

Readopt with amendment Part 1400 effective 12-28-11 (Document #10064), to read as follows:

CHAPTER 1400 UNUSED PRESCRIPTION DRUG AND MEDICAL DEVICES PROGRAM RULES

PART Ph 1401 PURPOSE

Ph 1401.01 Purpose: The purpose of these rules is to allow the voluntary donation of unused prescription drugs and medical devices to the uninsured and the underinsured individuals.

(a) The rules of Ph 1400 describe the program to take unused prescription drugs and medical devices donated from nursing homes, pharmaceutical manufacturers, and other eligible donators and utilize them for dispensing to uninsured and underinsured persons who opt into the program.

(b) The rules of Ph 1400 describe unused prescription drug and medical devices eligibility, inclusive of donation, the protection for participants, accepting entities, redispersing entities, and prescription drug formulary.

(c) The rules of Ph 1400 describe the responsibilities and requirements of eligible entities to assure safe handling of drugs and medical devices to protect drug integrity, tracking, sanitation, security and dispensing requirements for these unused prescription drugs and medical devices.

(d) The rules of Ph 1400 describe confidentiality requirements as well as violations.

Readopt with amendment Part Ph 1402 effective 12-28-11 (Document #10064), to read as follows:

PART Ph 1402 DEFINITIONS

Ph 1402.01 “Abandoned drug” means a prescription only drug that was dispensed for a patient that was never in a patient’s possession and is no longer needed by the patient or was left behind at a facility after the patient’s discharge from the facility. The term includes Patient Assistance Program drugs when the manufacturer does not provide a shipping-paid option for the provider to return the drug to the manufacturer or the manufacturer’s agent and:

(a) The provider has determined and documented that the patient should not receive or is unable to receive the drug, or

(b) The patient has not returned to receive the drug within 8 weeks of the time the prescriber received the drug.

Ph 1402.02 “Agent” means any person who is legally authorized to make medical decisions for a patient.

Ph 1402.03 “Charitable provider” means any pharmacist or practitioner licensed by this state to dispense drugs as defined by RSA 318:42 who chooses to participate in an unused prescription drug and medical devices program.

Ph 1402.04 “Dispense” means to distribute, leave with, give away, dispose of, deliver, or sell one or more doses of a drug or medical devices that will be administered or taken at a later date, time, or location

and the transfer of more than a single dose of a medication from one container to another and the labeling or otherwise identifying a container holding more than a single dose of a drug.

Ph 1402.05 “Donate” means the giving free of charge of an eligible prescription drug or medical device to an unused prescription drug program.

Ph 1402.06 “Eligible prescription drug ” (EPD) means any unused prescription only drug that has not reached its expiration date, is contained in an unopened unit dose or other tamper evident packaging, has not been in the possession of the patient and has been stored properly and is not a controlled substance, compounded drug, radiopharmaceutical therapeutic or diagnostic drug.

Ph 1402.07 “Manifest” means an itemized invoice of eligible prescription drugs or medical devices donated, accepted, or destroyed.

Ph 1402.08 “Medical supplies” means any prescription or nonprescription medical supplies needed to administer a prescription drug.

Ph 1402.09 “Original packaging” means the packaging in which the drug was donated by the donor.

Ph 1402.10 “Pharmacy” means “pharmacy” as defined by RSA 318:1 XI.

Ph 1402.11 “Practitioner” or "licensed practitioner" as defined by RSA 318:1 XV.

Ph 1402.12 “Program pharmacist” means any licensed pharmacist in New Hampshire that is participating in an unused prescription drug and medical device program.

Ph 1402.13 “Redispense” means to dispense an eligible prescription drug or medical device that was accepted by an unused prescription drug and medical device program for the purpose of providing medication to an individual who is uninsured or underinsured.

Ph 1402.14 “Underinsured” means a person who lacks adequate prescription related insurance coverage such that purchasing prescription drugs and devices create a financial hardship.

Ph 1402.15 “Uninsured” means a person who does not presently have an active insurance policy that reimburses fully or partially for prescription drugs or devices.

Ph 1402.16 “Unopened tamper-evident packaging” means the packing and storage requirements as described in the United States Pharmacopeia (USP) general chapter 659 including but not limited to unopened unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.

