



Rules of Department of Health and Senior Services

Division 20—Division of Environmental Health and Communicable Disease Prevention Chapter 50—Prescription Drug Repository Program

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**Title 19—DEPARTMENT OF
HEALTH AND SENIOR SERVICES**
**Division 20—Division of Environmental
Health and Communicable Disease
Prevention**
**Chapter 50—Prescription Drug
Repository Program**

19 CSR 20-50.005 Definitions

PURPOSE: This rule contains definitions which establish the intended meaning of certain terms used throughout this chapter.

(1) As used in this chapter, the following terms shall have the meanings specified:

(A) “Dispenser” means a pharmacy, hospital, prescriber or other person who is licensed and authorized to independently dispense prescription drugs in Missouri;

(B) “Institutional facility” means a long-term care, mental care or other licensed facility that provides health care to resident patients;

(C) “Original sealed and tamper evident unit-dose packaging” means sealed and tamper-evident unit of use packaging by the original manufacturer, by a federally registered repackager, or by a licensed pharmacy in compliance with 4 CSR 220-2.130 and 4 CSR 220-3.040;

(D) “Program” means the Prescription Drug Repository Program established by the Department of Health and Senior Services pursuant to sections 196.970 through 196.984, RSMo to accept and dispense prescription drugs donated for the purpose of being dispensed to persons who are residents of Missouri and who meet eligibility requirements of the program.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expired June 29, 2005. Original rule filed Dec. 15, 2004, effective June 30, 2005.*

**Original authority: 196.984, RSMo 2004.*

19 CSR 20-50.010 Eligibility Requirements for Pharmacies, Hospitals and Nonprofit Clinics to Receive Donated Prescription Drugs

PURPOSE: This rule contains the criteria by which pharmacies, hospitals and nonprofit clinics will be determined eligible to receive donated drugs under the Prescription Drug Repository Program.

(1) Pharmacies, hospitals or nonprofit clinics may elect to participate in the Prescription

Drug Repository Program pursuant to sections 196.970 to 196.984, RSMo.

(2) Any participating pharmacy shall be licensed as a pharmacy by the Missouri State Board of Pharmacy.

(3) Any participating hospital shall be licensed as a hospital by the Department of Health and Senior Services when required by law to be so licensed.

(4) Any participating nonprofit clinic shall be under the supervision of a physician licensed by the Missouri State Board of Registration for the Healing Arts.

(5) All participating pharmacies, hospitals or nonprofit clinics shall comply with all federal and state laws, rules and regulations applicable to the storage and distribution of drugs.

(6) All participating pharmacies, hospitals or nonprofit clinics shall comply with all state laws, rules and regulations applicable to the Prescription Drug Repository Program.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expired June 29, 2005. Original rule filed Dec. 15, 2004, effective June 30, 2005.*

**Original authority: 196.984, RSMo 2004.*

19 CSR 20-50.015 Eligibility Requirements for Recipients in the Program

PURPOSE: This rule contains the criteria by which pharmacies, hospitals and nonprofit clinics will determine eligibility of individual patients to receive donated drugs under the Prescription Drug Repository Program.

(1) A pharmacy, hospital, or nonprofit clinic that elects to participate in the Prescription Drug Repository Program shall determine if a person is eligible to receive drugs. A person shall meet the following requirements to become an eligible recipient of drugs from the Prescription Drug Repository Program:

(A) Is a resident of Missouri;

(B) Has a net family income below three hundred percent (300%) of the federal poverty level; and

(C) Has no active third party prescription drug reimbursement coverage for the drug prescribed.

(2) The pharmacy, hospital or nonprofit clinic shall provide each individual recipient with an identification card after determining that

the recipient is eligible to receive drugs from the program.

(A) The card shall confirm to other participating pharmacies, hospitals or nonprofit clinics that the recipient is eligible to receive drugs from the program.

(B) The card shall be prepared in a format obtained from the Department of Health and Senior Services and shall contain the following:

1. The full name of the recipient;

2. The address of the recipient;

3. The Social Security number of the recipient;

4. The name of the issuing pharmacy, hospital or nonprofit clinic;

5. The address and telephone number of the issuing pharmacy, hospital or nonprofit clinic;

6. A statement that the issuing pharmacy, hospital or nonprofit clinic has determined that the recipient is eligible to receive drugs from the program;

7. The date the card was issued; and

8. The expiration date of the card, which shall be no later than twelve (12) months from the date the card was issued.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expired June 29, 2005. Original rule filed Dec. 15, 2004, effective June 30, 2005.*

**Original authority: 196.984, RSMo 2004.*

19 CSR 20-50.020 Standards and Procedures for Donating Prescription Drugs

PURPOSE: This rule contains the criteria by which pharmacies, hospitals and nonprofit clinics will determine a person eligible to donate drugs under the Prescription Drug Repository Program.

