

2022 -- H 7133 SUBSTITUTE B

LC003452/SUB B

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2022

A N A C T

RELATING TO HEALTH AND SAFETY -- PHARMACEUTICAL REDISTRIBUTION PROGRAM ACT

Introduced By: Representatives McNamara, Potter, Corvese, Donovan, and Ranglin-Vassell

Date Introduced: January 20, 2022

Referred To: House Health & Human Services

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 25.6

4 PHARMACEUTICAL REDISTRIBUTION PROGRAM ACT

5 **23-25.6-1. Short title.**

6 This act shall be known and may be cited as the "Pharmaceutical Redistribution Program
7 Act."

8 **23-25.6-2. Definitions.**

9 (a) As used in this chapter, the following words shall have the following meanings:

10 (1) "Cancer drug" means a prescription drug that is used to treat cancer, the side effects of
11 cancer, or the side effects from a cancer medication. A cancer drug must be deemed a non-harmful
12 substance by the Federal Drug Administration (FDA) and shall only be administered by a licensed
13 professional of the state.

14 (2) "Controlled substance" means a drug, substance, immediate precursor, or synthetic drug
15 in schedules I-V of chapter 28 of title 21 with high risk of dependency and addiction. Controlled
16 substances include certain depressants, stimulants, narcotics, hallucinogens, and anabolic steroids.
17 Controlled substances are regulated by the Drug Enforcement Agency under the Controlled
18 Substances Act. "Controlled substance" does not include distilled spirits, wine, or malt beverages.

1 as those terms are defined or used in chapter 1 of title 3, nor tobacco.

2 (3) "Distributor" means a person defined in § 21-28-1.02.

3 (4) "Department" means the Rhode Island department of health.

4 (5) "Donor" means any person or institution who is authorized to possess prescription drugs
5 and who is willing to provide them to a redistributor once they are recommended to be discontinued
6 by a physician. "Donor" includes, but is not limited to, any patient in legal possession of a
7 prescribed drug, a health care proxy, and any licensed health care facility or health care provider
8 such as a hospital, pharmacy, or long-term care facility, or a state or federal prison.

9 (6) "Most in need" means priority provided to a person in need of a drug based on the
10 person's ability to pay.

11 (7) "Non-controlled substance prescription drugs" means any non-controlled substance
12 drug meant for human use pursuant to a prescription administered by a prescriber.

13 (8) "Out-of-state redistributor" means a redistributor that is based outside of this state. An
14 out-of-state redistributor shall abide by this state's laws in addition to the laws of their own state.
15 Out-of-state redistributors must be licensed by the department as distributors in accordance with
16 the provisions of chapter 28 of title 21.

17 (9) "Pharmaceutical redistribution program" means the program established pursuant
18 to the provisions of this chapter for the redistribution of unused prescription drugs and shall
19 include any facility that may accept the return of unused non-controlled substance prescription
20 drugs and orchestrate their redistribution to aid persons of this state who have difficulty
21 affording or accessing the non-controlled substance drugs. This program shall prevent the
22 waste of unused non-controlled substance prescription drugs through the preservation and
23 redistribution to persons or licensed facilities based on their lack of access or ability to pay for
24 the drugs at full market value.

25 (10) "Prescriber" means any person who has occupational licensing by relevant boards to
26 prescribe a drug. Prescribers include, but are not limited to, doctors, physicians, or any other person
27 legally permitted by this state.

28 (11) "Receiver" means any person or institution who receives a donated drug, including,
29 but not limited to, a wholesaler, a drug manufacturer, a repackager, a returns processor, a third-
30 party logistics provider, a health care facility, a pharmacy, a hospital, or a patient. Donated
31 medications shall be obtained legally, with informed consent of the donor, and without coercion.

