

1 S.164

2 Introduced by Senator Ayer

3 Referred to Committee on

4 Date:

5 Subject: Health; prescription drugs; ~~Board of Pharmacy~~[Agency of Human](#)
6 [Services](#); Unused Prescription Drug Repository Program

7 Statement of purpose of bill as introduced: This bill proposes to establish the
8 Unused Prescription Drug Repository Program to accept unused prescription
9 drugs and supplies and donate them to Vermont residents who meet eligibility
10 standards.

11 An act relating to establishing the Unused Prescription Drug Repository
12 Program

13 It is hereby enacted by the General Assembly of the State of Vermont:

14 Sec. 1. 18 V.S.A. chapter 91, subchapter 4 is added to read:

15 Subchapter 4. Unused Prescription Drug Repository Program

16 § 4651. DEFINITIONS

17 As used in this subchapter:

18 (1) “Drug manufacturer” means anyone who is engaged in the
19 manufacturing, preparing, propagating, compounding, processing, packaging,
20 repackaging, or labeling of a prescription drug.

1 (2) “Health care facility” shall have the same meaning as in section
2 9402 of this title and shall include residential care homes, as defined in 33
3 VSA 7102(10), and assisted living residences, as defined in 33 VSA 7102(1).

4 (3) “Health care professional” means an individual, partnership,
5 corporation, facility, or institution licensed, certified, or otherwise authorized
6 by Vermont law to provide professional health services.

7 (4) “Hospital” means an acute care hospital licensed under chapter 43 of
8 this title.

9 (5) “Prescription drug” means any human drug required by federal law
10 or regulation to be dispensed only by a prescription, including finished dosage
11 forms and active ingredients subject to Section 503(b) of the Federal Food,
12 Drug, and Cosmetic Act.

13 (6) “Supplies” means the supplies necessary to administer the
14 prescription drugs donated.

15 (7) “Wholesale drug distributor” means any person who is engaged in
16 wholesale distribution of prescription drugs, as defined in 26 V.S.A. § 2022,
17 but does not include any for-hire carrier or person hired solely to transport
18 prescription drugs.

19 § 4652. UNUSED PRESCRIPTION DRUG REPOSITORY PROGRAM

20 (a) Creation. The Board of Pharmacy created pursuant to 26 V.S.A.
21 chapter 36 shall Agency of Human Services may establish, or contract for

1 services related to, an ~~establish the~~ Unused Prescription Drug Repository
2 Program to accept and dispense donated prescription drugs and supplies to
3 Vermont residents who meet the eligibility standards adopted by the ~~Board~~
4 Agency by rule in accordance with ~~section 4653 of this title~~ 3 V.S.A. Chapter
5 25.

6 (b) Donations. Any person may donate prescription drugs and supplies for
7 use by persons who meet the eligibility standards adopted by the ~~Board of~~
8 Pharmacy Agency of Human Services by rule. Donations of prescription drugs
9 and supplies may be made on the premises of a pharmacy, hospital, or other
10 health care facility that elects to participate in the Program and meets the
11 requirements established by the Board.

12 (c) Program requirements.

13 (1) The Program shall accept and dispense a prescription drug or
14 supplies only if the following conditions are met:

15 (A) The prescription drug is in its original sealed and tamper-evident
16 packaging, except that the Program may accept and dispense a prescription
17 drug packaged in a single-unit dose with the outside packaging opened if the
18 single-unit dose packaging remains intact.

19 (B) The prescription drug bears an expiration date that is more than
20 six months after the date of donation, except that a donated prescription drug
21 with a date that is six months or less after the date of donation may be accepted

1 and distributed if the drug is in high demand and can be dispensed for use prior
2 to the drug's expiration date.

3 (C) The prescription drug or supplies are inspected before they are
4 dispensed by a licensed pharmacist employed by or under contract with the
5 health care facility, hospital, or pharmacy, and the licensed pharmacist
6 determines that the prescription drug or supplies are not adulterated or
7 misbranded.

8 (D) The prescription drug or supplies are prescribed by a health care
9 professional acting within his or her scope of practice for use by an eligible
10 individual and are dispensed by a licensed pharmacist or other authorized
11 dispensers. ~~are dispensed to an eligible individual by the prescribing health~~
12 ~~care professional or by the health care professional's authorized agent.~~

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13 (2) A prescription drug or supplies donated pursuant to this chapter shall
14 not be resold.

15 (3)(A) -If a person who donates prescription drugs under this chapter to a
16 pharmacy, hospital, or other health care facility receives a notice from a
17 pharmacy that a prescription drug has been recalled, the person shall inform
18 the pharmacy, hospital, or other health care facility of the recall.

19 (B) If a pharmacy, hospital, or other health care facility receives a
20 recall notification from a person who donated prescription drugs pursuant to
21 this chapter, the pharmacy, hospital, or other health care facility shall perform

1 a uniform destruction of all of the recalled prescription drugs in the pharmacy,
2 hospital, or facility, regardless of the source of the recalled drugs.

3 (4) A prescription drug dispensed through the Unused Prescription Drug
4 Repository Program shall not be eligible for reimbursement from Medicaid or
5 other publicly-funded drug benefits program reimbursement.

6 (d) Nothing in this section is intended to supersede or otherwise conflict with
7 the federal Drug Supply Chain Security Act (DSCSA).

