

## HOUSE SUBSTITUTE

FOR

## HOUSE COMMITTEE SUBSTITUTE

FOR

## SENATE COMMITTEE SUBSTITUTE

FOR

## SENATE BILL NO. 1160

## AN ACT

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

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

8 Section A. Chapter 196, RSMo, is amended by adding thereto  
9 six new sections, to be known as sections 196.970, 196.973,  
10 196.976, 196.979, 196.981, and 196.984, to read as follows:

11 196.970. Sections 196.970 to 196.984 shall be known and may  
12 be cited as the "Prescription Drug Repository Program Act".

13 196.973. As used in sections 196.970 to 196.984, the  
14 following terms shall mean:

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

1       (a) A licensed physician or surgeon;

2       (b) A registered nurse or licensed practical nurse;

3       (c) A physician assistant;

4       (d) A dentist;

5       (e) A dental hygienist;

6       (f) An optometrist;

7       (g) A pharmacist; and

8       (h) A podiatrist;

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

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

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

22       196.976. 1. By January 1, 2005, the department of health  
23 and senior services shall establish the "Prescription Drug  
24 Repository Program" to accept and dispense prescription drugs  
25 donated for the purpose of being dispensed to persons who are

1 residents of Missouri and who meet eligibility requirements  
2 established by rules promulgated pursuant to section 196.984.

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

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

8 (2) The packaging must be unopened; except that  
9 prescription drugs packaged in single-unit doses may be accepted  
10 and dispensed when the outside packaging is opened if the single-  
11 unit-dose packaging is undisturbed;

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

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

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

23 196.979. 1. Any person, including but not limited to a  
24 prescription drug manufacturer or health care facility, may  
25 donate prescription drugs to the prescription drug repository

1 program. The drugs shall be donated at a pharmacy, hospital, or  
2 nonprofit clinic that elects to participate in the prescription  
3 drug repository program and meets the criteria for participation  
4 established by rule of the department pursuant to section  
5 196.984. Participation in the program by pharmacies, hospitals,  
6 and nonprofit clinics shall be voluntary. Nothing in sections  
7 196.970 to 196.984 shall require any pharmacy, hospital, or  
8 nonprofit clinic to participate in the program.

9 2. A pharmacy, hospital, or nonprofit clinic which meets  
10 the eligibility requirements established in section 196.984 may  
11 dispense prescription drugs donated under the program to persons  
12 who are residents of Missouri and who meet the eligibility  
13 requirements of the program, or to other governmental entities  
14 and nonprofit private entities to be dispensed to persons who  
15 meet the eligibility requirements of the program. A prescription  
16 drug shall be dispensed only pursuant to a prescription issued by  
17 a health care professional who is authorized by statute to  
18 prescribe drugs. A pharmacy, hospital, or nonprofit clinic which  
19 accepts donated prescription drugs shall comply with all  
20 applicable federal and state laws dealing with the storage and  
21 distribution of dangerous drugs and shall inspect all  
22 prescription drugs prior to dispensing the prescription drugs to  
23 determine that they are not adulterated as described in section  
24 196.095. The pharmacy, hospital, or nonprofit clinic may charge  
25 persons receiving donated prescription drugs a handling fee, not

1 to exceed a maximum of two hundred percent of the Medicaid  
2 dispensing fee, established by rule of the department promulgated  
3 pursuant to section 196.984. Prescription drugs donated to the  
4 program shall not be resold. Any individual who knowingly  
5 resells any donated prescription drugs pursuant to sections  
6 196.970 to 196.984 shall be guilty of a class D felony.

7 196.981. 1. The following persons and entities when acting  
8 in good faith shall not be subject to criminal or civil liability  
9 for injury, death, or loss to person or property, or professional  
10 disciplinary action for matters related to donating, accepting,  
11 or dispensing prescription drugs under the prescription drug  
12 repository program:

13 (1) The department of health and senior services;

14 (2) The director of the department of health and senior  
15 services;

16 (3) Any prescription drug manufacturer, governmental  
17 entity, or person donating prescription drugs to the program;

18 (4) Any pharmacy, hospital, nonprofit clinic, or health  
19 care professional that prescribes, accepts or dispenses  
20 prescription drugs under the program; and

21 (5) Any pharmacy, hospital, or nonprofit clinic that  
22 employs or has a hospital medical staff affiliation with a health  
23 care professional who accepts or dispenses prescription drugs  
24 under the program.

25 2. A prescription drug manufacturer shall not, in the

1 absence of bad faith, be subject to criminal or civil liability  
2 for injury, death, or loss to person or property for matter  
3 related to the donation, acceptance, or dispensing of a  
4 prescription drug manufactured by the prescription drug  
5 manufacturer that is donated by any person under the program,  
6 including but not limited to liability for failure to transfer or  
7 communicate product or consumer information or the expiration  
8 date of the donated prescription drug.

9 196.984. 1. In consultation with the board of pharmacy,  
10 the director of the department of health and senior services  
11 shall adopt and promulgate rules to implement the prescription  
12 drug repository program. Such rules shall include:

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

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

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

23 (4) Eligibility requirements for recipients in the program  
24 shall be based on economic need for persons to receive  
25 prescription drugs under the program. For purposes of this

1 subdivision, "economic need" means a net family income below  
2 three hundred percent of the federal poverty level;

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

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

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

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

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

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

24 (9) For prescription drugs donated to the program by health  
25 care facilities, a list of prescription drugs, arranged by

1 category or by individual drug, that the program will and will  
2 not accept from health care facilities. If a drug is ineligible  
3 for donation, the list must include a statement as to the reason  
4 the drug is ineligible for donation; and

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

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