

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 34 PRESCRIPTION DRUG DONATIONS

16.19.34.1 ISSUING AGENCY: Board of Pharmacy.
[16.19.34.1 NMAC - Rp, 16.19.34.1, 2/10/2026]

16.19.34.2 SCOPE: This section applies to eligible recipients involved in the donation and redistribution of unused prescription drugs.
[16.19.34.2 NMAC - Rp, 16.19.34.2, 2/10/2026]

16.19.34.3 STATUTORY AUTHORITY: Section 26-1-3.2 of the New Mexico Drug, Device and Cosmetic Act mandates the Board of Pharmacy to establish rules for the safe redistribution of unused prescription drugs.
[16.19.34.4 NMAC - Rp, 16.19.34.3, 2/10/2026]

16.19.34.4 DURATION: Permanent.
[16.19.34.4 NMAC - Rp, 16.19.34.4, 2/10/2026]

16.19.34.5 EFFECTIVE DATE: February 10, 2026, unless a different date is cited at the end of a section.
[16.19.34.5 NMAC - Rp, 16.19.34.5, 2/10/2026]

16.19.34.6 OBJECTIVE: The objective of Part 34 of Chapter 19 is to ensure the safe donation and redistribution of unused prescription drugs by establishing standards and procedures for accepting, storing, packaging, labeling, inspecting, record keeping and disposal.
[16.19.34.6 NMAC - Rp, 16.19.34.6, 2/10/2026]

16.19.34.7 DEFINITIONS:

- A. “Board”** means the New Mexico board of pharmacy.
 - B. “Donor”** means a person, including persons from other states, who donates unused prescription drugs to an eligible recipient for the purpose of redistribution to patients.
 - C. “Eligible drug”** means an unused, unexpired prescription drug stored in a tamper-evident container, or by a tamper-evident process preventing unauthorized access, that the eligible recipient has inspected and has no reason to believe was improperly handled, stored, adulterated or is unsuitable for redistribution.
 - D. “Eligible recipient”** means a person who registers with the board to participate in the collection of donated drugs and is:
 - (1)** licensed pursuant to Section 61-11-14 NMSA 1978 to receive and distribute prescription drugs;
 - (2)** a health care facility licensed by the health care authority pursuant to the Health Care Code Section 24A NMSA 1978; or
 - (3)** a practitioner licensed in New Mexico to prescribe prescription drugs.
 - E. “Ineligible drug”** means controlled substances, or any prescription medication that is subject to a Risk Evaluation and Mitigation Strategy (REMS) under Section 505-1, 21 USC 355-1 of the Federal Food Drug and Cosmetic Act unless in compliance with all applicable REMS requirements, including being accompanied by a MedGuide (as set forth in Title 34 CFR, Subsection 208), or patient package insert (PPI).
 - F. “Patient”** means an individual who voluntarily receives donated prescription drugs.
 - G. “Prescription drug”** means any drug required by federal or state law to be dispensed only by a prescription, including Food and Drug Administration (FDA)-approved drugs labeled for investigational use.
 - H. “Tamper-evident”** means a device or process that makes unauthorized access to protected pharmaceutical packaging easily detected.
 - I. “REMS”** means Risk Evaluation and Mitigation Strategy.
- [16.19.34.7 NMAC - Rp, 16.19.34.7, 2/10/2026]

16.19.34.8 PROCEDURES: Eligible recipients must adhere to procedures for accepting and redistributing donated prescription drugs, including refrigerated drugs, consistent with public health and safety standards. Any person, including persons from other states, may donate unexpired and unused prescription drugs to an eligible recipient, and an eligible recipient may accept and redistribute the donated prescription drugs in accordance with board rules. An eligible recipient may dispense or administer prescription drugs to a patient only if otherwise permitted by law. Donated prescription drugs shall only be redistributed to a patient if the drugs will not expire before the patient is able to completely use the drugs, based on the directions for use given by the patient's prescribing health care professional

A. Before accepting donated prescription drugs the eligible recipient shall:

- (1) register with the board as an eligible recipient;
- (2) identify drug as eligible or ineligible prior to accepting the donated drug into inventory;
 - (a) ineligible drugs may not be accepted for donation;
 - (b) single unit doses that consist of two or more separately manufactured drug products may not be separated and repackaged. This restriction does not apply to finished, manufactured combination drug products that contain multiple active ingredients in a single dosage form;
 - (c) drugs packed in single unit doses may be accepted and redistributed when the outside packaging is opened if the single unit dose packaging is undisturbed;
 - (d) specialty medication delivered to a facility or practitioner that cannot administer or distribute to the patient originally dispensed for may be donated and redistributed if the medication was stored properly and kept under restricted access to prevent tampering or adulteration.

