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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2005

A N A C T

RELATING TO FOOD AND DRUGS -- DRUG REPOSITORY PROGRAM

Introduced By: Representatives McNamara, Sullivan, Malik, Long, and Ginaitt

Date Introduced: February 15, 2005

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

1 SECTION 1. Title 21 of the General Laws entitled "Food and Drugs" is hereby amended
2 by adding thereto the following chapter:

3 CHAPTER 28.6

4 DRUG REPOSITORY PROGRAM

5 **21-28.6-1. Definitions.** – As used in this chapter:

6 (1) "Director" means the director of the Rhode Island state department of health.

7 (2) "Health care facility" means any institutional health service provider, facility or
8 institution, place, building, agency or portion thereof, whether a partnership or corporation,
9 whether public or private, whether organized for profit or not, used, operated, or engaged in
10 providing health care services, including, but not limited to, hospitals; nursing facilities; home
11 nursing care provider (which shall include skilled nursing services and may also include activities
12 allowed as a home care provider or as a nursing service agency); home care provider (which may
13 include services such as personal care or homemaker services); rehabilitation centers; kidney
14 disease treatment centers; health maintenance organizations; free-standing emergency care
15 facilities, and facilities providing surgical treatment to patients not requiring hospitalization
16 (surgi-centers); hospice care, and physician ambulatory surgery centers and podiatry ambulatory
17 surgery centers providing surgical treatment. The term "health care facility" also includes
18 organized ambulatory care facilities which are not part of a hospital but which are organized and
19 operated to provide health care services to outpatients such as central services facilities serving

1 more than one health care facility or health care provider, treatment centers, diagnostic centers,
2 outpatient clinics, infirmaries and health centers, school based health centers and neighborhood
3 health centers. The term "health care facility" shall not apply to organized ambulatory care
4 facilities owned and operated by professional service corporations as defined in chapter 5.1 of
5 title 7, as amended (the "Professional Service Corporation Law"), or to a private practitioner's
6 (physician, dentist, or other health care provider) office or group of the practitioners' offices
7 (whether owned and/or operated by an individual practitioner, alone or as a member of a
8 partnership, professional service corporation, organization, or association).

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

10 (a) Under the "Food, Drug and Cosmetic Act" 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as
11 amended, the drug is required to bear a label containing the legend, "Caution: Federal law
12 prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or
13 on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be
14 dispensed only upon a prescription.

15 (b) Under the "Uniform Controlled Substances Act," RIGL 21-28 et seq., the drug may
16 be dispensed only upon a prescription.

17 **21-28.6-2. Drug repository program established.** – The state board of pharmacy shall
18 establish a drug repository program to accept and dispense prescription drugs donated for the
19 purpose of being dispensed to individuals who are residents of this state and meet eligibility
20 standards established in rules adopted by the board in accordance with this chapter. Only drugs
21 in their original sealed and tamper-evident unit dose packaging may be accepted and dispensed.
22 The packaging must be unopened, except that drugs packaged in single unit doses may be
23 accepted and dispensed when the outside packaging is opened if the single unit dose packaging is
24 undisturbed. Drugs donated by individuals bearing an expiration date that is less than six (6)
25 months from the date the drug is donated shall not be accepted or dispensed. A drug shall not be
26 accepted or dispensed if a reasonable person would believe that it is or may have been
27 adulterated. Subject to the limitation specified herein, unused drugs dispensed for purposes of the
28 Medicaid program may be accepted and dispensed under the drug repository program.

29 **21-28.6-3. Donation of prescription drugs to program.** – Any person, including a drug
30 manufacturer or any health care facility as defined in this chapter, may donate prescription drugs
31 to the drug repository program. The drugs must be donated at a pharmacy, hospital or other
32 health care facility that elects to participate in the drug repository program and meets criteria for
33 participation in the program established in rules adopted by the state board of pharmacy.
34 Participation in the program by pharmacies, hospitals and other health care facilities is voluntary.

1 Nothing in this or any other section of the general laws requires a pharmacy, hospital or other
2 health care facility to participate in the program.