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8 § 4653. BOARD OF PHARMACY; RULEMAKING

9 The Board of Pharmacy Agency of Human Services, in consultation with the
10 Department of Health Board of Pharmacy and the Board of Medical Practice,
11 shall adopt rules establishing all of the following:

12 (1) Requirements for pharmacies, hospitals, and other health care
13 facilities to accept and dispense donated prescription drugs and supplies,
14 including the following:

15 (A) eligibility criteria for participation by pharmacies, hospitals, and
16 other health care facilities;

17 (B) standards and procedures for accepting, safely storing, and
18 dispensing donated prescription drugs and supplies;

19 (C) standards and procedures for inspecting donated prescription
20 drugs to determine if the prescription drugs are in their original sealed and
21 tamper-evident packaging, or if the prescription drugs are in single-unit doses

1 or blister packs and the outside packaging is opened, if the single-unit dose
2 packaging or blister pack remains intact; and

3 (D) standards and procedures for inspecting donated prescription
4 drugs and supplies to determine that the prescription drugs and supplies are not
5 adulterated or misbranded.

6 (2) Eligibility criteria for individuals to receive donated prescription
7 drugs and supplies dispensed by pharmacies, hospitals, and other health care
8 facilities under the Program. ~~The standards shall prioritize dispensing to~~
9 ~~individuals with income at or below 400 percent of the federal poverty level,~~
10 ~~but may permit dispensing to other individuals if an individual with income at~~
11 ~~or below 400 percent of the federal poverty level is unavailable.~~

Comment [de1]: This can all be accomplished in the rulemaking process.

12 (3) A means by which an individual who is eligible to receive donated
13 prescription drugs may indicate such eligibility.

14 (4) Necessary forms for administration of the Unused Prescription Drug
15 Repository Program, including forms for use by individuals who donate,
16 accept, distribute, or dispense prescription drugs or supplies under the
17 Program.

18 (5) The maximum handling fee that a pharmacy, hospital, or other health
19 care facility may charge for accepting, distributing, or dispensing donated
20 prescription drugs and supplies under the Program.

1 (6) A list of prescription drugs and supplies that the Unused Prescription
2 Drug Repository Program will accept.

3 (7) An outreach and education plan to inform the public of the
4 availability of the Program, including information regarding:

5 (A) who may be eligible to receive donated prescription drugs and
6 supplies pursuant to this subchapter;

7 (B) how to demonstrate eligibility; and

8 (C) which prescription drugs and supplies may be donated and how
9 to donate them.

10 § 4654. LIMITATION OF LIABILITY

11 (a) The following persons shall not, in the absence of bad faith, be subject
12 to civil or criminal liability or professional disciplinary action for injury, death,
13 or loss to person or property resulting from the use of prescription drugs or
14 supplies accepted or dispensed under the Unused Prescription Drug Repository
15 Program established pursuant to this chapter:

16 (1) a physician licensed pursuant to 26 V.S.A. chapter 23;

17 (2) an osteopathic physician licensed pursuant to 26 V.S.A. chapter 33;

18 (3) a podiatric physician licensed pursuant to 26 V.S.A. chapter 7;

19 (4) a registered nurse, licensed practical nurse, or advanced practice
20 registered nurse licensed pursuant to 26 V.S.A. chapter 28;

21 (5) a physician assistant licensed pursuant to 26 V.S.A. chapter 31;

Comment [de2]: This section could be characterized rather than having a list.

- 1 (6) a dentist licensed pursuant to 26 V.S.A. chapter 12;
- 2 (7) an optometrist licensed pursuant to 26 V.S.A. chapter 30;
- 3 (8) a pharmacist licensed pursuant to 26 V.S.A. chapter 36;
- 4 (9) a member of the Vermont Board of Pharmacy;
- 5 (10) a wholesale drug distributor;
- 6 (11) a hospital or other health care facility; and
- 7 (12) any other State governmental officer, agency, or department.

8 (b) A drug manufacturer or supply manufacturer shall not, in the absence of
9 bad faith, be subject to civil or criminal liability for injury, death, or loss to
10 person or property for matters related to the donation, acceptance, or
11 dispensing of a prescription drug or supply manufactured by that drug
12 manufacturer or supply manufacturer that is donated under the Program,
13 including liability for failure to transfer or communicate product or consumer
14 information or liability related to the expiration date of the donated
15 prescription drug or supply.

16 § 4655. FORMS

17 The Board of Pharmacy, in consultation with the Board of Health and with
18 the Departments of Vermont Health Access, of Health, and of Disabilities,
19 Aging, and Independent Living, shall create forms necessary to implement the
20 provisions of this chapter. The forms shall include:

Comment [de3]: Necessary? Could be a part of rulemaking.

1 ~~(1) a form that an individual receiving a prescription drug or supply~~
2 ~~from the Program shall sign before receiving the drug or supply to confirm that~~
3 ~~the individual understands the limitations on liability under the Program;~~

4 ~~(2) a form that each donor shall sign stating that the donor is the owner~~
5 ~~of the prescription drugs or supplies and intends to donate them voluntarily to~~
6 ~~the Program; and~~

7 ~~(3) a form, such as an identification card, that an individual who is~~
8 ~~eligible to receive donated drugs or supplies may use to demonstrate eligibility.~~

9 Sec. 2. EFFECTIVE DATE

10 ~~This act shall take effect on July 1, 2019, except that the Board of~~
11 ~~Pharmacy Agency of Human Services may adopt rules prior to that date to~~
12 ~~ensure that the Program is operational on July 1, 2019the effective running of~~
13 ~~the program.~~