

SECOND REGULAR SESSION  
SENATE COMMITTEE SUBSTITUTE FOR  
HOUSE COMMITTEE SUBSTITUTE FOR

# HOUSE BILL NO. 898

## 92ND GENERAL ASSEMBLY

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Reported from the Committee on Aging, Families, Mental and Public Health, April 23, 2004, with recommendation that the Senate Committee Substitute do pass.

2719S.04C

TERRY L. SPIELER, Secretary.

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### AN ACT

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

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*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,  
2 to be known as sections 196.970, 196.973, 196.976, 196.979, 196.981, and 196.984, to  
3 read as follows:

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

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

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

6 **(a) A licensed physician or surgeon;**

7 **(b) A registered nurse or licensed practical nurse;**

8 **(c) A physician assistant;**

9 **(d) A dentist;**

10 **(e) A dental hygienist;**

11 **(f) An optometrist;**

12 **(g) A pharmacist; and**

13 **(h) A podiatrist;**

14 **(2) "Hospital", the same meaning as such term is defined in section  
15 197.020, RSMo;**

16 **(3) "Nonprofit clinic", a facility organized as not-for-profit in which**

17 advice, counseling, diagnosis, treatment, surgery, care, or services relating  
18 to the preservation or maintenance of health are provided on an outpatient  
19 basis for a period of less than twenty-four consecutive hours to persons not  
20 residing or confined at such facility;

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

196.976. 1. By January 1, 2005, the department of health and senior  
2 services shall establish the "Prescription Drug Repository Program" to accept  
3 and dispense prescription drugs donated for the purpose of being dispensed  
4 to persons who are residents of Missouri and who meet eligibility  
5 requirements established by rules promulgated pursuant to section 196.984.

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

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

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

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

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

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

196.979. 1. Any person, including but not limited to a prescription drug  
2 manufacturer or health care facility, may donate prescription drugs to the  
3 prescription drug repository program. The drugs shall be donated at a  
4 pharmacy, hospital, or nonprofit clinic that elects to participate in the  
5 prescription drug repository program and meets the criteria for participation  
6 established by rule of the department pursuant to section

7 **196.984. Participation in the program by pharmacies, hospitals, and nonprofit**  
8 **clinics shall be voluntary. Nothing in sections 196.970 to 196.984 shall require**  
9 **any pharmacy, hospital, or nonprofit clinic to participate in the program.**

10 **2. A pharmacy, hospital, or nonprofit clinic which meets the eligibility**  
11 **requirements established in section 196.984 may dispense prescription drugs**  
12 **donated under the program to persons who are residents of Missouri and who**  
13 **meet the eligibility requirements of the program, or to other governmental**  
14 **entities and nonprofit private entities to be dispensed to persons who meet**  
15 **the eligibility requirements of the program. A prescription drug shall be**  
16 **dispensed only pursuant to a prescription issued by a health care professional**  
17 **who is authorized by statute to prescribe drugs. A pharmacy, hospital, or**  
18 **nonprofit clinic which accepts donated prescription drugs shall comply with**  
19 **all applicable federal and state laws dealing with the storage and distribution**  
20 **of dangerous drugs and shall inspect all prescription drugs prior to**  
21 **dispensing the prescription drugs to determine that they are not adulterated**  
22 **as described in section 196.095. The pharmacy, hospital, or nonprofit clinic**  
23 **may charge persons receiving donated prescription drugs a handling fee, not**  
24 **to exceed a maximum of two hundred percent of the Medicaid dispensing fee,**  
25 **established by rule of the department promulgated pursuant to section**  
26 **196.984. Prescription drugs donated to the program shall not be resold. Any**  
27 **individual who knowingly resells any donated prescription drugs pursuant**  
28 **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**  
2 **faith shall not be subject to criminal or civil liability for injury, death, or loss**  
3 **to person or property, or professional disciplinary action for matters related**  
4 **to donating, accepting, or dispensing prescription drugs under the**  
5 **prescription drug repository program:**

6 **(1) The department of health and senior services;**

7 **(2) The director of the department of health and senior services;**

8 **(3) Any prescription drug manufacturer, governmental entity, or**  
9 **person donating prescription drugs to the program;**

10 **(4) Any pharmacy, hospital, nonprofit clinic, or health care professional**  
11 **that prescribes, accepts or dispenses prescription drugs under the program;**  
12 **and**

13 **(5) Any pharmacy, hospital, or nonprofit clinic that employs or has a**  
14 **hospital medical staff affiliation with a health care professional who accepts**  
15 **or dispenses prescription drugs under the program.**

16           **2. A prescription drug manufacturer shall not, in the absence of bad**  
17 **faith, be subject to criminal or civil liability for injury, death, or loss to**  
18 **person or property for matter related to the donation, acceptance, or**  
19 **dispensing of a prescription drug manufactured by the prescription drug**  
20 **manufacturer that is donated by any person under the program, including but**  
21 **not limited to liability for failure to transfer or communicate product or**  
22 **consumer information or the expiration date of the donated prescription**  
23 **drug.**

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

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

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

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

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

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

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

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

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

28           **(a) A list of prescription drugs, arranged by category or by individual**  
29 **drug, that the program will and will not accept from individuals. If a drug is**

30 ineligible for donation, the list must include a statement as to the reason the  
31 drug is ineligible for donation; and

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

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

40 (10) Any other standards and procedures the department deems  
41 appropriate or necessary to implement the provisions of sections 196.970 to  
42 196.984.

43 2. Any rule or portion of a rule, as that term is defined in section  
44 536.010, RSMo, that is created under the authority delegated in sections  
45 196.970 to 196.984 shall become effective only if it complies with and is subject  
46 to all of the provisions of chapter 536, RSMo, and, if applicable, section  
47 536.028, RSMo. Sections 196.970 to 196.984 and chapter 536, RSMo, are  
48 nonseverable and if any of the powers vested with the general assembly  
49 pursuant to chapter 536, RSMo, to review, to delay the effective date, or to  
50 disapprove and annul a rule are subsequently held unconstitutional, then the  
51 grant of rulemaking authority and any rule proposed or adopted after August  
52 28, 2004, shall be invalid and void.

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