(1) The following may donate a prescription drug, pursuant to 19 CSR 30-5.025, to a pharmacy, hospital, or nonprofit clinic that elects to participate in the Prescription Drug Repository Program:

(A) A licensed dispenser of prescription drugs;

(B) A licensed wholesale distributor of prescription drugs; or

(C) A person who was legally dispensed a prescription drug pursuant to a patient-specific prescription or drug order.

(2) An individual electing to donate a prescription drug shall not have taken custody of



the drug prior to the donation. The individual may direct the donation through a dispenser of prescription drugs.

(3) A person designated to do so under a durable power of attorney, or acting in their capacity as legal guardian may make the decision to donate a prescription drug on behalf of another person who has lawful possession of the prescription drug.

(4) A person who resides in an institutional facility and was legally dispensed a prescription drug pursuant to a patient-specific prescription or order may elect to sign and date an ownership record prior to donating a drug, which shall state “from this day forward I wish to donate all my remaining unused drugs, pursuant to 19 CSR 20-50.025, to a participating pharmacy, hospital or nonprofit clinic of the Prescription Drug Repository Program. I authorize the institutional facility in which I reside to make the donation on my behalf.”

(A) The record shall include the resident’s typed or printed name, and the name and address of the institutional facility.

(B) If the institutional facility is a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), the facility shall comply with HIPAA regarding the transfer of any personal health information that may occur as part of the donation.

(5) Each donor must sign an ownership record stating that the donor is the owner of the drug and intends to voluntarily donate the drug to the drug repository program. The ownership record must be completed prior to any donation and include at least the following:

(A) The name of the person to whom the drug was originally dispensed, or the name of the dispenser of prescription drugs or wholesale distributor of prescription drugs that owns the drug;

(B) The signature of the donor or the donor’s representative, or the signature of the responsible person or his/her designee from a dispenser of prescription drugs or a wholesale distributor of prescription drugs; and

(C) The date the record was signed.

(6) The following donor information must also be documented on the original signed ownership record or on an alternate donor record that is kept with the ownership record:

(A) The name of the donor of the drug;

(B) The name and address of the institutional facility donor location, when applicable;

(C) The brand name or the generic name of the drug;

(D) Either the name of the manufacturer or the national drug code number (NDC #), if available;

(E) The lot number of the drug, if available;

(F) The strength of the drug;

(G) The quantity of the drug;

(H) The date the drug was donated to a participating pharmacy, hospital or nonprofit clinic;

(I) A statement that the drug has been stored according to manufacturer and/or *United States Pharmacopoeia* requirements;

(J) A statement that the drug has been examined to determine that no controlled substance or drug that requires storage temperatures other than normal room temperature has been included; and

(K) The name and address of the receiving pharmacy, hospital or nonprofit clinic.

(7) A copy of the ownership record or the alternate donor record that contains the required information shall be maintained by the donor or the institutional facility, when applicable, and the receiving pharmacy, hospital or nonprofit clinic.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expired June 29, 2005. Original rule filed Dec. 15, 2004, effective June 30, 2005.*

**Original authority: 196.984, RSMo 2004.*

19 CSR 20-50.025 Standards and Procedures for Accepting Donated Prescription Drugs

PURPOSE: This rule contains the criteria by which pharmacies, hospitals and nonprofit clinics will determine drugs to be acceptable for donation under the Prescription Drug Repository Program.

(1) No controlled substances or drugs that require storage temperatures other than normal room temperature as specified by the manufacturer and/or *United States Pharmacopoeia* shall be donated or accepted as part of the Prescription Drug Repository Program.

(A) Controlled substances shall not be donated or accepted because a pharmacy, hospital or nonprofit clinic cannot accept controlled substances from a person to whom they have been dispensed, according to applicable state and federal law.

(B) Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer and/or *United States Pharmacopoeia* shall not be donated or accepted because of the potential for these drugs to become adulterated.

