

2013 -- H 5230 SUBSTITUTE A

LC00655/SUB A/3

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2013

A N A C T

RELATING TO HEALTH AND SAFETY - THE RETURN OR EXCHANGE OF DRUGS ACT

Introduced By: Representatives DeSimone, Palangio, Slater, and Palumbo

Date Introduced: January 31, 2013

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

1 SECTION 1. Chapter 23-25.4 of the General Laws entitled "Utilization of Unused
2 Prescription Drugs Act" is hereby repealed in its entirety.

~~CHAPTER 23-25.4~~

~~Utilization of Unused Prescription Drugs Act~~

5 ~~23-25.4 1. Short title. --- This act may be cited as the "Utilization of Unused Prescription
6 Drugs Act."~~

7 ~~23-25.4 2. Legislative purpose. --- The general assembly has determined that the high
8 cost of prescription drugs is a burden on the uninsured who may forego the drugs they need or
9 take only partial doses which can ultimately increase health costs. The general assembly has also
10 determined that many nursing facilities and assisted living residences destroy quantities of unused
11 but viable prescription medications when residents pass away or when medications otherwise are
12 no longer needed by the resident. In an effort to improve the quality, efficiency and utilization of
13 the state's health care system, the general assembly hereby establishes a voluntary statewide pilot
14 program allowing nursing facilities and assisted living residences to transfer from their facilities
15 unused prescription drugs to authorized participating pharmacies for distribution to medically
16 indigent Rhode Island residents.~~

17 ~~23-25.4 3. Definitions. --- For the purposes of this chapter:~~

18 ~~(1) "Assisted living residence" has the same meaning as such term is defined in section
19 23-17.4-2 and the regulations promulgated thereunder.~~

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

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

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

8 ~~(i) Holds a valid exemption from federal income taxation issued pursuant to Section~~
9 ~~501(a) of the Internal Revenue Code, 26 U.S.C. section 501(1);~~

10 ~~(ii) Has a licensed outpatient pharmacy located at the organized ambulatory care facility~~
11 ~~or a contract with a retail pharmacy to participate in the program established under this chapter.~~

12 ~~(5) "Health care prescriber" means any of the following persons licensed and authorized~~
13 ~~to prescribe drugs or to provide medical, dental, or other health related diagnoses, care or~~
14 ~~treatment within the scope of their professional license:~~

15 ~~(i) A physician holding a current license to practice medicine pursuant to chapter 37 of~~
16 ~~title 5;~~

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

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

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

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

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

22 ~~(vii) A nurse—midwife licensed pursuant to chapter 13 of title 23; and~~

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

25 ~~(6) "Medically indigent" means a person eligible to receive Medicaid or Medicare or a~~
26 ~~person who has no health insurance and who otherwise lacks reasonable means to purchase~~
27 ~~prescribed drugs.~~

28 ~~(7) "Prescription drug" means a drug that may be dispensed only upon prescription by a~~
29 ~~health care prescriber authorized by his or her licensing authority and as defined in chapter 5-~~
30 ~~19.1.~~

31 ~~(8) "Unit dose container" is one that is designed to hold a quantity of a drug intended for~~
32 ~~use as a single dose and used promptly after the container is opened. The immediate container,~~
33 ~~and/or the outer container or protective packaging shall be designed to show evidence of any~~
34 ~~tampering with the contents. Each individual container shall be fully identifiable containing a~~

1 ~~single dose of a single entity and shall protect the integrity of the dosage form. Labeling shall be~~
2 ~~in accordance with USP standards compendia and federal and state law and shall include the~~
3 ~~identity, quantity, and strength of the product, name of the manufacturer, and lot number and~~
4 ~~expiration date of the article.~~

5 ~~**23-25.4-4. Program established.** -- (a) The department of health and the board of~~
6 ~~pharmacy shall jointly develop and implement a pilot program consistent with public health and~~
7 ~~safety through which unused prescription drugs, other than prescription drugs defined as~~
8 ~~controlled substances in section 21-28-1.02, shall be transferred from nursing facilities, assisted~~
9 ~~living residences, residential care facilities or community health organizations that centrally store~~
10 ~~prescription drugs and are licensed at the M1 licensure level by the department of health to~~
11 ~~charitable clinics for the purpose of re-dispensing the medication to Rhode Island residents who~~
12 ~~are medically indigent.~~