3 **21-28.6-4. Disbursement of donated drugs.** – A pharmacy, hospital or other health care
4 facility eligible to participate in the program shall dispense drugs donated under this section to
5 individuals who are residents of this state and meet the eligibility standards established in rules
6 adopted by the board pursuant to this chapter or to other government entities and nonprofit
7 private entities to be dispensed to individuals who meet the eligibility standards. A drug may be
8 dispensed only pursuant to a prescription issued by a licensed health professional authorized to
9 prescribe drugs. A pharmacy, hospital or other health care facility that accepts donated drugs
10 shall comply with all applicable federal laws and laws of this state dealing with storage and
11 distribution of dangerous drugs and shall inspect all drugs prior to dispensing them to determine
12 that they are not adulterated. The pharmacy, hospital or other health care facility may charge
13 individuals receiving donated drugs a handling fee established in accordance with rules adopted
14 by the board pursuant to this chapter. Drugs donated to the repository may not be resold.

15 **21-28.6-5. Limitation of liability.** – (A) As used in this section, "health care
16 professional" means any of the following who provide medical, dental or other health-related
17 diagnosis, care or treatment:

- 18 (1) Individuals authorized under the general laws to practice medicine and surgery,
19 osteopathic medicine and surgery, or podiatric medicine and surgery;
- 20 (2) Registered nurses and licensed practical nurses;
- 21 (3) Physician assistants;
- 22 (4) Dentists and dental hygienists;
- 23 (5) Optometrists;
- 24 (6) Pharmacists.

25 (B) The state board of pharmacy: the director of the department of health; any person,
26 including a drug manufacturer, or government entity that donates drugs to a repository program;
27 any pharmacy, hospital, nonprofit clinic, or health care professional that accepts or dispenses
28 drugs under the program; and any pharmacy, hospital or nonprofit clinic that employs a health
29 care professional who accepts or dispenses drugs under the program shall not, in the absence of
30 bad faith, be subject to any of the following for matters related to donating, accepting, or
31 dispensing drugs under the program; criminal prosecution; liability in tort or other civil action for
32 injury, death or loss to person or property; or professional disciplinary action.

33 A drug manufacturer shall not, in the absence of bad faith, be subject to criminal
34 prosecution or liability in tort or other civil action for injury, death, or loss to person or property

1 for matters related to the donation, acceptance, or dispensing of a drug manufactured by the drug
2 manufacturer that is donated by any person under the program, including, but not limited to,
3 liability for failure to transfer or communicate product or consumer information or the expiration
4 date of the donated drug.

5 **21-28.6-6. Rules and regulations.** – In consultation with the director of the department
6 of health, the state board of pharmacy shall adopt rules governing the drug repository program
7 that establish all of the following:

8 (A) Eligibility criteria for pharmacies, hospitals, and other health care facilities to receive
9 and dispense donated drugs under the program;

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

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

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

15 (E) A means, such as an identification card, by which an individual who is eligible to
16 receive donated drugs may demonstrate eligibility to the pharmacy, hospital, or other health care
17 facility dispensing the drugs;

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

21 (G) A formula to determine the amount of a handling fee that pharmacies, hospitals, and
22 other health care facilities may charge to drug recipients to cover restocking and dispensing costs;

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

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

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

29 (3) A form each donor must sign stating that the donor is the owner of the drugs and
30 intends to voluntarily donate them to the repository.

31 (I) In addition, for drugs donated to the repository by health care facilities;

32 (1) A list of drugs, arranged either by category or by individual drug, that the repository
33 will accept from health care facilities;

34 (2) A list of drugs, arranged either by category or by individual drug, that the repository

1 will not accept from health care facilities. The list must include a statement as to why the drug is
2 ineligible for donation.

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

4 The rules shall be adopted in accordance with the Administrative Procedures Act.

5 **21-28.6-7. Severability.** – The provisions of this chapter are severable, and if any of its
6 provisions shall be held unconstitutional by any court of competent jurisdiction, the decision of
7 that court shall not affect or impair any of the remaining provisions.

8 SECTION 2. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
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RELATING TO FOOD AND DRUGS -- DRUG REPOSITORY PROGRAM

- 1 This act would establish a drug repository program for unused prescription drugs.
- 2 This act would take effect upon passage.

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