B. Storage: Comply with the manufacturer's storage requirements per the drug monograph.

C. Labeling prior to redistribution:

- (1) Remove previous patient information.
- (2) Comply with FDA and state labeling requirements.

D. Redistribution:

- (1) Comply with all applicable federal and state laws that deal with the inspection, storage, labeling and redistribution of donated prescription drugs.
- (2) Examine the donated prescription drug to determine that it has not been adulterated or misbranded and certify that the drug has been stored in compliance with the requirements of the product.
- (3) Have all patients receiving donated prescription drugs read and electronically or physically sign the patient form.
- (4) Prescription or order required:
 - (a) A prescription is required for an eligible recipient pharmacy to dispense donated prescription drug to a patient.
 - (b) A practitioner may redistribute donated prescription drug to their own patient pursuant to a valid patient-practitioner relationship with records maintained consistent with the standard of care and as required by this Part.

- (5) Comply with all applicable REMS requirements, including:
 - (a) registration and reporting;
 - (b) provide patient with MedGuide or PPI

E. Inspection: Determine that the donated prescription drugs are in tamper-evident packaging, unadulterated, unexpired, and safe and suitable for redistribution.

- (1) When inspecting packaging ensure:
 - (a) tamper-evident packaging is intact;
 - (b) there are no breaks, cracks or holes in packaging;
 - (c) consistency of information, such as expiration date and lot number on inner and outer packaging, if applicable.
- (2) When inspecting liquids observe, if possible, without removing tamper evident primary container seal:
 - (a) color;
 - (b) thickness;
 - (c) unusual particles;
 - (d) transparency;
 - (e) odor.
- (3) When inspecting tablets or capsules observe and confirm uniformity, if possible, without removing tamper evident primary container seal:

- (a) color;
- (b) shape;
- (c) unusual spots;
- (d) texture;
- (e) odor;
- (f) imprint or markings;
- (g) physical damage, cracks, breaks, erosion, abrasion.

F. Payment, handling fee: A handling fee not to exceed the reasonable costs of participating in the collection of donated prescription drugs may be charged to the patient by the eligible recipient to cover the costs of inspecting, storing, labeling and redistributing the donated prescription drug. Prescription drugs donated under this Part shall not be resold, and donors may be reimbursed only for reasonable, donation-related costs, including shipping and logistics.

G. Interstate Participation: A properly licensed eligible recipient pharmacy operating in another state may participate in the activities described under this Part and may dispense donated drugs to patients in this state in compliance with state and federal laws, unless compliance would violate the laws of the resident state.

H. Transfer and Repackaging: Notwithstanding any other law or rule, an eligible recipient pharmacy may:

- (1) Transfer donated prescription drugs to another eligible recipient pharmacy. The receiving pharmacy must maintain records of the transfer. Any subsequent transfer of a donated prescription drug must include pedigree records tracing to the original eligible recipient. The transferring pharmacy may assess a handling fee not to exceed the reasonable costs of transferring the drug.
- (2) Repackage donated prescription drugs as necessary for storage, dispensing, administration, or transfers in accordance with this Part.
- (3) Repackaged prescription drugs shall be labeled with the drug name, strength, and expiration date. If multiple packaged donated prescription drugs with varied expiration dates are repackaged together for dispensing, the shortest expiration date shall be used.

I. An eligible recipient that engages in sales or other monetary transactions for prescription drugs shall keep donated drug inventory in a manner that distinguishes them physically or electronically from non-donated inventory.

