New Mexico Drug Donation Guide

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.

16.19.34.3 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.

16.19.34.6 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.

Requirements for Practitioners and Clinics Participating in Drug Donation

1. Participating practitioners and clinics may only accept eligible drugs – meaning 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 (6) months or greater listed on the packaging. No drug shall be re-dispensed more than one time.
2. Participating practitioners and clinics may only accept donated drugs originally prescribed for use by established patients of that participating practitioner or licensed clinic. Practitioners may <u>not</u> accept donated drugs prescribed by other practitioners. Clinics may not accept donated drugs prescribed at other clinics.
3. Participating practitioners and clinics must register with the New Mexico Board of Pharmacy as a practitioner or licensed clinic that will participate in prescription drug donation
4. Registrants in the drug donation program must notify the New Mexico Board of Pharmacy if they do not want to participate in the drug donation program any longer.
5. Participating practitioners and clinics must provide the Board of Pharmacy with the updated sections of their policy and procedures manual that indicate how they will accept, reuse and keep records of donated/reused medications
6. Participating practitioners and clinics must store donated medications separately from all other medication stock
7. Participating practitioners and clinics must store all donated drugs in compliance with the manufacturer's storage requirements per the drug monograph
8. Participating practitioners and clinics shall label donated medications in compliance with requirements of FDA and the State of New Mexico for prescription drugs. This includes:
    - name of patient
    - date dispensed
    - name and address of the person dispensing the drug
    - name and strength of the drug
    - adequate directions for use
    - expiration date
    - prescription number when applicable

9. Participating practitioners and clinics shall remove all confidential patient identifiers and personal information from donated prescription medications
10. Participating practitioners and clinics shall have all donors read and sign the Board approved Donor Form which includes the following information:
    - Date the drug was donated.
    - Name, address and telephone number of the donor.
    - Name, strength and quantity of the drug.
    - Manufacturer and lot number (if available) of drug
    - The expiration date of drug.
    - Name, date and signature of the practitioner or pharmacist who is accepting and inspecting the donated drugs.

This Donor Form must be kept by the participating practitioner/clinic in their records separately for at least 3 years

11. Participating practitioners and clinics shall 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 (see below for inspection requirements for packaging, tablets, capsules and liquids)
12. Participating practitioners and clinics shall have all recipients of donated prescription drugs read and sign the Board approved Recipient Form which includes the following:
    - Date the recipient received the drug.
    - Name, address and phone number of the recipient.
    - Name, strength and quantity of the drug.
    - Manufacturer and lot number (if available) of drug.
    - The expiration date of drug.
    - Documentation that donated drug was dispensed with applicable forms as deemed by the REMS requirements.
    - No product where integrity cannot be assured shall be accepted for redistribution.

This Recipient Form must be kept by the participating practitioner/clinic in their records separately for at least 3 years

13. Participating practitioners and clinics shall provide recipients of any prescription drug with REMS required patient-directed instructional document accompanying the medication, which could be either a Medication Guide (MedGuide) or a Patient Package Insert (PPI). To see REMS required documents for medications click the following link: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm

14. Participating practitioners and clinics shall confirm they have received and read the formal communication plan from the drug manufacturer as part of the REM's requirement for that prescription drug if applicable
15. Participating practitioners and clinics shall provide separate records or forms documenting the receipt and redistribution of all unused prescription drugs and maintain the records for 3 years. All re-used drug records must be kept separately from other records

16. Participating practitioners and clinics shall dispose of unused donated prescription drugs that were collected but not re-distributed, in accordance with state and federal requirements for the disposal of prescription drugs.
17. Clinics or practitioners may charge a handling fee not to exceed twenty dollars ($20.00) to the recipient of donated drugs to cover the costs of inspecting, storing, labeling and redistributing the donated prescription drug.
18. Participating practitioners and clinics 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. To see all FDA drug recalls click here: http://www.fda.gov/Drugs/DrugSafety/DrugRecalls/default.htm

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

When inspecting donated prescription drugs please look at the following characteristics to make sure packaging is tamper-evident and that the drugs are unadulterated, within the labeled expiration date (6 months or greater), and are safe and suitable for redistribution.

When inspecting donated prescription drug packaging ensure:

1. Tamper-resistant packaging is intact
2. There are no breaks, cracks or holes in packaging
3. Appropriate quantity as indicated on package
4. Consistency of information is maintained on packaging (expiration date, lot number) and outer packaging if applicable.

When inspecting liquids observe:

1. Color
2. Thickness
3. Unusual particles
4. Transparency
5. Odor

When inspecting tablets or capsules observe and confirm uniformity of:

1. Color
2. Shape
3. Unusual spots
4. Texture
5. Odor
6. Imprint or markings
7. Physical damage (cracks, breaks, erosion, abrasion)

To add a drug to the eligible list, practitioners must submit an appeal to the board of pharmacy and get a letter of approval from the drug's manufacturer

"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 (6) months or greater listed on the packaging. No drug shall be re-dispensed more than one time.

"Ineligible drug" means any controlled substances or any prescription drug within the Risk Evaluation and Mitigation Strategies (REMS) requirements as set forth by Sec 505-1[21 USC355-1] of the Food Drug and Cosmetic Act (FD&C Act), with the exception of a MedGuide as set forth in Title 34, CFR, Subsection 208, Patient Package Insert (PPI) or a communication plan, without prior board approval

"REMS" means Risk Evaluation and Mitigation Strategy as required by The Food and Drug Administration Amendments Act of 2007.

To See Current List of REMS drugs go to:
http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm

Ineligible Drug List (all controlled substances are ineligible for prescription drug donation)

Abstral (fentanyl) Sublingual Tablets

Actiq (fentanyl citrate) Oral Transmucosal Lozenge

Aranesp (darbepoetin alfa)

Avandamet (rosiglitazone and metformin) Tablets

Avandaryl (rosiglitazone and glimepiride) Tablets

Avandia (rosiglitazone maleate) Tablets

Butrans (buprenorphine) Transdermal System

Caprelsa (vandetanib) Tablets

Entereg (alvimopan) Capsules

Epogen/Procrit (epoetin alfa) Injection

Exalgo (hydromorphone hydrochloride) Ext. Rel. Tablets

Extraneal (icodextrin) Intraperitoneal Solution

Fentora (fentanyl citrate) Buccal Tablets

Isotretinoin Capsules

Lazanda (fentanyl) Nasal Spray

Letairis (ambrisentan) Tablets

Lotronex (alosetron hydrochloride) Tablets

Lumizyme (alglucosidase alfa)

Mifeprex (mifepristone) Tablets

Nplate (romiplostim) for subcutaneous injection

Nucynta (tapentadol) ER Tablets

Onsolis (fentanyl) buccal soluble film

Oxycontin (oxycodone) Controlled Release Tablets

Promacta (eltrombopag) Tablets

Revlimid (lenalidomide) Capsules

Sabril (vigabatrin) Tablets & Oral Solution

Soliris (eculizumab) Injection

Suboxone (buprenorphine and naloxone) Sublingual Film

Thalomid (thalidomide) Capsules

Tikosyn (dofetilide) Capsules

Tracleer (bosentan) Tablets

Vandetanib Tablets

Zyprexa Relprevv (olanzapine) Ext. Rel. Injection

Revised 10/27/2011