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

16.19.34.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.34.1 NMAC - N, 11-27-11]

16.19.34.2 SCOPE: This section applies to licensed clinics and participating practitioners located within the state of New Mexico who provide for the donation and redistribution of previously dispensed prescription drugs that have not been used.
[16.19.34.2 NMAC - N, 11-27-11]

16.19.34.3 STATUTORY AUTHORITY: Section 26-1-3.2 of the New Mexico Drug, Device and Cosmetic Act requires the board of pharmacy to promulgate rules establishing standards and procedures necessary for the safe redistribution of previously dispensed prescription drugs.
[16.19.34.4 NMAC - N, 11-27-11]

16.19.34.4 DURATION: Permanent.
[16.19.34.4 NMAC - N, 11-27-11]

16.19.34.5 EFFECTIVE DATE: November 27, 2011, unless a different date is cited at the end of a section.
[16.19.34.5 NMAC - N, 11-27-11]

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 licensed clinics and participating practitioners by establishing standards and procedures including but not limited to accepting, storing, packaging, labeling, inspecting, record keeping and disposal.
[16.19.34.6 NMAC - N, 11-27-11]

16.19.34.7 DEFINITIONS:

A. "Board" means the New Mexico board of pharmacy.

B. "Clinic" means a facility licensed pursuant to Section 61-22-14 NMSA 1978 in which one or more licensed practitioners diagnose and treat patients and in which drugs are stored, dispensed or administered for the diagnosis and treatment of the facility's patients; provided that "clinic" does not include the privately owned practice of a licensed practitioner or group of licensed practitioners exempt under Section 61-11-11 NMSA 1978.

C. "Donor" means an individual who donates an unused prescription drug to a clinic or participating practitioner, who originally prescribed that prescription drug for their patient, for the purpose of redistribution of established patients of that clinic or practitioner.

D. "Eligible drug" means an unused prescription drug stored in a tamper-evident container, or by a tamper-evident process preventing unauthorized access, and has an expiration date of six months or greater listed on the packaging. No drug shall be re-dispensed more than one time.

E. "Ineligible drug" means any controlled substances or any prescription drug within the risk evaluation and mitigation strategies (REMS) requirements as set forth by Section 505-1[21 USC355-1] of the Food Drug and Cosmetic Act (FD&C Act), with the exception of a medication guide (MedGuide) as set forth in Title 34, CFR, Subsection 208, patient package insert (PPI) or a communication plan, without prior board approval.

F. "Participating practitioner" means a licensed practitioner who is authorized to prescribe drugs, who registers with the board and is subject to rules promulgated by the board to participate in the collection of donated drugs prescribed for use by established patients of that practitioner, and donated for the purpose of redistribution to established patients of that practitioner.

G. "Prescription drug" for the purposes of this rule means any drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act.

H. "Recipient" means an individual who voluntarily receives donated prescription drugs.

I. "Tamper-evident" means a device or process that makes unauthorized access to protected pharmaceutical packaging easily detected.

J. **"REMS"** means risk evaluation and mitigation strategy as required by the Food and Drug Administration Amendments Act of 2007.
[16.19.34.7 NMAC - N, 11-27-11]

16.19.34.8 **PROCEDURES:** All clinics and participating practitioners shall follow the procedures for accepting and redistributing certain donated prescription drugs, including refrigerated drugs, consistent with public health and safety standards.

A. Before accepting donated prescription drugs the clinic or the participating practitioner shall:

(1) register with the New Mexico board of pharmacy as a practitioner who will facilitate prescription drug donation;

(2) provide donor with appropriate form for documentation and verification upon acceptance of an eligible donated drug;

(3) identify drug as eligible or ineligible prior to accepting the donated drug;

(a) ineligible drugs may not be accepted for donation;

(b) only drugs originally prescribed by a licensed clinic or practitioner may be accepted.

B. Standards and procedures for storing donated prescription drugs.

(1) Donated prescription drugs must be stored in compliance with the manufacturer's storage requirements per the drug monograph.

(2) All donated drugs must be stored in compliance with the manufacturer's storage requirements per the drug monograph.

C. Standards and procedures for labeling donated prescription drugs:

(1) all personal information from the donor must be removed from packaging;

(2) labeling donated prescription drugs must be in compliance with the food and drug administration (FDA) and the state of New Mexico's requirements for labeling prescription drugs.

D. Before redistributing donated prescription drugs the clinic or the participating practitioner shall.

(1) Comply with all applicable federal laws and the laws of the state that deal with the inspection, storage, labeling and redistribution of donated prescription drugs.

