

Volume 30, Number 2
Pages 135–228
January 18, 2005

SALUS POPULI SUPREMA LEX ESTO

“The welfare of the people shall be the supreme law.”



ROBIN CARNAHAN
SECRETARY OF STATE

MISSOURI
REGISTER

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The *Missouri Register* is published semi-monthly by

SECRETARY OF STATE

ROBIN CARNAHAN

Administrative Rules Division

James C. Kirkpatrick State Information Center

600 W. Main

Jefferson City, MO 65101

(573) 751-4015

EDITORS

BARBARA MCDUGAL

JAMES MCCLURE

ASSOCIATE EDITORS

CURTIS W. TREAT

SALLY L. REID

PUBLISHING STAFF

WILBUR HIGHBARGER

HEATHER M. KAMPETER

ISSN 0149-2942, USPS 320-630; periodical postage paid at Jefferson City, MO
Subscription fee: \$56.00 per year

POSTMASTER: Send change of address notices and undelivered copies to:

MISSOURI REGISTER

Office of the Secretary of State

Administrative Rules Division

PO Box 1767

Jefferson City, MO 65102

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May 2, 2005 May 16, 2005	June 1, 2005 June 15, 2005	June 30, 2005 June 30, 2005	July 30, 2005 July 30, 2005
June 1, 2005 June 15, 2005	July 1, 2005 July 15, 2005	July 31, 2005 July 31, 2005	August 30, 2005 August 30, 2005

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RULES—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 28, *Missouri Register*, page 27. The approved short form of citation is 28 MoReg 27.

The rules are codified in the *Code of State Regulations* in this system—

Title	Code of State Regulations	Division	Chapter	Rule
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific area regulated

They are properly cited by using the full citation, i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo—The most recent version of the statute containing the section number and the date.

Rules appearing under this heading are filed under the authority granted by section 536.025, RSMo 2000. An emergency rule may be adopted by an agency if the agency finds that an immediate danger to the public health, safety or welfare, or a compelling governmental interest requires emergency action; follows procedures best calculated to assure fairness to all interested persons and parties under the circumstances; follows procedures which comply with the protections extended by the *Missouri* and the *United States Constitutions*; limits the scope of such rule to the circumstances creating an emergency and requiring emergency procedure, and at the time of or prior to the adoption of such rule files with the secretary of state the text of the rule together with the specific facts, reasons and findings which support its conclusion that there is an immediate danger to the public health, safety or welfare which can be met only through the adoption of such rule and its reasons for concluding that the procedure employed is fair to all interested persons and parties under the circumstances.

Rules filed as emergency rules may be effective not less than ten (10) days after filing or at such later date as may be specified in the rule and may be terminated at any time by the state agency by filing an order with the secretary of state fixing the date of such termination, which order shall be published by the secretary of state in the *Missouri Register* as soon as practicable.

All emergency rules must state the period during which they are in effect, and in no case can they be in effect more than one hundred eighty (180) calendar days or thirty (30) legislative days, whichever period is longer. Emergency rules are not renewable, although an agency may at any time adopt an identical rule under the normal rulemaking procedures.

**Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 2—Health Requirements for Movement of
Livestock, Poultry and Exotic Animals**

EMERGENCY AMENDMENT

2 CSR 30-2.010 Health Requirements Governing the Admission of Livestock, Poultry and Exotic Animals Entering Missouri. The director of agriculture is amending paragraphs (4)(D)1. and 2. and adding paragraph (4)(D)3.

PURPOSE: This emergency amendment will help control the spread of tuberculosis from cattle entering Missouri from states with a high incidence of tuberculosis.

EMERGENCY STATEMENT: Tuberculosis is an infectious and contagious disease to the livestock industry and it is also a threat to public health safety and welfare as it is transmissible to humans.

In the past year, there were twelve (12) reported cases of tuberculosis in the cattle industry of the United States. This proposed amendment will give Missouri additional protection of its livestock industry and public welfare from the introduction of an infectious and contagious disease.

The agency has weighed the compelling governmental interest against the due process rights of the public to notice and comment. In light of potential threat to the public health, there is a compelling

governmental interest to enact this rule through emergency rulemaking.