(2) A prescription drug may only be accepted by a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program if the following requirements are met:

(A) The drug is in its original sealed and tamper-evident unit dose packaging;

(B) The packaging is unopened except that a drug packaged in single-unit doses may be accepted and dispensed when the outside packaging is opened if the single-unit-dose packaging is undisturbed;

(C) The drug has been in the possession of a licensed dispenser of prescription drugs, a licensed wholesale distributor of prescription drugs or a licensed health care professional and not in the possession of the ultimate user;

(D) The drug has been stored according to manufacturer and/or *United States Pharmacopoeia* storage requirements;

(E) The drug has an expiration date of six (6) months or greater;

(F) The packaging contains the lot number and expiration date of the drug;

(G) The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated as defined in section 196.095, RSMo;

(H) The packaging does not have any physical signs of tampering, deterioration, compromised integrity or adulteration; and

(I) Drugs that were dispensed for individuals are packaged and labeled in compliance with 4 CSR 220-2.130, 4 CSR 220-2.140 and 4 CSR 220-3.040.

(3) Prior to receiving each donation of donated drugs, a pharmacy, hospital or nonprofit clinic shall inquire of the donor or donor’s representative if the drugs have been examined to determine that no controlled substances or drugs that require storage temperatures other than normal room temperature as specified by the manufacturer and/or *United States Pharmacopoeia* are included.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expired June 29, 2005. Original rule filed Dec. 15, 2004, effective June 30, 2005.*

**Original authority: 196.984, RSMo 2004.*



19 CSR 20-50.030 Standards and Procedures for Inspecting and Storing Donated Prescription Drugs

PURPOSE: This rule contains the criteria by which pharmacies, hospitals and nonprofit clinics will determine drugs to be acceptable for dispensing under the Prescription Drug Repository Program. This rule also establishes documentation of receipt of donated drugs.

(1) A pharmacy, hospital or nonprofit clinic shall inspect donated prescription drugs to determine that they are safe and suitable for dispensing, the drug and the packaging are in compliance with 19 CSR 20-50.025, and there are no controlled substances or drugs that require storage temperatures other than normal room temperature as specified by the manufacturer and/or *United States Pharmacopoeia*. The person who inspects the drugs shall sign an inspection record stating the above and attach it to the copy of the ownership record or alternate donor record provided with the drugs.

(2) Donated drugs shall be stored in the pharmacy, hospital or nonprofit clinic in a location separate from other drugs.

(3) When donated drugs are not inspected immediately upon receipt, they shall not be placed in the dispensing area until they have been inspected.

(4) Donated non-controlled substances that are not suitable for dispensing, shall be destroyed and a record made of such destruction.

(5) Controlled substances found upon inspection shall not be accepted for donation.

(A) Controlled substances submitted for donation shall be documented and returned immediately to the donor or the donor's representative that provided the drugs.

(B) In the event that it is not possible to return the controlled substances to the donor or donor's representative due to inability to identify the donor or donor's representative or due to refusal by the donor or donor's representative to receive them, abandoned controlled substances shall be documented, quarantined and destroyed as required in this subsection.

1. Abandoned controlled substances shall be documented as required in subsection (C) of this section.

2. Abandoned controlled substances shall be quarantined separate from other controlled substances in a location that meets requirements of 19 CSR 30-1.

3. Abandoned controlled substances shall be destroyed beyond reclamation. Such destruction shall be performed by a pharmacist or other person that has authority to dispense controlled substances and witnessed by another responsible employee of the pharmacy, hospital or nonprofit clinic according to 19 CSR 30-1.078 and 21 CFR 1307.21.

(C) A controlled substance donor return or destruction record shall be prepared and retained by the pharmacy, hospital or nonprofit clinic. The controlled substance donor return or destruction record shall include the following when applicable:

1. The name and address of the pharmacy, hospital or nonprofit clinic;

2. The date the drug was received by the pharmacy, hospital or nonprofit clinic;

3. The brand name of the drug; or the generic name and either the name of the manufacturer or the national drug code number (NDC #) when available;

4. The strength of the drug;

5. The quantity of the drug;

6. The lot number of the drug when available;

7. The expiration date of the drug;

8. The name and address of the donor;

9. The name and address of the donor's representative;

10. The circumstances under which the drug was abandoned;

11. The signature of the donor or donor's representative when the drug is returned to the donor;

12. The signature of the representative of the pharmacy, hospital or nonprofit clinic when the drug is returned to the donor;

13. The signature of the individual performing the destruction of the drug;

14. The signature of the individual witnessing the destruction of the drug; and

15. The date the drug was returned or destroyed.

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**Original authority: 196.984, RSMo 2004.*

19 CSR 20-50.035 Standards and Procedures for Dispensing Donated Prescription Drugs

PURPOSE: This rule contains the criteria by which pharmacies, hospitals and nonprofit clinics will dispense donated drugs under the Prescription Drug Repository Program.

