- (g) Those prescribers and dispensers who are required to register but who have not done so shall, pursuant to RSA 318-B:36 III, be subject to penalties established by their respective regulatory board.

PART Ph 1504 REQUIREMENTS FOR DISPENSERS

Ph 1504.01 Reporting of Controlled Substances Dispensed.

- (a) Dispensers shall submit to the program the prescription drug monitoring information required by RSA 318-B:33, IV, and paragraph (b) below, for each dispensing of a schedule II–IV controlled substance, as follows:
 - (1) Electronically, through direct upload to the program software or website at <https://pmpclearinghouse.net>, unless a waiver is requested and granted in accordance with Ph 1504.02(a) below;
 - (2) Daily, by the close of business on the next business day after the prescription was dispensed, unless an extension is requested and granted in accordance with Ph 1504.03 below, with the following exceptions:
 - a. Veterinarians shall submit the information required under (a)(2) above no more than 7 days from the date the prescription was dispensed; and
 - b. Dispensers who have a federal Drug Enforcement Administration license but who do not dispense controlled substances may request a waiver as described in Ph 1504.02(c) below; and
 - (3) For registered dispensers located outside the state of New Hampshire, information only for patients who reside in New Hampshire.
- (b) The required prescription drug monitoring information to be submitted shall be as follows:
 - (1) Dispenser’s Drug Enforcement Administration (DEA) registration number and, if available, the dispenser’s National Provider Identification (NPI) number;
 - (2) Prescriber’s DEA registration number and, if available, the prescriber’s NPI number;
 - (3) Date of dispensing;
 - (4) Prescription number;
 - (5) Number of refills granted;
 - (6) National Drug Code (NDC) of drug dispensed;
 - (7) Quantity dispensed;
 - (8) Number of day’s supply of drug;
 - (9) Patient’s name, including first name, middle initial, if applicable, last name, and, suffix, if applicable;
 - (10) Patient’s address;
 - (11) Patient’s date of birth, or, for animals, the owner’s date of birth;
 - (12) Patient’s phone number, if available;
 - (13) Date prescription was written by prescriber;

- (14) Whether the prescription is new or a refill;
 - (15) Source of payment for prescription; and
 - (16) The species code human (1) or animal (2), and if animal, the animal's name.
- (c) Dispensers licensed by the board under common ownership, including those located outside of New Hampshire, may submit the required prescription drug monitoring information in (b) above in a single joint report provided that each dispenser is clearly identified for each prescription dispensed.
- (d) The program vendor shall perform data checks to ensure that the required prescription drug monitoring information submitted is accurate, complete, and timely.
- (e) The program vendor shall notify the dispenser, the program manager, and the board:
- (1) When the dispenser fails to submit the required prescription drug monitoring information within the required timeframe;
 - (2) When there are inaccuracies or omissions in the required prescription drug monitoring information submitted; and
 - (3) When a dispenser fails to correct any inaccuracies or omissions.
- (f) Dispensers shall:
- (1) Correct any failures, inaccuracies, or omissions, within 72 hours of the date of receipt of notice from the program vendor;
 - (2) Correct their own records and submit corrected information to the program or program vendor whenever they become aware of errors, omissions, or reversals;
 - (3) Comply with any provision of this section or be subject to disciplinary action as established pursuant to RSA 318:29; and
 - (4) If a dispenser has no dispensing transactions to report for the preceding reporting period, report this information to the New Hampshire Controlled Drug Prescription Health and Safety Program by filing a "zero report," as described in the Reporting Zero Dispensing topic in the Data Submission Dispenser Guide, effective June 29, 2017.

Ph 1504.02 Waivers.

- (a) Dispensers that are unable to electronically submit, through direct upload to the program software or secure website, the required prescription drug monitoring information may request a waiver to submit the information by other means by completing and submitting a "Request for Waiver of Reporting Requirements for New Hampshire Prescription Drug Monitoring Program" form, effective October 28, 2016, to the program manager, along with any supporting documentation.
- (b) A waiver request submitted pursuant to (a) above shall:

- (1) Demonstrate that, for any reason, including low volume of controlled substances being dispensed, financial hardship will result from the requirement of electronic submission[-]; and
 - (2) Include an alternative method by which the dispenser will submit the required prescription drug monitoring information with the time frame specified in Ph 1504.01(a)(2). Alternative methods of submission shall include but not be limited to, e-mail, flash drive, CD, or paper.
- (c) Dispensers that are authorized to dispense schedule II-IV controlled substances, but do not do so, may request a waiver from the program submission requirements by completing and submitting a “Request for Waiver of Reporting Requirements for New Hampshire Prescription Drug Monitoring Program” form, effective October 28, 2016, provided that such dispensers demonstrate that no schedule II-IV controlled substances have been dispensed in the 3 months immediately preceding the waiver request.
- (d) Dispensers shall be notified of the decision to grant a waiver within 30 days of the date of the receipt of the completed waiver request.
- (e) A waiver shall be specific to one United States DEA number and non-transferable.
- (f) A waiver shall be time-limited, not to exceed the dispenser’s license expiration date.
- (g) A waiver shall be subject to revocation if the bases for granting the waiver are determined to be no longer true.

