# Legislative Health and Human Services Committee

November 3, 2011

SB 37, 2011, Regular Session, Prescription Drug Donation Implementation Report

Bill Harvey, R.Ph, Executive Director, New Mexico Board of Pharmacy
Regulation and Licensing Department

## History:

SB 37 was signed into law on April 7, 2011 effective June 17, 2011.

A Prescription Drug Donation Committee was appointed by the Board on June 7, 2011. Draft regulations were presented to the Board of Pharmacy at the August 29, 2011, meeting. The Board noticed the proposed rule, NMAC 16.19.34 Prescription Drug Donations, for the October 17, 2011 meeting, when it was adopted without opposition. The rule was filed with the State Records Center on October 27, 2011. It will be in effect November 27, 2011.

## Implementation:

The Board's staff is currently working on written procedures for practitioners to follow in order to register with the Board of Pharmacy as a participant in the Prescription Drug Donation Program.

There is no fee associated with this registration. The Board will maintain a current list on its website, www.rld.state.nm.us/pharmacy , of all participating practitioners/licensed clinics.

Registration forms for participating practitioners and for clinics already licensed by the Board will be available through the Board's website. The Board will also provide the Donor and Recipient Forms which were approved by the Board during the October rule hearing.

Attachments

A. SB 37 (NMSA 26-1-3.2)
B. NMAC 16.19.34 Prescription Drug Donations
C. New Mexico Drug Donation Guide(Draft)
D. Participating Clinic Registration Form
E. Participating Practitioner Registration Form
F. Drug Donation-Recipient Form
G. Drug Donation-Donor Form

The New Mexico Drug, Device and Cosmetic Act

New Section:

**26-1-3.2. Prescription drug donation.**

A. As used in this section:

(1) "clinic" means a facility licensed pursuant to Section 61-11-14 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 61-11-22 NMSA 1978;

(2) "donor" means an individual who donates unused prescription drugs to a clinic or a participating practitioner for the purpose of redistribution to established patients of that clinic or practitioner;

(3) "participating practitioner" means a licensed practitioner who is authorized to prescribe drugs and 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;

(4) "recipient" means an individual who voluntarily receives donated prescription drugs; and

(5) "tamper-evident" means a device or process that makes unauthorized access to protected pharmaceutical packaging easily detected.

B. Unused prescription drugs may be donated to a clinic or a participating practitioner and a clinic or a participating practitioner may accept and redistribute the donated prescription drugs in accordance with rules promulgated by the board.

C. The board shall promulgate rules to establish:

(1) procedures to allow the donation and redistribution of certain prescription drugs, including refrigerated drugs, that:

(a) ensure that the redistribution process is consistent with public health and safety standards; and

(b) exclude controlled substances.

(2) standards and procedures for accepting, storing, labeling and redistributing donated prescription drugs;

(3) standards and procedures for inspecting donated prescription drugs to determine that the packaging is tamper-evident and that the donated prescription drugs are unadulterated, safe and suitable for redistribution;

(4) a form to be signed by the recipient specifying:

(a) knowledge that the donor is not a pharmacist and took reasonable care of the donated prescription drug;

(b) knowledge 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;

(c) that any person who exercises reasonable care in donating, accepting or redistributing 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; and

(d) that 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;

(5) a form to be signed by the donor verifying that:

(a) the donated prescription drug has been properly stored and the container has not been opened or tampered with;

(b) the donated prescription drug has not been adulterated or misbranded; and

(c) the donor is voluntarily donating the prescription drug;

(6) a handling fee not to exceed twenty dollars ($20.00) that 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; and

(7) any other standards deemed necessary by the board.

D. The board shall maintain and publish a current listing of clinics and participating practitioners.

E. 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; and

(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 label.

F. 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.

G. 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.

H. 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.

I. This section does not restrict the authority of an appropriate governmental agency to regulate or ban the use of any prescription drugs.

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# NMAC TRANSMITTAL FORM

1.24.10 NMAC [Sequence # _____ ]

| 1. Issuing Agency | 2. Agency Code (DFA) |
|---|---|
| New Mexico Board of Pharmacy | 36-420.85 |

3. Agency Address
5200 Oakland Ave., NE, Suite A, Albuquerque, NM 87113

4. Contact Person

| Name | Debra Wilhite | Phone # | (505) 222-9835 | FAX | (505) 222-9845 |
|---|---|---|---|---|---|
| E-mail | Debra.wilhite@state.nm.us | | | | |

5. Type of Rule Action

New [X] Amendment [ ] Renumber [ ] Repeal [ ] Emergency [ ]

| 6. Total number of pages: 4 | 7. Hearing date: 10-17-11 | 8. Effective date: 11-27-11 |
|---|---|---|

9. NMAC Number

| Title | Chapter | Part |
|---|---|---|
| 16 | 19 | 34 |

10. NMAC Name

| Title | Chapter | Part |
|---|---|---|
| Occupational and Professional Licensing | Pharmacists | Prescription Drug Donations |

| 11. Amendment Description | 12 Amendment's NMAC Citation |
|---|---|
| | |

13 Most recent filing date (if applicable)

14 Are there any materials incorporated by reference?

No X Yes ____

*Please list attachments and Internet site(s) if applicable*

Reference / Internet site

1.