Readopt with amendment Part Ph 1403 effective 12-28-11 (Document #10064), to read as follows:

PART Ph 1403 ELIGIBILITY TO DONATE, ACCEPT, AND REDESPENSE PRESCRIPTION DRUGS AND MEDICAL DEVICES

Ph 1403.01 Unused Prescription Drug and Medical Device Property.

(a) A donor may donate prescription drugs or medical supplies to a charitable provider at an eligible entity if the drug or supply meets the requirements of this section.

(b) A prescription drug and medical device shall be the property of the patient for whom it is prescribed, regardless of who paid for the prescription.

(c) The patient or agent of the patient may at any time authorize the donation of the unused prescription drugs or medical device.

(d) An unused prescription shall be eligible to be donated:

(1) When a patient has died; and

(2) When a drug is abandoned.

Ph 1403.02 Eligible Entities. The following entities shall be eligible to donate and accept prescription drugs and medical devices:

(a) A pharmacy defined under RSA 318:1, XI;

(b) Any licensed prescriber of prescription drugs pursuant to RSA 318:42, II;

(c) A hospice, hospital, or outpatient clinic if licensed pursuant to RSA 151;

(d) A New Hampshire nursing home, if it is licensed and in good standing with the New Hampshire department of health and human services (DHHS) and has a consultant pharmacist or program pharmacist;

(e) New Hampshire hospital, Glenclyff home, and New Hampshire veterans' home pursuant to RSA 318:58, III(c);

(f) A licensed manufacturer, wholesaler, or distributor, who voluntarily donates or accepts samples or eligible prescription drugs or medical devices from eligible charitable providers in this program; and

(g) A state or county correctional facility if it has a program pharmacist or charitable provider.

Ph 1403.03 Unused Prescription Drug and Medical Device Transfer.

(a) A prescription drug shall be eligible for transfer under the Ph 1400 when the following requirements are met:

(1) The accepting and donating entities are eligible to receive unused prescription drugs under these rules;

(2) The drug has not been in the possession of the patient or other member of the public;

(3) All patient identifiable information and the drug directions on the label have been redacted or removed before sending to the accepting entity to protect confidentiality;

(4) The donation is accompanied by a manifest for the internal and external transfer of the product defined by Ph 1406;

(5) The drug has been properly stored under appropriate temperature and humidity conditions;

(6) The drug is not expired;

(7) The drug is not a controlled substance or compounded drug;

(8) The drug or packaging is in its original, unopened, sealed, packaging that includes the expiration date. Unopened unit dose drugs may be accepted if the packaging is unopened; and

(9) The drug or packaging does not show evidence of contamination, adulteration, or misbranding.

(b) Drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration (FDA) requirements shall not be accepted or distributed.

(c) A medical device shall be eligible for transfer under Ph 1400 if the following requirements are met:

(1) The accepting and donating entities are eligible to receive unused medical devices under these rules;

(2) The device has not been in the possession of the patient or other member of the public;

(3) All patient identifiable information and the directions on the label will be redacted or removed before sending to the accepting entity to protect confidentiality;

(4) The donation is accompanied by a manifest for the internal and external transfer of the product defined by Ph 1406;

(5) The drug is not expired;

(6) The device is in its original, unopened, sealed packaging; and

(7) The device does not show evidence of contamination, adulteration, or misbranding.

(d) Prescription drugs or medical devices donated under Ph 1400 shall not be sold, resold, offered for sale, traded, or returned for financial credit. This shall not prohibit transfer between charitable providers.

Ph 1403.04 Eligible Redispensing Entities. The following entities shall be eligible to redispense prescription drugs and medical devices:

(a) A pharmacy; and

(b) Any licensed prescriber.

Readopt with amendment Part Ph 1404 effective 12-28-11 (Document #10064), to read as follows:

PART Ph 1404 RESPONSIBILITIES FOR CHARITABLE PROVIDERS

Ph 1404.01 Charitable Providers. A pharmacist or practitioner licensed by this state to dispense drugs as defined by RSA 318:42 who chooses to participate in an unused prescription drug and medical devices program shall:

