

LC00295/SUB A

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2005

A N A C T

RELATING TO HEALTH AND SAFETY

Introduced By: Representatives Sullivan, Corvese, Moura, McNamara, and Costantino

Date Introduced: January 18, 2005

Referred To: House Corporations

It is enacted by the General Assembly as follows:

1 SECTION 1. Title 23 of the General Laws entitled "Health and Safety" is hereby
2 amended by adding thereto the following chapter:

3 CHAPTER 25.4

4 UTILIZATION OF UNUSED PRESCRIPTION DRUGS ACT

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6 **23-25.4-1. Title.** -- This act may be cited as the "Utilization of Unused Prescription
7 Drugs Act."

8 **23-25.4-2. Legislative purpose.** -- The general assembly has determined that the high
9 cost of prescription drugs is a burden on the uninsured who may forego the drugs they need or
10 take only partial doses which can ultimately increase health costs. The general assembly has also
11 determined that many nursing facilities and assisted living residences destroy quantities of unused
12 but viable prescription medications when residents pass away or when medications otherwise are
13 no longer needed by the resident. In an effort to improve the quality, efficiency and utilization of
14 the state's health care system, the general assembly hereby establishes a voluntary statewide pilot
15 program allowing nursing facilities and assisted living residences to transfer from their facilities
16 unused prescription drugs to authorized participating pharmacies for distribution to medically
17 indigent Rhode Island residents.

18 **23-25.4-3. Definitions.** -- For the purposes of this chapter:

19 (a) "Assisted living residence" has the same meaning as such term is defined in section

1 23-17.4-2 and the regulations promulgated thereunder.

2 (b) "Blister packages" means multi-dose containers of a specific medication repackaged
3 by the pharmacy in accordance with section 13.7 of the regulations promulgated under chapter
4 19.1 of title 5 and intended for a specific patient.

5 (c) "Cancer drugs" means any of several drugs that control or kill neoplastic cells,
6 commonly referred to as "cancer-fighting chemotherapy" to destroy cancer cells.

7 (d) "Health care prescriber" means any of the following persons licensed and authorized
8 to prescribe drugs or to provide medical, dental, or other health-related diagnoses, care of
9 treatment within the scope of their professional license:

10 (i) A physician holding a current license to practice medicine pursuant to chapter 37 of
11 title 5;

12 (ii) A certified registered nurse practitioner licensed pursuant to chapter 34 of title 5;

13 (iii) A physician assistant licensed pursuant to chapter 54 of title 5;

14 (iv) A dentist licensed pursuant to chapter 31.1 of title 5;

15 (v) An optometrist licensed pursuant to chapter 35 of title 5; and

16 (vi) A pharmacist licensed pursuant to chapter 19.1 of title 5.

17 (vii) A nurse – midwife licensed pursuant to section 23-13-9 of chapter 13 of title 23; and

18 (viii) A psychiatric and mental health clinical nurse specialist licensed pursuant to chapter
19 34 of title 5.

20 (e) "Medically indigent" means a person eligible to receive Medicaid or Medicare or a
21 person who has no health insurance and who otherwise lacks reasonable means to purchase
22 prescribed drugs.

23 (f) "Charitable clinic" means an organized ambulatory care facility licensed pursuant to
24 chapter 17 of title 23 organized as a nonprofit corporation pursuant to section 7-6-2 that:

25 (1) Holds a valid exemption from federal income taxation issued pursuant to Section
26 501(a) of the Internal Revenue Code (26 U.S.C., Section 501(1));

27 (2) Is listed as an exempt organization under 501(c) of the Internal Revenue Code (26
28 U.S.C., Section 501(c));

29 (3) Has a licensed outpatient pharmacy located at the organized ambulatory care or a
30 contract with a retail pharmacy.

