

FIRST REGULAR SESSION

HOUSE BILL NO. 580

92ND GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE JOHNSON (47).

Read 1st time February 27, 2003, and copies ordered printed.

STEPHEN S. DAVIS, Chief Clerk

1958L.011

AN ACT

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

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

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

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

2 **(1) "Cancer drug", a prescription drug used in treatment of cancer;**

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

12 **(g) A pharmacist;**

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

14 **(4) "Nonprofit clinic", a facility organized as not-for-profit in which advice,
15 counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or**

16 maintenance of health are provided on an outpatient basis for a period of less than twenty-
17 four consecutive hours to persons not residing or confined at such facility;

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

196.976. 1. By January 1, 2004, the department of health and senior services shall
2 establish the "Cancer Drug Repository Program" to accept and dispense cancer drugs
3 donated for the purpose of being dispensed to persons who are residents of Missouri and
4 who meet eligibility requirements established by rule promulgated pursuant to section
5 196.984.

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

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

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

12 (3) Cancer drugs donated by individuals bearing an expiration date that is less than
13 six months from the date the cancer drug is donated shall not be accepted or dispensed;

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

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

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

9 2. A pharmacy, hospital, or nonprofit clinic which meets the eligibility
10 requirements established in section 196.984 may dispense cancer drugs donated under the
11 program to persons who are residents of Missouri and who meet the eligibility
12 requirements of the program, or to other governmental entities and nonprofit private
13 entities to be dispensed to persons who meet the eligibility requirements of the program.

14 A cancer drug shall be dispensed only pursuant to a prescription issued by a health care
15 professional. A pharmacy, hospital, or nonprofit clinic which accepts donated cancer
16 drugs shall comply with all applicable federal and state laws dealing with the storage and
17 distribution of dangerous drugs and shall inspect all cancer drugs prior to dispensing the
18 cancer drugs to determine that they are not adulterated as described in section 196.095.
19 The pharmacy, hospital, or nonprofit clinic may charge persons receiving donated cancer
20 drugs a handling fee established by rule of the department promulgated pursuant to
21 section 196.984. Cancer drugs donated to the program shall not be resold.

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

- 5 (1) The department of health and senior services;
- 6 (2) The director of the department of health and senior services;
- 7 (3) Any cancer drug manufacturer, governmental entity, or person donating cancer
8 drugs to the program;
- 9 (4) Any pharmacy, hospital, nonprofit clinic, or health care professional that
10 accepts or dispenses cancer drugs under the program; and
- 11 (5) Any pharmacy, hospital, or nonprofit clinic that employs a health care
12 professional who accepts or dispenses cancer drugs under the program.

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

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

- 4 (1) Eligibility criteria for pharmacies, hospitals, and nonprofit clinics to receive and
5 dispense donated cancer drugs under the program;
- 6 (2) Standards and procedures for accepting, safely storing, and dispensing donated
7 cancer drugs;
- 8 (3) Standards and procedures for inspecting donated cancer drugs to determine
9 that the original single-unit-dose packaging is sealed and tamper-evident and that the
10 cancer drugs are unadulterated, safe, and suitable for dispensing;

11 **(4) Eligibility requirements for recipients in the program based economic need for**
12 **persons to receive cancer drugs under the program;**

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

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

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

21 **(8) For cancer drugs donated to the program by individuals:**

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

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

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

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

34 **2. No rule or portion of a rule promulgated pursuant to the authority of sections**
35 **196.970 to 196.984 shall become effective unless it has been promulgated pursuant to**
36 **chapter 536, RSMo.**