Ph 1504.03 Extensions.

- (a) Dispensers that are unable to submit required prescription information within the required timeframe may request from the program manager an extension of the timeframe by telephone confirmed by email from the program manager.
- (b) The program manager shall allow an extension for as long as the dispenser is making a good-faith effort to submit the required information, but no later than 10 calendar days after the established 7 day timeframe.
- (c) The program manager shall notify the board if a dispenser ceases to demonstrate good faith in its efforts to submit the required information or if the dispenser fails to submit the required information by the extended timeframe.

PART Ph 1505 ACCESS TO PRESCRIPTION DRUG MONITORING INFORMATION

Ph 1505.01 Patient Access.

- (a) A patient for whom a prescription for a schedule II–IV controlled substance is dispensed, or his or her authorized representative, may request and obtain a report listing all prescription monitoring information that pertains to that patient.

- (b) The request in (a) above shall be submitted to the program manager, either by mail or in person, on a complete, "Patient Prescription Monitoring Information Request" form (February 2014 Edition) signed by the patient, or the patient's authorized representative.
- (c) Patient information shall not be mailed or otherwise transmitted to the patient, or the patient's authorized representative, except as allowed by (d) below.
- (d) Upon notice that the requested information is available, the patient, or the patient's authorized representative, shall receive the information in person, only after he or she produces valid government-issued photographic proof of identity. With the consent of the patient, or the patient's authorized representative, the program manager shall photocopy the identification. If the patient, or patient's authorized representative, does not consent to the photocopying of the identification, the patient, or patient's authorized representative, shall provide written verification attesting to their identity.

Ph 1505.02 Prescriber and Dispenser Access.

- (a) Registered prescribers and dispensers, or their designees, and federal health prescribers and dispensers working in federal facilities located in New Hampshire, Massachusetts, Maine, and Vermont shall have electronic program access to information on a specific patient, and in the case of veterinarians a specific patient's owner(s), both past and present, for which a prescription was written or an appointment was scheduled or conducted.
- (b) Requests shall be made by electronically or in writing.
- (c) Electronic requests shall be made through the program's secure web portal.
- (d) Written requests shall:
 - (1) Be made by submitting to the program a completed "NH Prescriber/Dispenser Prescription Monitoring Information Request" form, effective 11/2017; and
 - (2) Be fulfilled by secure mail or fax.
- (e) To enable the timely and efficient delivery of medical or pharmaceutical care for a specific patient, a prescriber or dispenser registered with the program may delegate the task of retrieving program information for a specific patient to an individual working under the direction and supervision of the registered prescriber or dispenser provided that written documentation of the delegation to the individual is provided to the program. Both the prescriber or dispenser who authorized the delegation and the individual to whom the task of retrieving the program information was delegated shall be subject to the provisions and penalties in RSA 318-B:36 regarding proper access to and use of program information.
- (f) All program information, as listed in Ph 1504.01(b), to the extent that it is medical information shall be treated and protected as all protected health information.
- (i) The program information may be placed in the patient medical records.

Ph 1505.03 Law Enforcement Access.

- (a) Authorized law enforcement officials may request and obtain information from the program on a case-by-case basis for the purpose of investigation and prosecution of a criminal offense.
- (b) For the purposes of (a) above, a law enforcement official shall be considered authorized if he or she provides a court order based on probable cause, or a search warrant signed by a judge, which includes sufficient information to correctly identify the patient, prescriber, or dispenser whose prescription monitoring information is the subject of the court order.
- (c) A law enforcement official shall present the court order or search warrant to the representative of the board designated by the board to receive such orders, who shall notify the program manager to provide the information identified in the court order in the format requested by the court order.

Ph 1505.04 Regulatory Board Access.