31 (g) "Prescription drug" means a drug which may be dispensed only upon prescription by
32 a health care prescriber authorized by his or her licensing authority and which is approved for
33 safety and effectiveness as a prescription drug under Section 505 or 507 of the Federal Food,
34 Drug and Cosmetic Act (52 Stat. 1040 (1938), 21 U.S.C.A., Section 301).

1 (h) "Unit-dose container" is one that is designed to hold a quantity of a drug intended for
2 use as a single dose and used promptly after the container is opened. The immediate container,
3 and/or the outer container or protective packaging shall be designed to show evidence of any
4 tampering with the contents. Each individual container shall be fully identifiable containing a
5 single dose of a single entity and shall protect the integrity of the dosage form. Labeling shall be
6 in accordance with USP standards compendia and federal and state law and shall include the
7 identity, quantity, and strength of the product, name of the manufacturer, and lot number and
8 expiration date of the article.

9 **23-25.4-4. Program established.** -- (a) The department of health and the board of
10 pharmacy shall jointly develop and implement a pilot program consistent with public health and
11 safety through which unused prescription drugs, other than prescription drugs defined as
12 controlled substances in section 21-28-1.02, may be transferred from nursing facilities or assisted
13 living residences that centrally store prescription drugs and are licensed at the M1 licensure level
14 by the department of health to pharmacies authorized for the purpose of re-dispensing the
15 medication to Rhode Island residents who are medically indigent.

16 (b) The pilot program shall conform to the requirements established in rules promulgated
17 by the state department of health and the board of pharmacy. The pilot program shall remain in
18 effect until January 1, 2007.

19 (c) The state department of health and the board of pharmacy shall review and evaluate
20 the pilot program and shall submit a report and any recommendations to the governor, the speaker
21 of the house of representatives, and the president of the senate on or before January 1, 2007.

22 (d) Beginning January 1, 2006, the department of health and the board of pharmacy shall
23 implement statewide a program consistent with public health and safety through which unused
24 prescription drugs, other than prescription drugs defined as controlled substances in section 21-
25 28-1.02, may be transferred from nursing facilities of assisted living residences or to pharmacies
26 authorized by the board for the purpose of re-dispensing the unused prescription drugs to Rhode
27 Island residents who are medically indigent.

28 (e) The department of health and the board of pharmacy shall promulgate rules and
29 establish procedures necessary to implement the program established pursuant to this chapter.

30 (f) The board of pharmacy shall provide technical assistance to entities who may wish to
31 participate in the program.

32 **23-25.4-5. Criteria.** -- The following criteria shall be used in soliciting and accepting
33 unused prescription drugs for use pursuant to this chapter:

34 (a) Nursing facilities and assisted living residences that have entered into an agreement to

1 participate with an eligible charitable clinic shall solicit residents to participate in the program by
2 requiring the residents to sign a statement whereby their excess and otherwise eligible unused
3 prescription drugs shall be donated to a specific pharmacy associated with an eligible charitable
4 clinic for the purpose of re-dispensing to eligible recipients of such prescription drugs.
5 Participation in this program by residents of participating nursing facilities and assisted living
6 residences shall be strictly voluntary.

7 (b) Only prescription drugs in their original sealed multi-dose blister packages, unit dose
8 containers or perforated blister packages shall be accepted and re-dispensed;

9 (c) Expired prescription drugs shall not be accepted;

10 (d) A prescription drug shall not be accepted or re-dispensed if the pharmacist accepting
11 or re-dispensing the drug, in his or her judgment has reason to believe that the drug is adulterated
12 mislabeled, or has been improperly stored;

13 (e) No controlled substances shall be accepted; and

14 (f) Subject to the limitation specified in this section, unused prescription drugs dispensed
15 for purposes of a medical assistance program may be accepted and re-dispensed pursuant to this
16 chapter.