The scope of this rule is limited to the circumstances which created this emergency and complies with the protection extended in the *Missouri* and *United States Constitutions*. In developing this rule the agency has encouraged discussion with interested parties and provided them the opportunity to offer their comments. The agency believes this emergency amendment to be fair to all persons and parties under the circumstances. This emergency amendment was filed on December 2, 2004 effective December 12, 2004, expires May 31, 2005.

(4) Cattle.

(D) Tuberculosis.

1. [All breeding cattle eight (8) months of age or over entering Missouri must meet one (1) of the following requirements:] All sexually intact dairy cattle six (6) months of age and older must be negative to an official tuberculosis test within sixty (60) days prior to entry.

A. Originate from a tuberculosis-free state;

B. Originate from a tuberculosis-accredited free herd. The herd number and current herd test date must be shown on the Certificate of Veterinary Inspection;

C. Test negative within thirty (30) days of shipment;

D. Originate from a state having a reciprocal agreement with Missouri.

E. All sexually intact cattle and bison, from any foreign country or part thereof with no recognized tuberculosis status comparable to the Uniform Methods and Rules standards of the U.S. Bovine Tuberculosis Eradication Program, imported for reasons other than immediate slaughter or feeding for slaughter must meet the following criteria:

(I) Obtain a permit issued by the Missouri Department of Agriculture prior to entry; and

(II) Be quarantined to the Missouri premises approved in the entry permit pending two (2) consecutive negative tuberculosis tests. The first test to be conducted not less than ninety (90) nor more than one hundred twenty (120) days after arrival and the second test to be not less than two hundred ten (210) days nor more than two hundred forty (240) days after arrival in Missouri; or

F. Importation of steers and spayed heifers from Mexico.

(I) Steers and spayed heifers from Mexican states that have been determined by the state veterinarian of Missouri, based on the recommendation of the Bi-National Committee, to have fully implemented the Control/Preparatory Phase of the Mexican Tuberculosis Eradication Program may enter Missouri provided they have been tested negative for tuberculosis in accordance with the Norma Oficial Mexicana (NOM) within sixty (60) days prior to entry into the United States and obtain an entry permit prior to entering Missouri.

(II) Steers and spayed heifers from Mexican states that have been determined by the state veterinarian of Missouri, based on the recommendation of the Bi-National Committee to have fully implemented the Eradication Phase of the Mexican Tuberculosis Eradication Program by March 1, 1997, may enter Missouri provided they have been tested negative for tuberculosis in accordance with the Norma Oficial Mexicana (NOM) within sixty (60) days prior to entry into the United States. Steers and spayed heifers from these same Mexican states that originate from herds equal to U.S. Accredited TB-Free herds may enter Missouri without testing provided they are moved directly from the herd of origin across the border as a single group and not commingled with

other cattle prior to arriving at the border and obtain an entry permit prior to entering Missouri.

(III) Steers and spayed heifers from Mexican states that have been determined by the state veterinarian of Missouri, based on the recommendation of the Bi-National Committee, to have achieved Accredited Free status may enter Missouri without testing provided they are moved as a single group and not commingled with cattle of a different status prior to arriving to the border and obtain an entry permit prior to entering Missouri.

(IV) Holstein and Holstein-cross steers and spayed heifers from Mexico are prohibited from entering Missouri regardless of test history.

(V) Rodeo stock from Mexico must be tested negative for tuberculosis within sixty (60) days prior to their utilization as rodeo or roping stock under the supervision of a USDA/APHIS port veterinarian or by a U.S. accredited veterinarian, retested for tuberculosis every twelve (12) months thereafter, and obtain an entry permit prior to entering Missouri. No sexually intact rodeo stock from Mexico will be permitted into Missouri.]