- (a) Coordinate retrieval and transportation of donated unused prescription drugs and medical devices from entities eligible to donate;
- (b) Be responsible for determining that the patient has authorized the donation of the drugs or medical devices;
- (c) Inspect all unused prescription drugs and medical devices to assure that:
 - (1) All patient identifiable information and the directions on the label have been redacted or removed before sending to the accepting entity to protect confidentiality;
 - (2) Any discrepancies against the manifest are communicated to the entity eligible to donate;
 - (3) The drug is identifiable;
 - (4) Proper storage has been maintained at all times for drugs that require storage temperatures other than normal room temperature as specified by the manufacturer;
 - (5) The drug or device shows no evidence of contamination, adulteration, or misbranding;
 - (6) The drug or device has not expired;
 - (7) The drug is not for a controlled substance, compounded drug, or prescription drug that can only be dispensed to a patient registered with the drug's manufacturer; and
 - (8) The drug has not been subject to a recall. If a drug is recalled by the FDA or manufacturer and the eligible provider cannot ascertain the lot number on the label to differentiate between the recalled and non-recalled drug, all such donated drugs shall be considered recalled and destroyed or returned in the manner specified by the recall;
- (d) Insure that in the event a drug is received that does not meet the criterion for donation set forth in these rules, the shipment delivery is documented and returned immediately to the donor or the donor's representative that provided the drugs; and
- (e) Store and secure unused prescription drugs and medical devices in a manner that distinguishes them from general stock and store them according to state and federal laws, rules, and Regulations.

Readopt with amendment Part Ph 1405 effective 12-28-11 (Document #10064), to read as follows:

PART Ph 1405 DISPENSING REQUIREMENTS

Ph 1405.01 Dispensing Requirements. Unused prescription drugs and medical devices shall be dispensed in compliance with the following:

- (a) The drugs or supplies are prescribed by a practitioner for use by an eligible patient and are dispensed by a charitable provider;

(b) Eligible New Hampshire licensed pharmacies and prescribers shall establish the following policies and procedures for the dispensing of unused prescription drugs to the uninsured or underinsured patients as follows:

- (1) Limit the number of prescriptions per patient per visit or per month, to allow a greater number of individuals access to such prescription drugs;
 - (2) If no underinsured or uninsured patients are available, how donated medications are made available to other patients; and
 - (3) How the policies and procedures shall be enforced equally to prevent discrimination;
- (c) Pharmacies shall follow the requirements established in RSA 318 and RSA 146:6;
- (d) New Hampshire licensed pharmacies and prescribers dispensing unused prescription drugs shall:
- (1) Maintain a current drug identification book, or shall have a current computer program or online service for the same;
 - (2) Provide information to all recipients regarding the program and maintain a participation consent form for each eligible recipient or patient representative agent of any unused prescription drug; and
 - (3) Maintain samples in the original package as required under federal law, and the samples shall not be removed from original packaging for dispensing;
- (e) If it is determined by the charitable provider's professional judgment that it would be best for the patient, the drugs may be removed from patient specific packaging or unit dose packaging (UDP), commonly referred to as bingo cards, and repackaged;
- (f) Pharmacies may transfer unused prescription drugs to another pharmacy in the program when one pharmacy has the need for a drug and another pharmacy has it available. The transferring pharmacy shall follow the rules of the donating entity and the receiving pharmacy shall follow the rules of the accepting entity;
- (g) Prescription drugs or medical devices donated under Ph 1400 shall not be sold, resold, offered for sale, traded, or returned for financial credit. This shall not prohibit transfer between charitable providers.

Ph 1405.02 Labeling. Dispensed prescription(s) shall clearly indicate the final charitable provider and the current patient information to assure clarity for receiving patient and shall be properly labeled according to RSA 318:47 and shall include the expiration date.

Ph 1405.03 Handling Fee. Whenever possible the dispensing facility for service shall provide at least a 30 day supply and a handling fee, not exceeding \$15, may be charged according to RSA 318:58, V.

Repeal Part Ph 1406 effective 12-28-11 (Document #10064), to read as follows:

~~[PART Ph 1406 PROGRAM PHARMACIST RESPONSIBILITIES~~

~~— Ph 1406.01 Program Pharmacist.~~

~~— (a) All entities eligible to accept shall have the program pharmacist approved by the New Hampshire board of pharmacy.~~

~~— (b) Program pharmacists for the nursing home eligible to donate unused prescription drugs and medical devices shall:~~

~~(1) Review quality and suitability of the unused prescription drugs for reuse as follows:~~

~~a. The drugs and medical devices shall be kept under the control of a health care professional;~~

~~b. The drugs and medical devices shall be stored properly against heat, cold and moisture;~~

