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H.635

Introduced by Representatives Pugh of South Burlington, Dunn of Essex, Haas
of Rochester, Houghton of Essex, and McFaun of Barre Town

Referred to Committee on

Date:

Subject: Health; prescription drugs; Board of Pharmacy; Unused Prescription
Drug Repository Program

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

An act relating to establishing the Unused Prescription Drug Repository
Program

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

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

Subchapter 4. Unused Prescription Drug Repository Program

§ 4651. DEFINITIONS

As used in this subchapter:

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

4 (2) “Health care facility” shall have the same meaning as in section
5 9402 of this title.

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

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

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

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

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

1 § 4652. UNUSED PRESCRIPTION DRUG REPOSITORY PROGRAM

2 (a) Creation. The Board of Pharmacy created pursuant to 26 V.S.A.
3 chapter 36 shall establish the Unused Prescription Drug Repository Program to
4 accept and dispense donated prescription drugs and supplies to Vermont
5 residents who meet the eligibility standards adopted by the Board by rule in
6 accordance with section 4653 of this title.

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

13 (c) Program requirements.

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

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

20 (B) The prescription drug bears an expiration date that is more than
21 six months after the date of donation, except that a donated prescription drug

1 with a date that is six months or less after the date of donation may be accepted
2 and distributed if the drug is in high demand and can be dispensed for use prior
3 to the drug's expiration date.

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

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

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

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

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

1 this chapter, the pharmacy, hospital, or other health care facility shall perform
2 a uniform destruction of all of the recalled prescription drugs in the pharmacy,
3 hospital, or facility, regardless of the source of the recalled drugs.

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

6 § 4653. BOARD OF PHARMACY; RULEMAKING

7 The Board of Pharmacy, in consultation with the Department of Health and
8 the Board of Medical Practice, shall adopt rules establishing all of the
9 following:

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

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

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

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

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

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

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

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

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

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

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

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

5 (B) how to demonstrate eligibility; and

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

8 § 4654. LIMITATION OF LIABILITY

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

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

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

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

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

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

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

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

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

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

3 (10) a wholesale drug distributor;

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

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

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

14 § 4655. FORMS

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

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

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

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

6 Sec. 2. EFFECTIVE DATE

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