- (a) New Hampshire regulatory boards, and equivalent out-of-state boards, may request and obtain information from the program, provided, however, that the request is pursuant to the regulatory board's official duties and responsibilities and the disclosures to each regulatory board relate only to its licensees and only with respect to those licensees whose prescribing or dispensing activities indicate possible fraudulent conduct.
- (b) Requests in (a) above shall be in writing, signed by the regulatory board's executive director, investigator, or other person authorized to discharge equivalent functions of the regulatory board, and sent to the program manager via mail or electronically as an email attachment or facsimile.
- (c) The address for the program shall be:

Pharmacy Board
Program Manager
Prescription Drug Monitoring Program
121 South Fruit Street
Concord New Hampshire 03301
nhpdmp@nh.gov
(603) 271-2856 (fax)

Ph 1505.05 Other Access.

- (a) Requests in (b) - (c) below shall be completed electronically via email or facsimile, or legibly in ink, signed by an authorized individual, and sent to the program manager at the address in Ph 1505.04(c).
- (b) Out-of-state prescription drug monitoring programs may request and obtain information from the program on a case-by-case basis provided that an agreement is in place with the other state to ensure that the information is used and disseminated pursuant to the applicable requirements of the NH controlled drug prescription health and safety program.
- (c) Entities that operate a secure interstate prescription drug data exchange system for the purpose of interoperability and the mutual secure exchange of information among prescription drug monitoring programs may request and obtain information from the program on a case-by-case basis provided

that an agreement is in place with the entity to ensure that the information is used or disseminated pursuant to the applicable requirements of the NH controlled drug prescription health and safety program.

- (d) The office of the chief medical examiner may request and obtain information from the program on a case by case basis to determine the cause of death of an individual, provided the information is used or disseminated pursuant to the applicable requirements of the NH controlled drug prescription health and safety program.
- (e) Requests in (d) above shall be made by submitting a board provided “NH Medical Examiner Office PDMP Data Request Form,” effective August 2016.

PART Ph 1506 REVIEW AND REPORTING OF PRESCRIPTION DRUG MONITORING INFORMATION

Ph 1506.01 Review of Program Data.

- (a) The program vendor shall collect and monitor all prescription drug monitoring information required by RSA 318-B:33, IV, and Ph 1504.01(b).
- (b) The program vendor shall review and evaluate the collected information in order to identify behavior that suggests possible drug abuse, misuse, or diversion, or possible violations of law or breaches of professional standards.
- (c) The program vendor shall consider, at a minimum, the following patient-related factors in its evaluation in (b) above:
 - (1) Number of in-state prescribers;
 - (2) Number of out-of-state prescribers;
 - (3) Number of prescriptions;
 - (4) Number of doses;
 - (5) Overlapping prescriptions;
 - (6) Unhealthy combinations of controlled substances;
 - (7) Method of payment;
 - (8) Number and frequency of pharmacies used; and
 - (9) Dangerous levels of controlled substances.
- (d) The program vendor shall consider, at a minimum, the following prescriber/dispenser-related factors in its evaluation in (b) above:
 - (1) Number of prescriptions;

- (2) Number of doses;
- (3) Overlapping prescriptions;
- (4) Unhealthy combinations of controlled substances;
- (5) Number and frequency of pharmacies used;
- (6) Dangerous levels of controlled substances;
- (7) Electronic program access and use; and
- (8) For dispensers only, method of payment.

Ph 1506.02 Reporting of Program Data.

- (a) The program shall report to the appropriate regulatory boards identified in RSA 318-B:35, I(b)(2), relevant information to be used by the regulatory board for further investigation:
 - (1) When there is cause to believe a potential violation of law or a breach of professional standards may have occurred; and
 - (2) When there is cause to believe that a failure to report the dispensing of a schedule II–IV controlled substance conceals a potential pattern of diversion of controlled substances into illegal use.
- (b) The program shall notify prescribers and dispensers:
 - (1) When there is cause to believe a potential violation of law or a breach of professional standards may have occurred, unless such notice is likely to interfere with an investigation conducted by the regulatory board; and
 - (2) When there is cause to believe a patient might be obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances, including obtaining controlled substances from multiple practitioners or dispensers.
- (c) The program vendor shall report to the board on at least a quarterly basis all the reports made in (a) and (b) above.
- (d) The board may use and release information and reports from the program for program analysis and evaluation, statistical analysis, public research, public policy, and educational purposes, provided the data are aggregated or otherwise de-identified.

Appendix

Rule	Statute Implemented
Ph 1501.01	RSA 318-B:31-38
Ph 1502.01	RSA 318-B:31
Ph 1503.01	RSA 318-B:33, I & II
Ph 1504.01	RSA 318-B:33, III, IV & V
Ph 1504.02	RSA 318-B:33, VI
Ph 1504.03	RSA 318-B:33, VII
Ph 1505.01 – 1505.05	RSA 318-B:35, I
Ph 1506.01 – 1506.02	RSA 318-B:35, II & III