J. The donation, transfer, receipt or facilitation of donation, transfer, and receipt of prescription drugs under this Part is not wholesale distribution and shall not require a wholesale distributor license. [16.19.34.8 NMAC - Rp, 16.19.34.8, 2/10/2026]

16.19.34.9 RECORD KEEPING: Eligible recipients shall maintain records of receipt and redistribution for three years.

A. Receipt Records:

- the container has not been opened or tampered with, and the drug has not been adulterated or misbranded;
- (1) donor verification that the prescription drug is voluntarily donated, was properly stored, and the container has not been opened or tampered with, and the drug has not been adulterated or misbranded;
 - (2) date of donation;
 - (3) name, address and telephone number of donor;
 - (4) name, strength and quantity of the drug;
 - (5) drug manufacturer;
 - (6) drug expiration date;

B. Redistribution Records, Patient Form:

- (1) Prior to the initial dispensing of a donated prescription drug, a patient will electronically or physically sign a form that specifies:
 - (a) knowledge that the donor took reasonable care of the donated prescription drug;
 - (b) knowledge that the donated prescription drug has been inspected and there is no reason to believe that the donated prescription drug was improperly handled or stored;
 - (c) that any person who exercises reasonable care in donating, accepting or redistributing pursuant to Section 26-1-3.2 NMSA 1978 shall be immune from civil or criminal liability or professional disciplinary action of any kind for any related injury, death or loss;
 - (d) that the immunity provided by Section 26-1-3.2 NMSA 1978 shall not decrease or increase the civil or criminal liability of a drug manufacturer, distributors or dispenser that would have existed but for the donation;

(2) Patients receiving donated prescription drugs from an eligible recipient that predominantly dispenses donated prescription drugs shall be required to sign the form only at their initial dispense.

C. Custodial care facility, licensed facility or clinic as donor:

(1) A custodial care facility or licensed facility as defined in 16.19.11.7 NMAC, or clinic as defined in 16.19.10.7 NMAC that engages in donation shall maintain records that include:

- (a) date of donation;
- (b) entity the drug was donated to;
- (c) patient name, as applicable;
- (d) drug name, strength, dosage form, and quantity;
- (e) date dispensed, as applicable;
- (f) prescription number, as applicable;
- (g) dispensing pharmacy name, as applicable

(2) This record will be maintained for three years.

(3) The consultant pharmacist will be responsible for donation oversight.

D. A donor or eligible recipient may contract with one another or a third-party to create or maintain records on each other's behalf. An identifier, such as a serial number or barcode, may be used in place of any or all information required by a record or label under this section if it allows for such information to be readily retrievable. Upon request by a state or federal regulator the identifier used for requested records shall be replaced with the original information. An identifier shall not be used on patient labels when dispensing or administering a drug.

E. All records and forms required by this Section may be in electronic form.

F. All records required under this part will be available for inspection by the Board.

[16.19.34.9 NMAC - Rp, 16.19.34.9, 2/10/2026]

16.19.34.10 LIABILITY:

A. Any person who exercises reasonable care in donating, accepting or redistributing prescription drugs pursuant to this Part shall be immune from civil or criminal liability or professional disciplinary action of any kind for any related injury, death or loss.

B. The immunity provided by this Part shall not decrease or increase the civil or criminal liability of a drug manufacturer, distributor or dispenser that would have existed but for the donation.

C. A manufacturer shall not be liable for failure to transfer or communicate product consumer information or the expiration date of the donated prescription drug pursuant to this Part.

D. This Part does not restrict the authority of an appropriate government agency to regulate or ban the use of any prescription drugs.

[16.19.34.10 NMAC - Rp, 16.19.34.10, 2/10/2026]

16.19.34.11 ELIGIBLE RECIPIENTS:

A. Eligible recipients must submit the required application provided by the board to obtain eligibility for participation.

B. The board may remove at any time eligible recipients from participating in prescription drug donation activities should they fail to comply with this Part.

C. The board shall maintain and publish a current listing of eligible recipients – the board's online license lookup function shall fulfill this requirement.

[16.19.34.11 NMAC - Rp, 16.19.34.11, 2/10/2026]

16.19.34.12 DISPOSAL: Eligible recipients may dispose of unused donated prescription drugs, that were not redistributed, in accordance with state and federal requirements. A record of such disposed prescription drugs shall consist of the disposal method, the date of disposal, and the name, strength, and quantity of each drug disposed.

[16.19.34.12 NMAC - Rp, 16.19.34.12, 2/10/2026]

16.19.34.13 RECALLS: Eligible recipients shall monitor FDA recalls, market withdrawals, and safety alerts and will communicate with patients if medications they received may be impacted by this FDA action. Prescription drugs listed in a recall notice are considered recalled unless an affixed lot number demonstrates they are excluded.

[16.19.34.13 NMAC - Rp, 16.19.34.13, 2/10/2026]

HISTORY OF 16.19.34 NMAC:

History of Repealed Material: 16.19.34 NMAC, Prescription Drug Donations filed 11/27/2011, was repealed and replaced, effective 2/10/2026.