(1) A pharmacy, hospital or nonprofit clinic shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs.

(2) A pharmacy, hospital or nonprofit clinic shall dispense donated prescription drugs in compliance with section 338.059, RSMo Prescriptions, how labeled; 4 CSR 220-2.130 Drug Repackaging; and 4 CSR 220-3.040 Return and Reuse of Drugs and Devices.

(3) A pharmacy, hospital or nonprofit clinic shall have an established mechanism to notify recipients in the event of a drug recall.

(4) A pharmacy, hospital or nonprofit clinic shall remove the original donor's identification from the package when the drug is dispensed.

(5) Recipients of a donated drug from the drug repository program shall sign an immunity acceptance record form stating they understand the criminal and civil immunity provisions of the program pursuant to section 196.981, RSMo. The immunity acceptance record shall also include at least the following:

(A) The printed name and address of the recipient;

(B) The signature of the recipient;

(C) The date the form was signed by the recipient;

(D) The brand name of the drug received; or the generic name and either the name of the manufacturer or the national drug code number (NDC #);

(E) The lot number of the drug if available;

(F) The strength of the drug received by the recipient;

(G) The quantity of the drug received by the recipient;

(H) The name and address of the dispensing pharmacy, hospital or nonprofit clinic; and

(I) The dispenser's initials.

(6) Each recipient of a donated drug from the drug repository program shall sign a waiver of the requirement for child-resistant packaging of the Poison Prevention Packaging Act.

(7) A pharmacy, hospital or nonprofit clinic may charge the recipient of a donated drug a handling fee, not to exceed a maximum of two hundred percent (200%) of the standard Medicaid professional dispensing fee to cover stocking and dispensing costs.



(8) A pharmacy, hospital or nonprofit clinic may transfer donated drugs to another governmental entity or nonprofit private entity, to be dispensed to persons who meet the eligibility requirements of the program, when the other governmental entity or nonprofit private entity is a pharmacy, hospital or nonprofit clinic.

(A) The transferring pharmacy, hospital or nonprofit clinic shall be licensed as a drug distributor with the Board of Pharmacy.

(B) If the transferring pharmacy, hospital or nonprofit clinic is a covered entity under the Health Portability and Accountability Act (HIPAA), it shall comply with HIPAA regarding the disclosure of any personal health information that may occur as a result of the transfer of a donated drug. A copy of any authorization to release patient identifying information received by the transferring pharmacy, hospital or nonprofit clinic in relation to a donated drug shall be provided to the pharmacy, hospital or nonprofit clinic receiving any transferred drug.

(C) Both the transferring and receiving pharmacy, hospital or nonprofit clinic shall maintain a record that includes:

1. The brand name of the drug received; or the generic name and either the name of the manufacturer or the national drug code number (NDC #);
2. The lot number of the drug, if available;
3. The strength of the drug;
4. The quantity of the drug;
5. The name and address of both the transferring and receiving pharmacy, hospital or nonprofit clinic; and
6. The date of the transfer.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expired June 29, 2005. Original rule filed Dec. 15, 2004, effective June 30, 2005..*

**Original authority: 196.984, RSMo 2004.*

hospitals, nonprofit clinics and institutional facilities.

(2) Records required as part of the program shall be maintained separate from other records.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expired June 29, 2005. Original rule filed Dec. 15, 2004, effective June 30, 2005.*

**Original authority: 196.984, RSMo 2004.*

19 CSR 20-50.040 Record Keeping Requirements

PURPOSE: This rule contains the criteria by which pharmacies, hospitals and nonprofit clinics will maintain records required under the Prescription Drug Repository Program.

(1) All records required to be maintained as a part of the Prescription Drug Repository Program shall be maintained for a minimum of five (5) years by participating pharmacies,