~~c. The drugs shall be identifiable; and~~

~~d. The drugs are not adulterated, misbranded or mutilated.~~

~~(2) Determine that the expiration date exceeds 90 days to allow time for redistribution;~~

~~(3) Make sure a manifest contains the following if applicable: supplier (donor) name, and receiver name, donor and receiver address, phone numbers, state permit numbers, signatures, date sent, date received, date destroyed, name, strength and dosage form of drug, NDC #, package size, quantity, initials;~~

~~(4) Provide a copy of this manifest to the accepting entity and maintain a copy at the donating entity for at least 2 years;~~

~~(5) Assure controlled substances, that is, Drug Enforcement Agency (DEA) controlled substances are not donated or accepted;~~

~~(6) Assure that the accepting and donating entities are eligible to receive unused prescription drugs and medical devices under these rules; and~~

~~(7) Have transportation of product and manifest be the responsibility of both the donating and accepting entities to ensure that product integrity is maintained.]~~

Repeal Part Ph 1407 effective 12-28-11 (Document #10064), to read as follows:

~~[PART Ph 1407 ELIGIBLE PRESCRIPTION DRUG FORMULARY~~

~~— Ph 1407.01 Formulary. All Food and Drug Administration (FDA) approved prescription drugs excluding controlled substances shall be subject to the following:~~

~~— (a) They shall not have been in the possession of the patient or other member of the public;~~

~~— (b) They shall not have reached within 90 days of their expiration date;~~

~~— (c) They shall be contained in unopened unit dose or other tamper evident packaging and show no evidence of contamination;~~

~~— (d) Medical devices shall not be unsanitary, broken, dangerous or otherwise unfit for practical use;~~

~~— (e) They shall not be compounded drugs;~~

~~— (f) Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer shall only be donated or accepted if the program pharmacist(s) can ascertain the proper storage has been maintained at all times and transferred internally under the same ownership; and~~

~~— (g) Drugs that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration (FDA) requirements shall not be accepted or distributed.]~~

Repeal Part Ph 1408 effective 12-28-11 (Document #10064), to read as follows:

~~[PART Ph 1408 REQUIREMENTS FOR PHARMACIES DISPENSING UNUSED PRESCRIPTION DRUGS~~

~~— Ph 1408.01 Dispensing Requirements. Unused prescription drugs shall be dispensed in compliance with the following:~~

~~— (a) Pharmacies shall follow the requirements established in RSA 318;~~

~~— (b) New Hampshire licensed pharmacies dispensing unused prescription drugs shall:~~

~~(1) Maintain a current drug identification book, or shall have a current computer program or online service for the same;~~

~~(2) Provide information to all recipients regarding the program and maintain a participation consent form for each eligible recipient or patient representative agent of any unused prescription drug; and~~

~~(3) Maintain samples in the original package as required under federal law, and the samples shall not be removed from original packaging for dispensing.~~

~~— (c) If it is determined by the pharmacist's professional judgment that it would be best for the patient, the drugs can be removed from patient specific packaging or unit dose packaging (UDP), commonly referred to as bingo cards, and repackaged.~~

~~— (d) Eligible New Hampshire pharmacies shall establish the following policies and procedures for the dispensing of unused prescription drugs to the uninsured or underinsured patients as follows:~~

~~(1) They may limit the number of prescriptions per patient per visit or per month, to allow a greater number of individuals access to such prescription drugs;~~

~~(2) If no underinsured or uninsured patients are available, donated medications may be made available to other patients; and~~

~~(3) There shall be a written policy that is enforced equally to prevent discrimination.~~

~~— (e) Pharmacies may transfer unused prescription drugs to another pharmacy in the program when one pharmacy has the need for a drug and another pharmacy has it available. The transferring pharmacy shall follow the rules of the donating entity and the receiving pharmacy shall follow the rules of the accepting entity.~~

~~— (f) Unused prescription drugs and medical devices shall not be resold.]~~

Repeal Part Ph 1409 effective 12-28-11 (Document #10064), to read as follows:

~~[PART Ph 1409 RESPONSIBILITIES OF CHARITABLE PROVIDERS~~

~~— Ph 1409.01 Charitable Providers. A charitable provider shall:~~

~~— (a) Coordinate retrieval of donated unused prescription drugs and medical devices from entities eligible to donate;~~