13 ~~(b) The pilot program shall conform to the requirements established in rules promulgated~~
14 ~~by the state department of health and the board of pharmacy. The pilot program shall remain in~~
15 ~~effect until January 1, 2012.~~

16 ~~(c) The state department of health and the board of pharmacy shall review and evaluate~~
17 ~~the pilot program and shall submit a report and any recommendations to the governor, the speaker~~
18 ~~of the house of representatives, and the president of the senate on or before January 1, 2012.~~

19 ~~(d) Beginning April 1, 2010, the department of health and the board of pharmacy shall~~
20 ~~implement statewide a program consistent with public health and safety through which unused~~
21 ~~prescription drugs, other than prescription drugs defined as controlled substances in section 21-~~
22 ~~28-1.02, shall be transferred from nursing facilities or assisted living residences to charitable~~
23 ~~clinics for the purpose of re-dispensing the unused prescription drugs.~~

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

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

28 ~~(g) The department of health shall be required to provide written notification to all~~
29 ~~eligible nursing homes, assisted living facilities, residential care facilities and community health~~
30 ~~organizations and to post a sign clearly and conspicuously in each facility to notify its residents of~~
31 ~~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 ~~(1) Nursing facilities and assisted living residences that have entered into an agreement~~

1 ~~to participate with a charitable clinic shall document residents' participation in the program with a~~
2 ~~written statement that their excess and otherwise eligible unused prescription drugs shall be~~
3 ~~donated to a charitable clinic for the purpose of re-dispensing to medically indigent persons.~~
4 ~~Participation in this program by residents of participating nursing facilities and assisted living~~
5 ~~residences shall be strictly voluntary.~~

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

8 ~~(3) Expired or beyond-use date prescription drugs shall not be accepted;~~

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

12 ~~(5) No controlled substances shall be accepted; and~~

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

16 ~~**23-25.4-6. Participation.** (a) Participation in the program established in this chapter by~~
17 ~~individual residents of any assisted living residence or nursing facility, pharmacies, nursing~~
18 ~~facilities, assisted living residences, charitable clinics or prescription drug manufacturers shall be~~
19 ~~voluntary. Nothing in this chapter shall require any resident of any assisted living residence or~~
20 ~~nursing facility, pharmacy, pharmacist, charitable clinic or prescription drug manufacturer to~~
21 ~~participate in the program.~~

22 ~~(b) A pharmacy operating in conjunction with a charitable clinic may:~~

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

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

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

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

32 ~~(3) Re-dispense prescription drugs only pursuant to a valid prescription issued by a~~
33 ~~health care prescriber.~~

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

1 ~~**23-25.4.7. Liability.** --- (a) For matters related only to the lawful donation, acceptance, or~~
2 ~~re-dispensing of prescription drugs under this chapter, the following persons and entities, in~~
3 ~~compliance with the criteria set forth in this chapter, in the absence of bad faith shall not be~~
4 ~~subject to criminal or civil liability for injury, death, or loss to person or property, or professional~~
5 ~~disciplinary action:~~

6 ~~(1) The board of pharmacy;~~

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

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

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

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

16 ~~(6) Any charitable clinic, health care prescriber or pharmacy that accepts or re-dispenses~~
17 ~~prescription drugs pursuant to this chapter; and~~

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

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

27 ~~**23-25.4.8. Rules.** --- (a) The board of pharmacy shall promulgate rules by December 1,~~
28 ~~2005, to implement the provisions of this chapter. Such rules may include:~~

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

31 ~~(2) Establishment of a formulary which shall include all prescription drugs approved by~~
32 ~~the federal Food and Drug Administration;~~

33 ~~(3) Standards and procedures for transfer, acceptance, safe storage, security, and~~
34 ~~dispensing of donated prescription drugs;~~

1 ~~(4) A process for seeking input from the state department of health in establishing~~
2 ~~provisions which affect nursing homes and assisted living residences;~~