2

3.

15 If materials are attached, has copyright permission been received?

No [ ] Yes [ ] Public domain [ ]

16 Legal citation(s) that allows the *Issuing Agency* to regulate and the *Issuing Authority* to promulgate regulations on this subject (provide all that apply).

26-1-3.2NMSA

17 Signature & Title of Issuing Authority (*Delegated authority must be on file*)

Name: William Harvey *Check if delegated authority* [X]

Title: Chief Inspector/Executive Director

Signature [signature] Date Signed 10-27-2011

SRC-2000-02
5/26/2000

B

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]

# 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

C

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**

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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

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## 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

New Mexico Regulation and Licensing Department
BOARDS AND COMMISSIONS DIVISION
Board of Pharmacy
5200 Oakland Avenue, NE • Suite A • Albuquerque, New Mexico 87113
(505) 222-9830 • Fax (505) 222-9845 • (800) 565-9102
www.rld.state.nm.us/pharmacy

# New Mexico Drug Donation Program
# Clinic Registration Form

Clinics in the New Mexico Drug Donation Program may only accept donated drugs prescribed for use by established patients of that clinic. Clinics may only redistribute donated drugs to established patients of that clinic.

Clinics may only accept eligible drugs – unused prescription drugs 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. Please see the NM Drug Donation Guide for a list of ineligible drugs.

## CLINIC INFORMATION

Clinic Name: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Clinic License #: _____
Phone #: _____ E-mail: _____

By signing this form all persons and agencies participating in the New Mexico Prescription Drug Donation Program agree to comply with the following rules and regulations promulgated in NMAC 16.19.34

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

Signature: _____ Date: _____

New Mexico Regulation and Licensing Department
BOARDS AND COMMISSIONS DIVISION
Board of Pharmacy
5200 Oakland Avenue, NE ▪ Suite A ▪ Albuquerque, New Mexico 87113
(505) 222-9830 ▪ Fax (505) 222-9845 ▪ (800) 565-9102
www.rld.state.nm.us/pharmacy

# New Mexico Drug Donation Program
# Practitioner Registration Form

Practitioners participating in the New Mexico Drug Donation Program may only accept donated drugs prescribed by them for their own established patients. Practitioners may only redistribute donated drugs to their own established patients.

Practitioners may only accept eligible drugs – meaning unused prescription drugs 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. Please see the NM Drug Donation Guide for a list of ineligible drugs.

## PRACTITIONER INFORMATION

Practitioner: _____
Address: _____
City: _____ State: _____ Zip Code: _____
Practitioner License #: _____
Phone #: _____ E-mail: _____

By signing this form all persons and agencies participating in the New Mexico Prescription Drug Donation Program agree to comply with the following rules and regulations promulgated in NMAC 16.19.34

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

Signature: _____ Date: _____



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F

New Mexico
Drug Donation Program
**DONOR**

Donor's Name:_____Date:_____

Telephone Number:_____Address:_____

DONATED DRUG RECORD

| Drug Name | Strength | Quantity | Manufacturer | Lot # If known | Expiration Date | Eligible upon visual inspection |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
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I _____ am voluntarily donating the drugs listed above. I certify that the donated drug(s) have not been tampered with and have been properly stored-protected from light and humidity, and have been not experienced temperature extremes outside the manufacturer's recommendations.

_____ _____

Signature of donor Date

**To be filled out by Facility**

I _____ have inspected the donated drugs listed above and certify that they were originally dispensed from this facility and the drugs are suitable for redispensing.

_____ _____

Signature of person inspecting donated drugs Date

_____

Title

G

New Mexico
Drug Donation Program

# RECIPIENT

Recipient's Name:_____Date:_____

Telephone Number:_____Address:_____

RECIPIENT DRUG RECORD

| Drug Name | Strength | Quantity | Manufacturer | Lot # If known | Expiration Date | REMS form dispensed |
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I _____ understand that the drug(s) listed above that I am receiving have been donated and that the donor is not a pharmacist and took reasonable care of the donated prescription drug(s). Any person who exercises reasonable care in donating, accepting or redistributing pursuant to this section (NMSA 26-1-3.2 1978) shall be immune from civil or criminal liability or professional disciplinary action of any kind for any related injury, death or loss; and that 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.

_____
Signature of the Recipient

_____
Signature of the Practitioner