

2022 -- H 7133

=====
LC003452
=====

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

7 (4) "Most in need" means priority provided to a person in need of a drug based on the
8 person's ability to pay.

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

11 (6) "Out-of-state redistributor" means a redistributor that is based outside of this state. An
12 out-of-state redistributor shall abide by this state's laws in addition to the laws of their own state.

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

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

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

28 (10) "Redistributor" means any person or institution partaking in the redistribution of non-
29 controlled substance prescription drugs pursuant to the provisions of this chapter. The entities a
30 redistributor may donate drugs to include, but are not limited to, patients, institutions, hospitals and
31 health care providers. Redistributors shall also include out-of-state redistributors engaged in
32 redistribution pursuant to the provisions of this chapter.

33 (11) "Tamper-evident packaging" means a package that has an outer or secondary seal that
34 must be broken to access the inner package and shall include clear messaging that the package had

1 previously been opened after its seal date. Tamper-evident packaging includes, but is not limited
2 to, blister packs and seal manufactured bottles.

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

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

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

17 **23-25.6-3. Eligibility criteria.**

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

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

28 **23-25.6-4. Voluntary participation and donation conditions.**

29 (a) All participation in the donation program shall be voluntary. No health professional,
30 insurer, agency or entity shall force any person to participate in the pharmaceutical distribution
31 program.

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

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

34 (2) The donated drugs shall be received in an intact, tamper-evident package with a clearly

1 displayed expiration date with no less than three (3) months until the expiration date.

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

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

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

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

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

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

20 **23-25.6-5. Redistribution of donated medications.**

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

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

27 (c) A redistributor's compensation from an institution will not constitute the resale of drugs.
28 The distributor shall make a record of that charge and provide it upon request to the supervising
29 government agency. This sale price shall reflect an incentive to offer the drugs at a price that is
30 affordable and reasonable for people who do not have the means to pay for such drugs at market
31 price. The price incurred by the patient shall not exceed the usual and customary dispensing fee
32 determined by the this state's Medicaid program.

33 (d) Donated drugs that cannot be utilized by the redistributor shall be destroyed through
34 lawful methods, or transferred to a returns processor. Redistributors shall keep a record of disposed

1 drugs, the quantity of drug, its name, and strength.

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

12 **23-25.6-6. Civil and criminal immunity.**

13 Any person or institution involved in a drug donation, including, but not limited to,
14 pharmacists, manufacturers, wholesalers, redistributors, health care providers, government
15 agencies, contract carriers, or hospitals, who act reasonably and in good faith shall be immune from
16 criminal and civil liability for any persons who are harmed from the reception of a donated drug.
17 Liability shall be absolved for any act associated, but not limited to, the transfer of the donated
18 drugs from one party to another, transportation, repackaging, or dispensing of donated drugs. Any
19 person involved in drug donation who acts reasonably and in good faith shall be protected from
20 any disciplinary action from their employers. "Good faith", as used in this section, may be defined
21 as the intent to help people, the adoption of honest and altruistic intentions and the preservation of
22 moral and ethical values.

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

24 (a) The department of health and the board of pharmacy shall jointly develop and
25 implement a program consistent with the public health and safety, through which unused
26 prescription drugs are donated pursuant to this chapter, to become operational on January 1, 2023.

27 (b) The department and the board shall promulgate rules and regulations necessary to
28 implement the program established pursuant to this chapter, on or before January 1, 2023.

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

=====
LC003452
=====

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

8 This act would take effect upon passage.

=====
LC003452
=====