17 **23-25.4-6. Participation.** -- (a) Participation in the "Utilization of Unused Prescription
18 Drugs Act" by individual residents of any assisted living residence or nursing facility,
19 pharmacies, nursing facilities, assisted living residences, charitable clinics or prescription drug
20 manufacturers shall be voluntary. Nothing in this chapter shall require any resident of any
21 assisted living residence or nursing facility, pharmacy, pharmacists, charitable clinic or
22 prescription drug manufacturer to participate in the program.

23 (b) A pharmacy operating in conjunction with a charitable clinic that meets the eligibility
24 requirements established in this chapter may:

25 (1) Re-dispense prescription drugs donated pursuant to this chapter to persons who are
26 medically indigent residents of Rhode Island.

27 (c) A pharmacy operating in conjunction with a charitable clinic wherein both meet the
28 eligibility requirements established and authorized by this chapter and that accepts donated
29 prescription drugs shall:

30 (1) Comply with all applicable federal and state laws relating to the storage, distribution,
31 and dispensing of prescription drugs;

32 (2) Inspect all prescription drugs prior to re-dispensing the prescription drugs to
33 determine that such drugs are not adulterated; and

34 (3) Re-dispense prescription drugs only pursuant to a valid prescription issued by a

1 health care prescriber.

2 (d) Prescription drugs donated pursuant to this chapter shall not be resold.

3 **23-25.4-7. Liability.** -- (a) For matters related only to the lawful donation, acceptance, or
4 re-dispensing of prescription drugs under this chapter, the following persons and entities, in
5 compliance with the criteria set forth in this chapter, in the absence of bad faith or gross
6 negligence, shall not be subject to criminal or civil liability for injury other than death, or loss to
7 person or property, or professional disciplinary action:

8 (1) The board of pharmacy;

9 (2) Any resident of a nursing facility or assisted living residence who agrees to donate
10 unused prescription drugs, or his/her next of kin or legal guardian;

11 (3) The department of mental health, retardation and hospitals;

12 (4) Any prescription drug manufacturer, governmental entity, nursing facility, or assisted
13 living residence who participates in the program for the reuse of prescription drugs pursuant to
14 this chapter;

15 (5) Any prescription drug manufacturer or its representative that directly donates
16 prescription drugs in professional samples to a charitable clinic or a pharmacy pursuant to this
17 chapter;

18 (6) Any health care prescriber or pharmacy that accepts or dispenses operating in
19 conjunction with a charitable clinic that accepts or re-dispenses prescription drugs pursuant to this
20 chapter; and

21 (7) Any pharmacy or pharmacist operating in conjunction with a charitable clinic, or
22 other state-contracted pharmacy that employs a health care professional who accepts or can
23 legally dispense prescription drugs pursuant to this chapter.

24 (b) For matters related to the donation, acceptance, or dispensing of a prescription drug
25 manufactured by the prescription drug manufacturer that is donated by any entity pursuant to this
26 chapter, a prescription drug manufacturer shall not, in the absence of bad faith be subject to
27 criminal or civil liability for injury death, or loss to person or property including, but not limited
28 to, liability for failure to transfer or communicate product or consumer information or the
29 expiration date of the donated prescription drug.

30 **23-25.4-8. Rules.** -- (a) The board of pharmacy shall promulgate emergency rules by
31 December 1, 2005, to implement the provisions of this chapter. Permanent rules shall be
32 promulgated pursuant to the administrative procedures act. Such rules shall include:

33 (1) Eligibility criteria for pharmacies and charitable clinics authorized to receive and
34 dispense donated prescription drugs pursuant to this chapter;