32 (12) "Redistributor" means any person or institution partaking in the redistribution of non-
33 controlled substance prescription drugs pursuant to the provisions of this chapter. The entities a
34 redistributor may donate drugs to include, but are not limited to, patients, institutions, hospitals and

1 health care providers. Redistributors shall also include out-of-state redistributors engaged in
2 redistribution pursuant to the provisions of this chapter. Redistributors must be licensed by the
3 department as distributors in accordance with the provisions of chapter 28 of title 21.

4 (13) "Tamper-evident packaging" means a package that has an outer or secondary seal that
5 must be broken to access the inner package and shall include clear messaging that the package had
6 previously been opened after its seal date. Tamper-evident packaging includes, but is not limited
7 to, blister packs and seal manufactured bottles.

8 (14) "Temperature-sensitive medication" means prescription medications that are unstable
9 at room temperature, or approximately 70 ± 15°F. Unstable medications may begin to decompose,
10 outside of this temperature range, affecting drug potency and thus efficacy. Temperature ranges
11 tolerable for a medication's storage are determined by the manufacturer. Common examples of
12 temperature-sensitive medications include drugs that must be refrigerated, such as biologics or
13 insulin.

14 (15) "Transaction date" means the date on which the drug was transferred from the donor
15 to the pharmaceutical redistribution program or to the redistributor. All available information
16 surrounding the transaction date shall be logged and recorded, such as the date when the medication
17 left the donor, and the date when the medication was received by the redistributor.

18 (16) "Underinsured" means any person who does not have adequate insurance coverage
19 and access to basic health care, or any person who spends more than ten percent (10%) of their
20 household income on out-of-pocket health care costs or more than five percent (5%) of their income
21 on their health care deductible.

22 **23-25.6-3. Eligibility criteria.**

23 (a) Eligibility criteria for the reception of donated drugs shall prioritize individuals who are
24 most in need, do not have insurance, are underinsured, or are reliant on public health programs.
25 Redistributors should ensure adequate allocation of donated medications for those in prioritized
26 populations. Once the need for these drugs amongst these prioritized people is fulfilled, the
27 redistributor can dispense medication to other populations reporting financial burden. Redistributed
28 drugs shall not be sold for an amount in excess of the price authorized pursuant to § 23-25.6-5(c).

29 (b) Donated drugs may be transferred from in-state redistributors to other in-state
30 redistributors or out-of-state redistributors, assuming this transaction is legal in the state of origin
31 and the state of transfer. The donation and redistribution of drugs is not categorized as wholesale
32 distribution and does not warrant licensing as a wholesaler.

33 **23-25.6-4. Voluntary participation and donation conditions.**

34 (a) All participation in the donation program shall be voluntary. No health professional,

1 insurer, agency or entity shall force any person to participate in the pharmaceutical distribution
2 program.

3 (b) The following conditions shall be met for the donation of a prescription drug to occur.

4 (1) All of the donated drugs shall pass inspection by a licensed pharmacist.

5 (2) The donated drugs shall be received in an intact, tamper-evident package with a clearly
6 displayed expiration date with no less than three (3) months until the expiration date.

7 (3) The donated drugs shall not be temperature-sensitive medications or a controlled
8 substance.

9 (4) The donated drugs shall be provided to the recipient in accordance with state law. The
10 drugs shall have been prescribed legally by a licensed health care professional after having been
11 properly transferred to and processed by an authorized pharmaceutical redistribution program or
12 redistributor.

13 (5) An authorized and properly licensed health care pharmacist shall deem the drug has not
14 been tampered with upon arrival and is properly labeled. If labels have degraded but drug identity
15 can be verified, new labels may be created. If the drugs have been combined in one package, the
16 information about all included drugs shall be labeled clearly. If the drugs have been donated from
17 out-of-state, this donation must abide by all of the laws of both states.

18 (6) The donated drugs shall have all prior patient information redacted in compliance with
19 HIPAA regulations or the pills shall be transferred to a new container.

20 (7) If the drugs donated have been combined, the closest expiration date for any drugs shall
21 be used for the entire package.