2. [The state veterinarian may designate high incidence areas within certain states that must meet additional import restrictions and retest requirements.] All beef breeding cattle eight (8) months of age or over entering Missouri must meet one (1) of the following requirements:

A. Originate from a tuberculosis-free state;

B. Originate from a tuberculosis-accredited free herd. The herd number and current herd test date must be shown on the Certificate of Veterinary Inspection;

C. Test negative within sixty (60) days of shipment;

D. Originate from a state having a reciprocal agreement with Missouri.

E. All sexually intact cattle and bison, from any foreign country or part thereof with no recognized tuberculosis status comparable to the Uniform Methods and Rules standards of the U.S. Bovine Tuberculosis Eradication Program, imported for reasons other than immediate slaughter or feeding for slaughter must meet the following criteria:

(I) Obtain a permit issued by the Missouri Department of Agriculture prior to entry; and

(II) Be quarantined to the Missouri premises approved in the entry permit pending two (2) consecutive negative tuberculosis tests. The first test to be conducted not less than ninety (90) nor more than one hundred twenty (120) days after arrival and the second test to be not less than two hundred ten (210) days nor more than two hundred forty (240) days after arrival in Missouri; or

F. Importation of steers and spayed heifers from Mexico.

(I) Steers and spayed heifers from Mexican states that have been determined by the state veterinarian of Missouri, based on the recommendation of the Bi-National Committee, to have fully implemented the Control/Preparatory Phase of the Mexican Tuberculosis Eradication Program may enter Missouri provided they have been tested negative for tuberculosis in accordance with the Norma Oficial Mexicana (NOM) within sixty (60) days prior to entry into the United States and obtain an entry permit prior to entering Missouri.

(II) Steers and spayed heifers from Mexican states that have been determined by the state veterinarian of Missouri, based on the recommendation of the Bi-National Committee to have fully implemented the Eradication Phase of the Mexican Tuberculosis Eradication Program by March 1, 1997, may enter Missouri provided they have been tested negative for tuberculosis in accordance with the Norma Oficial Mexicana (NOM) within sixty (60) days prior to entry into the United States. Steers and spayed heifers from these same Mexican states that originate from herds equal to U.S. Accredited TB-Free herds may enter

Missouri without testing provided they are moved directly from the herd of origin across the border as a single group and not commingled with other cattle prior to arriving at the border and obtain an entry permit prior to entering Missouri.

(III) Steers and spayed heifers from Mexican states that have been determined by the state veterinarian of Missouri, based on the recommendation of the Bi-National Committee, to have achieved Accredited Free status may enter Missouri without testing provided they are moved as a single group and not commingled with cattle of a different status prior to arriving to the border and obtain an entry permit prior to entering Missouri.

(IV) Holstein and Holstein-cross steers and spayed heifers from Mexico are prohibited from entering Missouri regardless of test history.

(V) Rodeo stock from Mexico must be tested negative for tuberculosis within sixty (60) days prior to their utilization as rodeo or roping stock under the supervision of a USDA/APHIS port veterinarian or by a U.S. accredited veterinarian, retested for tuberculosis every twelve (12) months thereafter, and obtain an entry permit prior to entering Missouri. No sexually intact rodeo stock from Mexico will be permitted into Missouri.

3. The state veterinarian may designate high incidence areas within certain states that must meet additional import restrictions and retest requirements.

AUTHORITY: 267.645, RSMo 2000. This version of rule filed Jan. 24, 1995, effective Feb. 3, 1995. For intervening history, please consult the Code of State Regulations. Emergency amendment filed Dec. 2, 2004, effective Dec. 12, 2004, expires May 31, 2005. A proposed amendment covering this same material is published in this issue of the Missouri Register.

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

EMERGENCY RULE

19 CSR 20-50.005 Definitions

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

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective disposal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have to pay for them. This rule establishes definitions necessary for the safe and effective implementation of the program. The medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications as quickly as possible, in a manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The

scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2005, effective January 1, 2005, expires June 29, 2005.

(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, expires June 29, 2005. A proposed rule covering this same material is published in this issue of the Missouri Register.

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

EMERGENCY RULE

**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.

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective disposal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have to pay for them. This rule establishes eligibility requirements for participating repository sites for medications donated through the program. Medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications as quickly as possible, in a

manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2004, effective January 1, 2005, expires June 29, 2005.

(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, expires June 29, 2005. A proposed rule covering this same material is published in this issue of the Missouri Register.

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

EMERGENCY RULE

**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.

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective disposal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have

to pay for them. This rule establishes eligibility requirements for individuals obtaining medications through the program. Medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications as quickly as possible, in a manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the *Missouri Register*. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the *Missouri and United States Constitutions*. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2004, effective January 1, 2005, expires June 29, 2005.

