

## AN ACT

To amend chapter 338, RSMo, by adding thereto four new sections relating to a drug repository program.

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BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI, AS FOLLOWS:

Section A. Chapter 338, RSMo, is amended by adding thereto four new sections, to be known as sections 338.400, 338.405, 338.410, and 338.415, to read as follows:

338.400. 1. As used in sections 338.400 to 338.415, the following terms mean:

(1) "Hospital", the same meaning as in section 197.010, RSMo;

(2) "Nonprofit clinic", any charitable nonprofit organization that provides health care services to indigent and uninsured persons. Nonprofit clinic does not include a hospital or a facility that is operated for profit;

(3) "Prescription drug", any drug to which the following applies:

(a) Under the federal Food, Drug, and Cosmetic Act, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without a prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a

prescription;

(b) Under chapter 195, RSMo, the drug may be dispensed only upon a prescription.

2. The state board of pharmacy shall establish a drug repository program to accept and dispense prescription drugs donated for the purpose of being dispensed to individuals who are residents of this state and meet eligibility standards established by rules adopted by the board. Only drugs in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed. The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. Drugs donated by individuals bearing an expiration date that is less than six months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be accepted or dispensed if there is reason to believe that it is adulterated as described in section 196.095, RSMo. Subject to the limitation specified in this subsection, unused drugs dispensed for purposes of the medicaid program may be accepted and dispensed under the drug repository program.

338.405. 1. Any person, including a drug manufacturer or any health care facility, may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital, or nonprofit clinic that elects to

participate in the drug repository program and meets criteria for participation in the program established in rules adopted by the state board of pharmacy. Participation in the program by pharmacies, hospitals, and nonprofit clinics shall be voluntary. Nothing in this section or any other state statute shall require a pharmacy, hospital, or nonprofit clinic to participate in the program.

2. A pharmacy, hospital, or nonprofit clinic eligible to participate in the program shall dispense drugs donated under this section to individuals who are residents of this state and meet the eligibility standards established by rules adopted by the board, or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a prescription issued by a licensed health care professional authorized to prescribe drugs. A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall comply with all applicable federal and state laws dealing with storage and distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine that they are not adulterated as described in section 196.095, RSMo. The pharmacy, hospital, or nonprofit clinic may charge individuals receiving donated drugs a handling fee established in accordance with rules adopted by the board. Drugs donated to the repository shall not be resold.

338.410. 1. As used in this section, "health care professional" means any of the following persons who provide medical, dental, or other health-related diagnosis, care, or treatment:

(1) Persons authorized under chapter 334, RSMo, to practice medicine and surgery, osteopathic medicine and surgery, or persons authorized under chapter 330, RSMo, to practice podiatric medicine or surgery;

(2) Registered nurses and licensed practical nurses licensed under chapter 335, RSMo;

(3) Physician assistants authorized to practice under chapter 334, RSMo;

(4) Dentists and dental hygienists licensed under chapter 332, RSMo;

(5) Optometrists licensed under chapter 336, RSMo;

(6) Pharmacists licensed under chapter 338, RSMo.

2. The state board of pharmacy; the director of the department of health and senior services; any person, including a drug manufacturer, or government entity that donates drugs to the repository program; any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who accepts or dispenses drugs under the program shall not, in the absence of bad faith, be

subject to any of the following for matters related to donating, accepting, or dispensing drugs under the program: criminal loss to person or property, or professional disciplinary action. A drug manufacturer shall not, in the absence of bad faith, be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug manufacturer that is donated by any person under the program, including but not limited to liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

338.415. 1. In consultation with the director of the department of health and senior services, the state board of pharmacy shall adopt rules governing the drug repository program that establish all of the following:

(1) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and dispense donated drugs under the program;

(2) Standards and procedures for accepting, safely storing, and dispensing donated drugs;

(3) Standards and procedures for inspecting donated drugs to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe, and suitable for dispensing;

(4) Eligibility standards based on economic need for individuals to receive drugs;

(5) A form that an individual receiving a drug from the repository must sign before receiving the drug to confirm that the individual understands the immunity provisions of the program;

(6) A formula to determine the amount of a handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;

(7) In addition, for drugs donated to the repository by individuals:

(a) A list of drugs, arranged either by category or by individual drug, that the repository will accept from individuals;

(b) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from individuals. The list shall include a statement as to why the drug is ineligible for donation;

(c) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the repository;

(8) In addition, for drugs donated to the repository by health care facilities:

(a) A list of drugs, arranged either by category or by

individual drug, that the repository will accept from health care facilities;

(b) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from health care facilities. The list shall include a statement as to why the drug is ineligible for donation;

(9) Any other standards and procedures the board considers appropriate.

2. No rule or portion of a rule promulgated under the authority of sections 338.400 to 338.415 shall become effective unless it has been promulgated under chapter 536, RSMo.