- 1 (2) Establishment of a formulary which shall include all prescription drugs approved by
2 the federal Food and Drug Administration;
- 3 (3) Standards and procedures for transfer, acceptance, safe storage, security, and
4 dispensing of donated prescription drugs;
- 5 (4) A process for seeking input from the state department of health in establishing
6 provisions which affect nursing homes and assisted living residences;
- 7 (5) A process for seeking input form the department of mental health, retardation and
8 hospitals in establishing provisions which affect mental heath and substance abuse clients;
- 9 (6) Standards and procedures for inspecting donated prescription drugs to ensure that the
10 drugs are in compliance with the provisions of this chapter and to ensure that, in the professional
11 judgment of the pharmacist, the medications meet all federal and state standards for product
12 integrity;
- 13 (7) Procedures for destruction of medications that are donated which are controlled
14 substances;
- 15 (8) Procedures for verifying whether the pharmacy and responsible pharmacist
16 participating in the program are licensed and in good standing with the board of pharmacy;
- 17 (9) Establishment of standards for acceptance of unused prescription medications from
18 assisted living residences; and
- 19 (10) Any other standards and procedures the board of pharmacy deems appropriate or
20 necessary to implement the provisions of this chapter.
- 21 (b) In accordance with the rules and procedures of the program established pursuant to
22 this section, a resident of a nursing facility or assisted living residence, or the representative or
23 guardian of a resident may donate unused prescription medications, other than prescription drugs
24 defined as controlled dangerous substances, for dispensation to medically indigent persons.
- 25 **23-25.4-9. Prohibitions. -- It shall be unlawful for any person, firm or corporation to:**
- 26 (a) Forge or increase the quantity of drug in any prescription, or to present a prescription
27 bearing forged, fictitious or altered information or to possess any drug secured by such forged,
28 fictitious or altered prescription;
- 29 (b) Sell, offer for sale, barter or give away any unused quantity of drugs obtained by
30 prescription, except through a program pursuant to this chapter or as otherwise provided by the
31 board of pharmacy;
- 32 (c) Sell, offer for sale, barter or give away any drugs damaged by fire, water, or other
33 causes without first obtaining the written approval of the board of pharmacy or the state
34 department of health;

1 (d) Enter into any arrangement whereby prescription orders are received, or prescriptions
2 delivered at a place other than the pharmacy in which they are compounded and dispensed.
3 However, nothing in this paragraph shall prevent a pharmacist or an employee of the pharmacy
4 from personally receiving a prescription or delivering a legally filled prescription at a residence,
5 office or place of employment of the patient for whom the prescription was written. Nothing in
6 this paragraph shall prevent veterinary prescription drugs from being shipped directly from a
7 wholesaler or distributor to a client; provided, such drugs may be dispensed only on prescription
8 of a licensed veterinarian and only when an existing veterinary-client-patient relationship exists;

9 (e) Sell, offer for sale or barter or buy any professional samples except through a program
10 established pursuant to this chapter. For purpose of this subsection, "professional samples"
11 means complimentary drugs packaged in accordance with federal and state statutes and
12 regulations and provided to a licensed practitioner free of charge by manufacturers or distributor
13 for the purpose of being distributed free of charge in such package by the licensed practitioner to
14 a patient;

15 (f) Refuse to permit or otherwise prevent members of the board of pharmacy or such
16 representative thereof from entering and inspecting any and all places, including premises,
17 equipment, contents, and records, where drugs, medicine, chemicals or poisons are stored, sold,
18 vended, given away, compounded, dispensed or manufactured; or

19 (g) Possess dangerous drugs without a valid prescription or a valid license to possess
20 such drugs.

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

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N A C T
RELATING TO HEALTH AND SAFETY

1 This act would create the Utilization of Unused Prescriptions Medications Act which
2 would authorize the department of health and the board of pharmacy to create and implement a
3 voluntary statewide pilot program allowing nursing homes, assisted living centers and
4 prescription drug manufacturers to transfer from their facilities unused prescription medications
5 to authorized participating pharmacies for distribution to medically indigent Rhode Island
6 residents. This act would establish standards for authorizing participants under this chapter,
7 would authorize the board of pharmacy to promulgate program rules and establish criteria for
8 accepting unused prescription drugs for use under the chapter. This act would also establish the
9 exclusion of liabilities for participants in the program and determine prohibited criminal acts
10 under the chapter.

11 This act would take effect upon passage.

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