

SECOND REGULAR SESSION
[TRULY AGREED TO AND FINALLY PASSED]
HOUSE SUBSTITUTE FOR
HOUSE COMMITTEE SUBSTITUTE FOR
SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 1160

92ND GENERAL ASSEMBLY

2004

3666L.07T

AN ACT

To amend chapter 196, RSMo, by adding thereto six new sections relating to the prescription drug repository program, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Chapter 196, RSMo, is amended by adding thereto six new sections, to be known as sections 196.970, 196.973, 196.976, 196.979, 196.981, and 196.984, to read as follows:

196.970. Sections 196.970 to 196.984 shall be known and may be cited as the "Prescription Drug Repository Program Act".

196.973. As used in sections 196.970 to 196.984, the following terms shall mean:

(1) "Health care professional", any of the following persons licensed and authorized to prescribe and dispense drugs and to provide medical, dental, or other health-related diagnoses, care, or treatment:

- (a) A licensed physician or surgeon;
- (b) A registered nurse or licensed practical nurse;
- (c) A physician assistant;
- (d) A dentist;
- (e) A dental hygienist;
- (f) An optometrist;
- (g) A pharmacist; and
- (h) A podiatrist;

(2) "Hospital", the same meaning as such term is defined in section 197.020, RSMo;

(3) "Nonprofit clinic", a facility organized as not-for-profit in which advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health are provided on an outpatient basis for a period of less than twenty-four consecutive hours to persons not residing or confined at such facility;

(4) "Prescription drug", a drug which may be dispensed only upon prescription by an authorized prescriber and which is approved for safety and effectiveness as a prescription drug under Section 505 or 507 of the Federal Food, Drug, and Cosmetic Act.

196.976. 1. By January 1, 2005, the department of health and senior services shall establish the "Prescription Drug Repository Program" 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 established by rules promulgated pursuant to section 196.984.

2. The following criteria shall be used in accepting drugs for use in the program:

(1) Only prescription drugs in their original sealed and tamper-evident unit dose packaging shall be accepted and dispensed pursuant to the program;

(2) The packaging must be unopened; except that prescription 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;

(3) Prescription drugs donated by individuals shall bear the manufacturer's lot number and an expiration date that is less than six months from the date the prescription drug is donated shall not be accepted or dispensed; and

(4) A prescription drug shall not be accepted or dispensed if there is reason to believe that the drug is adulterated as described in section 196.095;

(5) Subject to the limitations specified in this section, unused prescription drugs dispensed for purposes of a medical assistance program may be accepted and dispensed under the prescription drug repository program.

196.979. 1. Any person, including but not limited to a prescription drug manufacturer or health care facility, may donate prescription drugs to the prescription drug repository program. The drugs shall be donated at a pharmacy, hospital, or nonprofit clinic that elects to participate in the prescription drug repository program and meets the criteria for participation established by rule of the department pursuant to section 196.984. Participation in the program by pharmacies, hospitals, and nonprofit clinics shall be voluntary. Nothing in sections 196.970 to 196.984 shall require any pharmacy, hospital, or nonprofit clinic to participate in the program.

2. A pharmacy, hospital, or nonprofit clinic which meets the eligibility requirements established in section 196.984 may dispense prescription drugs donated under the program to persons who are residents of Missouri and who meet the eligibility requirements of the program, or to other governmental entities and nonprofit private entities to be dispensed to persons who meet the eligibility requirements of the program. A prescription drug shall be dispensed only pursuant to a prescription issued by a health care professional who is authorized by statute to prescribe drugs. A pharmacy, hospital, or nonprofit clinic which accepts donated prescription drugs shall comply with all applicable federal and state laws dealing with the storage and distribution of dangerous drugs and shall inspect all prescription drugs prior to dispensing the prescription drugs to determine that they are not adulterated as described in section 196.095. The pharmacy, hospital, or nonprofit clinic may charge persons receiving donated prescription drugs a handling fee, not to exceed a maximum of two hundred percent of the Medicaid dispensing fee, established by rule of the department promulgated pursuant to section 196.984. Prescription drugs donated to the program shall not be resold. Any individual who knowingly resells any donated prescription drugs pursuant to sections 196.970 to 196.984 shall be guilty of a class D felony.

196.981. 1. The following persons and entities when acting in good faith shall not be subject to criminal or civil liability for injury, death, or loss to person or property, or professional disciplinary action for matters related to donating, accepting, or dispensing prescription drugs under the prescription drug repository program:

- (1) The department of health and senior services;
- (2) The director of the department of health and senior services;
- (3) Any prescription drug manufacturer, governmental entity, or person donating prescription drugs to the program;
- (4) Any pharmacy, hospital, nonprofit clinic, or health care professional that prescribes, accepts or dispenses prescription drugs under the program; and
- (5) Any pharmacy, hospital, or nonprofit clinic that employs or has a hospital medical staff affiliation with a health care professional who accepts or dispenses prescription drugs under the program.

2. A prescription drug manufacturer shall not, in the absence of bad faith, be subject to criminal or civil liability for injury, death, or loss to person or property for matter related to the donation, acceptance, or dispensing of a prescription drug manufactured by the prescription 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 prescription drug.

196.984. 1. In consultation with the board of pharmacy, the director of the department of health and senior services shall adopt and promulgate rules to implement the prescription drug repository program. Such rules shall include:

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

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

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

(4) Eligibility requirements for recipients in the program shall be based on economic need for persons to receive prescription drugs under the program. For purposes of this subdivision, "economic need" means a net family income below three hundred percent of the federal poverty level;

(5) An identification card by which a person who is eligible to receive donated prescription drugs under the program may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic;

(6) A form that a person receiving a prescription drug from the program must sign before receiving the drug to confirm that such person understands the criminal and civil immunity from liability provisions of the program;

(7) Establish a maximum handling fee that pharmacies, hospitals, and nonprofit clinics may charge to drug recipients to cover restocking and dispensing costs;

(8) For prescription drugs donated to the program by individuals:

(a) A list of prescription drugs, arranged by category or by individual drug, that the program will and will not accept from individuals. If a drug is ineligible for donation, the list must include a statement as to the reason the drug is ineligible for donation; and

(b) A form each donor must sign stating that the donor is the owner of the prescription drugs and intends to voluntarily donate such drugs to the program;

(9) For prescription drugs donated to the program by health care facilities, a list of prescription drugs, arranged by category or by individual drug, that the program will and will not accept from health care facilities. If a drug is ineligible for donation, the list must include a statement as to the reason the drug is ineligible for donation; and

(10) Any other standards and procedures the department deems appropriate or necessary to implement the provisions of sections 196.970 to 196.984.

2. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in sections 196.970 to 196.984 shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. Sections 196.970 to 196.984 and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2004, shall be invalid and void.

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