

1 S.164

2 Introduced by Senator Ayer

3 Referred to Committee on

4 Date:

5 Subject: Health; prescription drugs; Board of Pharmacy; Unused Prescription
6 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.

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

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

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

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

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

18 § 4652. UNUSED PRESCRIPTION DRUG REPOSITORY PROGRAM

19 (a) Creation. The Board of Pharmacy created pursuant to 26 V.S.A.
20 chapter 36 shall establish the Unused Prescription Drug Repository Program to
21 accept and dispense donated prescription drugs and supplies to Vermont

1 residents who meet the eligibility standards adopted by the Board by rule in
2 accordance with section 4653 of this title.

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

9 (c) Program requirements.

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

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

16 (B) The prescription drug bears an expiration date that is more than
17 six months after the date of donation, except that a donated prescription drug
18 with a date that is six months or less after the date of donation may be accepted
19 and distributed if the drug is in high demand and can be dispensed for use prior
20 to the drug's expiration date.

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

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

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

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

17 (B) If a pharmacy, hospital, or other health care facility receives a
18 recall notification from a person who donated prescription drugs pursuant to
19 this chapter, the pharmacy, hospital, or other health care facility shall perform
20 a uniform destruction of all of the recalled prescription drugs in the pharmacy,
21 hospital, or facility, regardless of the source of the recalled drugs.

1 (4) A prescription drug dispensed through the Unused Prescription Drug
2 Repository Program shall not be eligible for Medicaid reimbursement.

3 § 4653. BOARD OF PHARMACY; RULEMAKING

4 The Board of Pharmacy, in consultation with the Department of Health and
5 the Board of Medical Practice, shall adopt rules establishing all of the
6 following:

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

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

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

14 (C) standards and procedures for inspecting donated prescription
15 drugs to determine if the prescription drugs are in their original sealed and
16 tamper-evident packaging, or if the prescription drugs are in single-unit doses
17 or blister packs and the outside packaging is opened, if the single-unit dose
18 packaging or blister pack remains intact; and

19 (D) standards and procedures for inspecting donated prescription
20 drugs and supplies to determine that the prescription drugs and supplies are not
21 adulterated or misbranded.

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

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

9 (4) Necessary forms for administration of the Unused Prescription Drug
10 Repository Program, including forms for use by individuals who donate,
11 accept, distribute, or dispense prescription drugs or supplies under the
12 Program.

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

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

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

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

1 (B) how to demonstrate eligibility; and

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

4 § 4654. LIMITATION OF LIABILITY

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

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

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

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

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

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

16 (6) a dentist licensed pursuant to 26 V.S.A. chapter 12;

17 (7) an optometrist licensed pursuant to 26 V.S.A. chapter 30;

18 (8) a pharmacist licensed pursuant to 26 V.S.A. chapter 36;

19 (9) a member of the Vermont Board of Pharmacy;

20 (10) a wholesale drug distributor;

21 (11) a hospital or other health care facility; and

1 (12) any other State governmental officer, agency, or department.

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

10 § 4655. FORMS

11 The Board of Pharmacy, in consultation with the Board of Health and with
12 the Departments of Vermont Health Access, of Health, and of Disabilities,
13 Aging, and Independent Living, shall create forms necessary to implement the
14 provisions of this chapter. The forms shall include:

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

18 (2) a form that each donor shall sign stating that the donor is the owner
19 of the prescription drugs or supplies and intends to donate them voluntarily to
20 the Program; and

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

3 Sec. 2. EFFECTIVE DATE

4 This act shall take effect on July 1, 2019, except that the Board of Pharmacy
5 may adopt rules prior to that date to ensure that the Program is operational on
6 July 1, 2019.