22 (c) If any one of the conditions contained in subsection (b) of this section is not satisfied,
23 the donated drugs shall not be distributed pursuant to the provisions of this program and may be
24 destroyed pursuant to department of health regulations.

25 **23-25.6-5. Redistribution of donated medications.**

26 (a) A redistributor may dispense prescription drugs to eligible persons as long as they abide
27 by the provisions of this chapter.

28 (b) A redistributor may repackage drugs prior to redistribution. Repackaged drugs shall be
29 labeled thoroughly and labels shall include the drug name, expiration date and kept separately from
30 other drugs until brought up for inspection. If multiple drugs are packaged together, the closest
31 expiration date shall be used pursuant to the requirements contained in § 23-25.6-4(b).

32 (c) A redistributor's compensation from an institution will not constitute the resale of drugs.
33 The distributor shall make a record of that charge and provide it upon request to the supervising
34 government agency. This sale price shall reflect an incentive to offer the drugs at a price that is

1 affordable and reasonable for people who do not have the means to pay for such drugs at market
2 price. The price incurred by the patient shall not exceed the usual and customary dispensing fee
3 determined by the this state's Medicaid program.

4 (d) Donated drugs that cannot be utilized by the redistributor shall be destroyed through
5 lawful methods, or transferred to a returns processor. Redistributors shall keep a record of disposed
6 drugs, the quantity of drug, its name, and strength.

7 (e) An authorized redistributor of drugs shall store the drugs legally, separate from other
8 non-donated drugs, and shall meet the requirements of the United States Pharmacopoeia (USP)
9 standards. The drugs shall be stored in a way which does not impair the quality and safety of the
10 drug. The drug shall be stored legally according to the methods described in this chapter. The
11 facilities and storage shall be subject to investigation and approval from the department of health
12 or a third party approved by the department of health. All records required pursuant to the
13 provisions of this chapter shall be retained in physical or electronic format for a period of two (2)
14 years. The drugs shall be labeled properly with a serial number or other effective label.
15 Redistributors shall keep records by either electronic or non-electronic means for the full two (2)
16 years.

17 **23-25.6-6. Civil and criminal immunity.**

18 Any person, except a person licensed from the Rhode Island department of health or any
19 other similar license from another jurisdiction involved in a drug donation, who acts reasonably
20 and in good faith shall be immune from criminal and civil liability for any persons who are harmed
21 from the reception of a donated drug. Liability shall be absolved for any act associated, but not
22 limited to, the transfer of the donated drugs from one party to another, transportation, repackaging,
23 or dispensing of donated drugs. Any person involved in drug donation who acts reasonably and in
24 good faith shall be protected from any disciplinary action from their employers. "Good faith", as
25 used in this section, may be defined as the intent to help people, the adoption of honest and altruistic
26 intentions and the preservation of moral and ethical values.

27 **23-25.6-7. Rules and regulations.**

28 (a) The department shall collaborate with the board of pharmacy to promulgate rules and
29 regulations necessary to regulate a program consistent with the public health and safety, through
30 which unused prescription drugs are donated pursuant to this chapter, to become operational on
31 January 1, 2023.

32 (b) The department shall collaborate with the board of pharmacy to promulgate rules and
33 regulations necessary to regulate the program established pursuant to this chapter, on or before
34 January 1, 2023.

1 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 -- PHARMACEUTICAL REDISTRIBUTION
PROGRAM ACT

1 This act would authorize the creation and implementation of a pharmaceutical
2 redistribution program, with rules and regulations to be promulgated by the department of health
3 in collaboration with the board of pharmacy, and to commence operations on January 1, 2023. This
4 program would provide for the redistribution of donated and unused non-controlled substance
5 prescription drugs from facilities to aid persons of this state who have difficulty affording or
6 accessing those drugs. The program would be voluntary and establish the conditions for donations
7 and redistribution with civil and criminal immunity for persons acting in good faith.

8 This act would take effect upon passage.

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