This is an amendment to 16.19.34 NMAC, Section 8 and 9 effective 11/17/2026.

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. An eligible recipient practitioner may only store drugs at the board-registered address, which may not be a mobile or home address.

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. A practitioner may not redistribute donated prescription drugs to themselves.

(5) Comply with all applicable REMS requirements, including:

(a) registration and reporting;

(b) provide patient with MedGuide or PPI

(6) Redistributed drugs will be provided to the patient with information on side effects, interactions, and precautions concerning the drug or device provided. Patient information will be written, or alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include, but not limited to, written information leaflets, pictogram labels and video programs.

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; A, 11/17/2026]

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

A. Receipt records:

(1) donor verification that the prescription drug is voluntarily donated, was properly stored, 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. Redistributed drugs administered, dispensed or distributed:

(1) An eligible recipient practitioner will maintain records including:

(a) patient name, date of birth

(b) drug name, strength, dosage form, quantity, and expiration date;

(c) date administered, dispensed, or distributed;

(2) These records will be maintained for three years, and available for inspection by the board.

(3) An eligible recipient clinic will maintain records as required by federal and state law, including 16.19.10 NMAC.

(4) An eligible recipient pharmacy will maintain records as required by federal and state law, including 16.19.6 NMAC.

[~~**C.**~~] **D. 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.**~~] **E.** 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.**~~] **F.** All records and forms required by this Section may be in electronic form.

[~~**F.**~~] **G.** 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; A, 11/17/2026]