(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, expires June 29, 2005. A proposed rule covering this same material is published in this issue of the Missouri Register.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 20—Division of Environmental Health and Communicable Disease Prevention

Chapter 50—Prescription Drug Repository Program

EMERGENCY RULE

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.

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective disposal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have to pay for them. This rule establishes standards and procedures for donating medications to the program. Medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications as quickly as possible, in a manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2004, effective January 1, 2005, expires June 29, 2005.

(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, expires June 29, 2005. A proposed rule covering this same material is published in this issue of the Missouri Register.

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

EMERGENCY RULE

**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.

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective dis-

posal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have to pay for them. This rule establishes standards and procedures to be followed by participating repository sites accepting medications into the program. Medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications as quickly as possible, in a manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2004, effective January 1, 2005, expires June 29, 2005.

(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 January 1, 2005, expires June 29,

2005. A proposed rule covering this same material is published in this issue of the *Missouri Register*.

**Title 19—DEPARTMENT OF HEALTH
AND SENIOR SERVICES**

**Division 20—Division of Environmental Health and
Communicable Disease Prevention**

Chapter 50—Prescription Drug Repository Program

EMERGENCY RULE

**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.

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective disposal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have to pay for them. This rule establishes standards and procedures which must be followed for inspecting and storing donated medications by participating repository sites accepting medications into the program. Medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications as quickly as possible, in a manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the *Missouri Register*. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the *Missouri* and *United States Constitutions*. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2004, effective January 1, 2005, expires June 29, 2005.

(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.

AUTHORITY: section 196.984, RSMo Supp. 2004. Emergency rule filed Dec. 15, 2004, effective Jan. 1, 2005, expires June 29, 2005. A proposed rule covering this same material is published in this issue of the *Missouri Register*.

**Title 19—DEPARTMENT OF HEALTH
AND SENIOR SERVICES**

**Division 20—Division of Environmental Health and
Communicable Disease Prevention**

Chapter 50—Prescription Drug Repository Program

EMERGENCY RULE

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.

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective disposal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have to pay for them. This rule establishes standards and procedures to be followed for dispensing donated medications by participating repository sites accepting medications into the program. Medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications in a manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2004, effective January 1, 2005, expires June 29, 2005.

(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, expires June 29, 2005. A proposed rule covering this same material is published in this issue of the Missouri Register.

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

EMERGENCY RULE

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.

EMERGENCY STATEMENT: During the Second Regular Session of the 92nd General Assembly, House Substitute for House Committee Substitute for Senate Committee Substitute for Senate Bill No. 1160 was passed. This legislation establishes that the Department of Health and Senior Services shall, by January 1, 2005, establish this new program to provide indigent citizens access to needed prescription medications. Some expensive medications, unused due to discontinuation of the patient's need for the medication or due to the death of the patient, may be returned for reuse rather than destroyed. This program will provide an option for the safe and effective disposal of unused medications that are in their original sealed and tamper-evident unit dose packaging and are unadulterated, safe and

*suitable for dispensing and prevent the waste of expensive medications that could be used by other patients that would otherwise have to pay for them. This rule establishes record keeping requirements for participating repository sites accepting medications into the program. Medications may not be donated to or received from the program until regulations are in place. Therefore the department finds that the emergency rule is necessary to provide a mechanism for patients to donate and obtain unused medications as quickly as possible, in a manner consistent with the public health. A proposed rule, which covers the same material, is published in this issue of the **Missouri Register**. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri and United States Constitutions**. The Department of Health and Senior Services thinks that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed December 15, 2004, effective January 1, 2005, expires June 29, 2005.*

(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, 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, expires June 29, 2005. A proposed rule covering this same material is published in this issue of the **Missouri Register**.*

**EXECUTIVE ORDER
04-29**

WHEREAS, Executive Order 04-22 issued on October 25, 2004 is no longer necessary.

NOW, THEREFORE, I, BOB HOLDEN, GOVERNOR OF THE STATE OF MISSOURI, by the virtue of the powers vested in me through the constitution and the laws of the State of Missouri, do hereby order Executive Order 04-22 rescinded.



IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Missouri, in the City of Jefferson, on this 4th day of January, 2005.

**Bob Holden
Governor**

ATTEST:

**Matt Blunt
Secretary of State**