3 ~~(5) A process for seeking input from the department of mental health, retardation and~~
4 ~~hospitals in establishing provisions which affect mental health and substance abuse clients;~~

5 ~~(6) Standards and procedures for inspecting donated prescription drugs to ensure that the~~
6 ~~drugs are in compliance with the provisions of this chapter and to ensure that, in the professional~~
7 ~~judgment of the pharmacist, the medications meet all federal and state standards for product~~
8 ~~integrity;~~

9 ~~(7) Procedures for destruction of medications that are donated which are controlled~~
10 ~~substances;~~

11 ~~(8) Procedures for verifying whether the pharmacy and responsible pharmacist~~
12 ~~participating in the program are licensed and in good standing with the board of pharmacy;~~

13 ~~(9) Establishment of standards for acceptance of unused prescription medications from~~
14 ~~assisted living residences; and~~

15 ~~(10) Any other standards and procedures the board of pharmacy deems appropriate or~~
16 ~~necessary to implement the provisions of this chapter.~~

17 ~~(b) In accordance with the rules and procedures of the program established pursuant to~~
18 ~~this section, a resident of a nursing facility or assisted living residence, or the representative or~~
19 ~~guardian of a resident may donate unused prescription medications, other than prescription drugs~~
20 ~~defined as controlled dangerous substances, to charitable clinics for dispensing to medically~~
21 ~~indigent persons.~~

22 ~~**23-25.4-9. Establishment of oversight commission on utilization of unused**~~
23 ~~**prescription drugs -- Membership.**~~ (a) ~~There is hereby established a commission on the~~
24 ~~utilization of prescription drugs to oversee the development and implementation of the pilot~~
25 ~~program for the utilization of unused prescription drugs as established pursuant to this chapter.~~

26 ~~(b) The commission shall consist of five (5) members to be appointed by the speaker of~~
27 ~~the house, not more than three (3) from the same political party. Any vacancy on the commission,~~
28 ~~occurring for any reason prior to the expiration of the term, shall be filled for the unexpired term~~
29 ~~by the appointing authority in the same manner as the original appointment.~~

30 SECTION 2. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby
31 amended by adding thereto the following chapter:

32 CHAPTER 25.5

33 THE RETURN OR EXCHANGE OF DRUGS ACT

34 23-25.5-1. Short title. -- This act shall be known and may be cited as "The Return or

1 [Exchange of Drugs Act."](#)

2 **23-25.5-2. Legislative purpose.** -- [The general assembly finds that many nursing](#)
3 [facilities and assisted living residences destroy quantities of unused but viable prescription](#)
4 [medication when residents pass away or when medications otherwise are no longer needed by the](#)
5 [resident. In an effort to improve the quality, efficiency and utilization of the state's healthcare](#)
6 [system, the general assembly hereby establishes a statewide program allowing pharmacies to](#)
7 [accept for return and redispensing certain prescription drugs.](#)

8 **23-25.5-3. Definitions.** – [For the purposes of this chapter:](#)

9 [\(1\) "Assisted living residence" has the same meaning as such term is defined in section](#)
10 [23-17.4-2 and the regulations promulgated thereunder.](#)

11 [\(2\) "Blister packages" means multi-dose containers of a specific medication repackaged](#)
12 [by the pharmacy in accordance with section 13.7 of the regulations promulgated under chapter](#)
13 [19.1 of title 5 and intended for a specific patient.](#)

14 [\(3\) "Department" means the department of health.](#)

15 [\(4\) "Healthcare prescriber" means any of the following persons licensed and authorized](#)
16 [to prescribe drugs or to provide medical, dental, or other health-related diagnoses, care or](#)
17 [treatment within the scope of their professional license:](#)

18 [\(i\) A physician holding a current license to practice medicine pursuant to chapter 37 of](#)
19 [title 5;](#)

20 [\(ii\) A certified registered nurse practitioner licensed pursuant to chapter 34 of title 5;](#)

21 [\(iii\) A physician assistant licensed pursuant to chapter 54 of title 5;](#)

22 [\(iv\) A dentist licensed pursuant to chapter 31.1 of title 5;](#)

