Adopt Ph 1500 to read as follows:

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

Statutory authority: RSA 318-B:37

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 may 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 who is lawfully authorized to deliver a schedule II-IV controlled substance, but does not include:

(a) A licensed hospital pharmacy that dispenses for administration in the hospital;

(b) A practitioner, or other authorized person who administers such a substance; or

(c) A wholesale distributor of a schedule II–IV controlled substance or its analog."

(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) "Practitioner" means "practitioner" as defined in RSA 318-B:31, VI, namely, "a physician, dentist, podiatrist, veterinarian, or other person licensed or otherwise permitted to prescribe, dispense, or administer a controlled substance in the course of licensed professional practice."

(i) "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."

(j) "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."

(k) "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."

(l) "Program manager" means the person designated by the board to oversee the implementation and operation of the program by the program vendor.

(m) "Program vendor" means a third party with which the board contracts for the implementation and operation of the program.

(n) "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 prescribers and dispensers 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.

(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.

(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 by June 30, 2015 shall be subject to disciplinary action as established pursuant to RSA 318:29.

(g) Those prescribers who are required to register who have not registered by June 30, 2015 shall 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, unless a waiver is requested and granted in accordance with Ph 1504.02 below;

(2) Within 7 days of the controlled substance being dispensed, unless an extension is requested and granted in accordance with Ph 1504.03 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, last name, and, if applicable, suffix;

(10) Patient's address;

(11) Patient'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; and

(15) Source of payment for prescription.

(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 correct their own records and submit corrected information to the program or program vendor whenever they become aware of errors, omissions, or reversals.

(g) Dispensers who do not comply with any provision of this section shall be subject to disciplinary action as established pursuant to RSA 318:29.

Ph 1504.02 Waivers.

(a) Dispensers that are unable to submit by electronic means the required prescription drug monitoring information may request a waiver to submit the information by other means.

(b) A waiver request shall be submitted at the time of registration to the program manager, along with any supporting documentation, on either:

(1) An "Electronic Submission Waiver Request" form (edition date) for dispensers in Ph 1503.01(b)(1); or

(2) A "Controlled Drug Prescription Program Registration Form" (edition date) for dispensers in Ph 1503.01(b)(2);

(c) A waiver shall be granted by the program manager only if any of the following is true:

(1) The dispenser demonstrates that for any reason, including low volume of controlled substances being dispensed, financial hardship will result from the requirement of electronic submission;

(2) The dispenser demonstrates that it has 15 or fewer controlled substance prescriptions per month; or

(3) The dispenser demonstrates a lack of technical capability for electronic submission.

(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 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.

(h) Waivers shall include an alternate method for submitting required prescription drug monitoring information.

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.

(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 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 (edition date) 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. The patient, or the patient's authorized representative, shall allow the photocopying of the identification.

Ph 1505.02 Prescriber and Dispenser Access.

(a) Registered prescribers and dispensers 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) Registered prescribers and dispensers for whom a waiver is requested and granted in accordance with Ph 1504.02 shall have program access to information as described in (a) above by written request in accordance with (c) through (e) below.

(c) Requests shall be made by electronic or written request.

(d) Electronic requests shall be made through the program's secure web portal.

(e) Written requests shall:

(1) Be made by submitting to the program a completed "Prescriber/Dispenser Prescription Monitoring Information Request" form (edition date); and

(2) Be fulfilled by secure mail or fax.

(f) 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.

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.

Ph 1505.05 Other Access.

(a) 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.

(b) Requests in (a) above shall be in writing, signed by the director of the out-of-state prescription drug monitoring program, or designee, and sent to the program manager.

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 may 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 of all the reports made in (a) and (b) above.

APPENDIX

RULE	STATE OF FEDERAL STATUTE THE RULE IMPLEMENTS
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