(2) Confirm that the donor of a prescription drug is or was a patient of that practitioner or clinic.

(3) 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.

(4) Have the donor read and sign the board approved donor form, this form will serve as documentation and verification upon acceptance of eligible donated drugs.

(5) Have all recipients of donated prescription drugs read and sign the board approved recipient form.

(6) Confirm the patient receiving the donated prescription drug has a valid prescription/order for the drug.

(7) Provide the recipient of any prescription drug with a REMS's required patient-directed instructional document accompanying the medication, which could be either a MedGuide or a PPI.

(8) Confirm they have received and read the formal communication plan from the drug manufacturer as part of the REMS requirement for that prescription drug if applicable.

E. Standards and procedures for inspecting donated prescription drugs to determine that the packaging is tamper-evident and that the donated prescription drugs are unadulterated, within the labeled expiration date, and are safe and suitable for distribution.

(1) When inspecting packaging ensure:

(a) tamper-resistant packaging is intact;

(b) there are no breaks, cracks or holes in packaging;

(c) appropriate quantity as indicated on package;

(d) consistency of information is maintained on packaging, expiration date, lot number and outer packaging is applicable.

(2) When inspecting liquids observe:

(a) color;

(b) thickness;

(c) unusual particles;

(d) transparency;

(e) odor.

(3) When inspecting tablets or capsules observe and confirm uniformity of:

(a) color;

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

F. A handling fee not to exceed twenty dollars ($20.00) may be charged to the recipient by the clinic or the participating practitioner to cover the costs of inspecting, storing, labeling and redistributing the donated prescription drug.

[16.19.34.8 NMAC - N, 11-27-11]

16.19.34.9 RECORD KEEPING: All clinics and participating practitioners shall provide separate records or forms documenting the receipt and redistribution of all unused prescription drugs and maintain the records for three years.

A. A form to be signed by the donor serving as receipt of the drug verifying the donor voluntarily donating the drug, the donated prescription drug has been properly stored-not stored at temperature extremes nor hazardous conditions and protected from light and humidity, the container has not been tampered with, and the drug has not been adulterated or misbranded. The form shall include at least the following:

(1) date the drug was donated;
(2) name, address and telephone number of donor;
(3) name, strength and quantity of the drug;
(4) manufacturer and lot number (if applicable) of drug;
(5) the expiration date of drug;
(6) name, date and signature of the practitioner or pharmacist who is accepting and inspecting the donated drugs.

B. A form to be signed by the recipient specifying; knowledge that the donor is not a pharmacist and took reasonable care of the donated prescription drug, that the donor is known to the clinic or the participating practitioner and that there is no reason to believe that the donated prescription drug was improperly handled or stored and any person who exercises reasonable care in donating, accepting or redistributing pursuant to this 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 lose, and that the immunity provided by this section 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. The form shall include at least the following:

(1) date the recipient received the drug;
(2) name, address and phone number of the recipient;
(3) name, strength and quantity of the drug;
(4) manufacturer and lot number (if applicable) of drug;
(5) the expiration date of drug;
(6) documentation that donated drug was dispensed with applicable forms as deemed by the REMS requirement;
(7) no product where integrity cannot be assured shall be accepted for redistribution.

C. All records and forms required by this rule may be in electronic form.

[16.19.34.9 NMAC - N, 11-27-11]

16.19.34.10 LIABILITY:

A. Any person who exercises reasonable care in donating, accepting or redistributing prescription drugs pursuant to this section 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 section 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 section.

D. This section 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 - N, 11-27-11]

16.19.34.11 PARTICIPATING PRACTITIONERS AND LICENSED CLINICS:

A. Practitioners and licensed clinics must submit the required application form provided by the board to obtain eligibility for participation.

B. The board may remove at any time practitioners or any licensed clinics from participating in the reuse of prescription drug donation should they fail to comply with regulations stated therein.

C. The board shall maintain and publish a current listing of participating practitioners and licensed clinics including names(s) and address.

[16.19.34.11 NMAC - N, 11-27-11]

16.19.34.12 DISPOSAL: Participating practitioners and licensed clinics may dispose of unused donated prescription drugs, that were collected but not redistributed, in accordance with state and federal requirements for disposal of prescription drugs.

[16.19.34.12 NMAC - N, 11-27-11]

16.19.34.13 RECALLS: Participating practitioners shall monitor FDA recalls, market withdrawals, and safety alerts and will communicate with recipients if medications they received may be impacted by this FDA action.

[16.19.34.13 NMAC - N, 11-27-11]

HISTORY OF 16.19.34 NMAC: [RESERVED]