23 [\(v\) An optometrist licensed pursuant to chapter 35 of title 5;](#)

24 [\(vi\) A pharmacist licensed pursuant to chapter 19.1 of title 5;](#)

25 [\(vii\) A nurse – midwife licensed pursuant to chapter 13 of title 23; and](#)

26 [\(viii\) A psychiatric and mental health clinical nurse specialist licensed pursuant to chapter](#)
27 [34 of title 5.](#)

28 [\(5\) "Pharmacy" means that portion or part of a premises where prescriptions are](#)
29 [compounded and dispensed including that portion utilized for the storage of prescription or](#)
30 [legend drugs.](#)

31 [\(6\) "Prescription drug" means a drug that may be dispensed only upon prescription by a](#)
32 [healthcare prescriber authorized by his or her licensing authority and as defined in chapter 5-19.1.](#)

33 [\(7\) "Unit-dose container" is one that is designed to hold a quantity of a drug intended for](#)
34 [use as a single dose and used promptly after the container is opened. The immediate container,](#)

1 and/or the outer container or protective packaging shall be designed to show evidence of any
2 tampering with the contents. Each individual container shall be fully identifiable containing a
3 single dose of a single entity and shall protect the integrity of the dosage form. Labeling shall be
4 in accordance with USP standards compendia and federal and state law and shall include the
5 identity, quantity, and strength of the product, name of the manufacturer, and lot number and
6 expiration date of the article.

7 (8) "Wholesaler" means a person who buys drugs or devices for resale and distribution to
8 corporations, individuals, or entities other than consumers.

9 **23-25.5-4. Program established.** -- (a) The department of health and the board of
10 pharmacy shall jointly develop and implement a program consistent with public health and safety
11 through which unused prescription drugs, other than prescription drugs defined as controlled
12 substances in section 21-28-1.02, and drugs that can only be dispensed to a patient registered with
13 the drug's manufacturer in accordance with federal Food and Drug Administration requirements,
14 may be accepted by wholesalers or pharmacies, from which they were purchased, for return from
15 nursing facilities, assisted living residences, residential care facilities, community health
16 organizations and state correctional facilities that centrally store prescription drugs and are
17 licensed at the M1 licensure level by the department of health, within forty-five (45) days of
18 dispensing.

19 (b) The program shall permit the wholesaler or pharmacy to which such medication is
20 returned to repackage, restock, and redistribute such medication.

21 (c) The program shall include the following prescription drugs:

22 (1) Unopened sections of blister pack prescription medication, with seal intact;

23 (2) Unopened unit-dose containers of liquids with the safety seal intact;

24 (3) Unopened unit-dose containers of powders for oral solution with safety seal intact;

25 (4) Unused injectables, with safety seal intact;

26 (d) The unused prescription drug shall not be accepted, repackaged or redispensed if:

27 (1) The prescription drug is expired or beyond use date;

28 (2) The pharmacist accepting or redispensing the drug, in his or her judgment has reason
29 to believe that the prescription drug is adulterated, mislabeled, or has been improperly stored;

30 (3) The prescription drug is defined as controlled substances in section 21-28-1.02; and

31 (4) It is a drug that can only be dispensed to a patient registered with the drug's
32 manufacturer in accordance with federal Food and Drug Administration requirements.

33 (e) The wholesaler or pharmacy shall be required to reimburse or credit the purchaser for
34 any such returned prescription drugs at original invoice price plus a restocking fee not to exceed

1 five dollars (\$5.00).

2 (f) The department and the board of pharmacy shall promulgate rules and regulations
3 necessary to implement the program established pursuant to this chapter within one hundred
4 eighty days (180) of passage of this act.

5 SECTION 3. This act shall take effect upon passage.

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LC00655/SUB A/3
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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF

A N A C T

RELATING TO HEALTH AND SAFETY - THE RETURN OR EXCHANGE OF DRUGS ACT

1 This act would repeal "The Utilization of Unused Prescription Drugs Act", and would
2 establish a new program known as "The Return or Exchange of Drugs Act" which would allow
3 pharmacies to accept for return and redispensing certain prescription drugs.

4 This act would take effect upon passage.

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LC00655/SUB A/3
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