~~— (b) Check unused prescription drugs (UPD) against the manifest and document any discrepancies and communicate those discrepancies to the entity eligible to donate;~~

~~— (c) Store and secure these UPDs in a manner that distinguishes them from general stock and store them according to state and federal laws, rules and regulations;~~

~~— (d) Check the unused prescription drugs for adulteration or misbranding;~~

~~— (e) Assure expired, adulterated, misbranded, and controlled drugs are not dispensed;~~

~~— (f) Segregate unacceptable drugs for destruction or return and prepare a manifest that is signed by both the pharmacist and a witness when it comes time for destruction;~~

~~— (g) Have access to FDA or manufacturer drug recall information. If a drug is recalled by the FDA or manufacturer and the eligible provider can not ascertain the lot number on the label to differentiate between the recall and non-recalled drug, all such donated drugs shall be considered recalled and destroyed or returned in the manner specified by the recall; and~~

~~— (h) Assure destruction as defined by Department of Environmental Service of expired, adulterated, and/or recalled unused prescription medications as follows:~~

~~(1) A manifest shall be made of unused prescription drugs expired, adulterated, misbranded and/or recalled to be destroyed;~~

~~(2) Following destruction such manifest shall be signed by the pharmacist and witness verifying such destruction; and~~

~~(3) The drug destruction manifest shall be kept in the files of the pharmacy for at least 2 years.~~

~~— Ph 1409.02 Labeling. Dispensed prescription(s) shall clearly indicate the final charitable provider and the current patient information to assure clarity for receiving patient and shall be properly labeled according to RSA 318:47 and shall include the expiration date.~~

~~Ph 1409.03 Handling Fee. Whenever possible the dispensing facility or service shall provide at least a 30 day supply and a handling fee may be charged according to RSA 318:58 V.~~

~~Ph 1409.04 Recordkeeping. Charitable providers shall comply with recordkeeping rules set forth by Ph 309.07.]~~

Readopt with amendment Part Ph 1410 effective 12-28-11 (Document #10064) and renumber as Part Ph 1406, to read as follows:

PART Ph 1406 FORMS AND RECORD KEEPING REQUIREMENTS

Ph 1406.01 Transfer Manifests.

(a) All participants may use their own manifest, provided they include:

- (1) Supplier or the donor name;
- (2) Receiver name;
- (3) Supplier or donor and receiver address;
- (4) State permit numbers;
- (5) Date the drug was sent, date received, and date destroyed; and
- (6) NDC number.

Readopt Part Ph 1411 effective 12-28-11 (Document #10064) and renumber as Part Ph 1407, to read as follows:

PART Ph1407 PARTICIPANT IMMUNITY

Ph 1407.01 Participant Immunity. Immunity shall be provided to the program as provided in RSA 318:60.

Readopt Part Ph 1412 effective 12-28-11 (Document #10064) and renumber as Part Ph 1408, to read as follows:

PART Ph 1408 VIOLATIONS

Ph 1408.01 Violations of the Unused Prescription Drug Program.

(a) Theft or diversion of any of the unused prescription drugs shall be a violation of these rules. This shall include any expired, misbranded drug, adulterated drug, recalled drug, or other drug found to be unusable under the requirements of Ph 1400.

(b) Any violation by any person of the unused prescription drug program shall be reported by the licensed entity upon discovery to the appropriate licensing agency within 30 days and other proper authorities for possible action.

(c) Such violation by any person licensed by the board shall result in action under RSA 318:55 or any licensee, permittee, registrant, or certificate holder as provided in RSA 318:29.

Appendix

Rule	Specific State Statute the Rule Implements
Ph 1401	RSA 541-A:8; RSA 318:56
Ph 1402	RSA 541-A:7; RSA 541-A:8; RSA 318:57
Ph 1403	RSA 318:58 I; RSA 318:58 III
Ph 1404	RSA 318:58 II; RSA 318:58 III
Ph 1405	RSA 318:56, VI
Ph 1406 (repealed)	RSA 318:58
Ph 1407 (repealed)	RSA 318:56
Ph 1408 (repealed)	RSA 318:58, III-a
Ph 1409 (repealed)	RSA 318:56, VI
Ph 1410 (renumbered as 1406)	RSA 318:59; RSA 318:58
Ph 1411 (renumbered as 1407)	RSA 318:60
Ph 1412 (renumbered as 1408)	RSA 318:55