H.588

Introduced by Representative Deen of Westminster

Referred to Committee on

Date:

Subject: Health; conservation and development; prescription drugs; extended producer responsibility

Statement of purpose of bill as introduced: This bill proposes to establish a statewide extended producer responsibility program for unused prescription drugs.

An act relating to an extended producer responsibility program for unused prescription drugs

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

Sec. 1. FINDINGS

The General Assembly finds:

(1) Prescription drugs are a necessary medical technology that successfully allows Vermonters to live longer, healthier, and more productive lives.

(2) The public, particularly children and elders, are at significant and unnecessary risk of poisoning due to improper or careless disposal of prescription drugs and the illegal resale and diversion of prescription drugs.

(3) Vermont's groundwater and drinking water are being contaminated by unwanted, leftover, or expired prescription drugs passing through Vermont's wastewater and treatment centers.

(4) Vermont does not have a voluntary or mandatory statewide drug stewardship program for unwanted drugs, and drug manufacturers and producers have not offered any support for a permanent collection program to date.

Sec. 2. 18 V.S.A. chapter 83 is added to read:

CHAPTER 83. SAFE DISPOSAL OF UNWANTED PRESCRIPTION DRUGS

§ 4101. DEFINITIONS

As used in this chapter:

(1) "Covered drug" means a drug as defined in 21 U.S.C. § 321, including both brand-name and generic drugs. The term does not include:

(A) nonprescription drugs;

(B) vitamins or supplements;

(C) herbal-based remedies and homeopathic drugs, products, or remedies;

(D) cosmetics, soap, laundry detergent, bleach, household cleaning products, shampoo, sunscreen, toothpaste, lip balm, antiperspirant, or other

personal care products that are regulated as both cosmetics and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. chapter 9;

(E) drugs for which producers provide a pharmaceutical product stewardship or take-back program as part of a risk evaluation and mitigation strategy managed by the U.S. Food and Drug Administration pursuant to 21 U.S.C. § 355-1;

(F) drugs that are biological products as defined by 21 C.F.R. § 600.3(h) if the producer already provides a pharmaceutical stewardship or take-back program;

(G) medical devices or their component parts or accessories; and

(H) pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other delivery systems.

(2) "Department" means the Department of Health.

(3) "Drug" means:

(A) any article recognized in the official National Formulary or the official U.S. Pharmacopoeia, or any supplement to them;

(B) any substance intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals;

(C) any substance, other than food, that is intended to affect the structure or any function of the bodies of humans or other animals.

(4) "Drug wholesaler" means a person who purchases or distributes drugs and covered drugs for resale and distribution to entities other than consumers.

(5) "Generic drug" means a drug that is chemically identical or bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, though inactive ingredients may vary.

(6) "Mail-back services" means a collection method for the return of unwanted covered drugs from Vermont residents using prepaid and preaddressed mailing envelopes.

(7) "Manufacturer" means a drug manufacturer or any other person who is engaged in the production, preparation, propagation, compounding, processing, marketing, packaging, repacking, distributing, or labeling of prescribed products. The term does not include a drug wholesaler.

(8) "Nonprescription drug" means a drug that may be lawfully sold without a prescription.

(9) "Prescription drug" means any drug that is required by federal or State law to be dispensed by prescription only or is restricted to use by health care providers.

(10)(A)(i) "Producer" means the person who manufacturers a covered drug and who sells, offers for sale, or distributes that covered drug in Vermont under that person's own name and brand.

(ii) If no person sells, offers for sale, or distributes the covered drug in Vermont under the person's own name or brand, the producer shall be the owner or licensee of a trademark or brand under which the covered drug is sold or distributed in Vermont, regardless of whether the trademark is registered.

(iii) If no person qualifies as a producer of the covered drug under subdivision (i) or (ii) of this subdivision (10)(A), the producer of that covered drug shall be the person who brings the covered drug into Vermont for sale or distribution.

(B) The term "producer" shall not include:

(i) a retailer that puts its store label on a covered drug; or

(ii) a pharmacist who dispenses prescription drugs to or compounds a prescribed individual drug product for a consumer.

(11) "Product stewardship plan" means a plan required under this chapter that describes the manner in which a product stewardship program will be provided.

(12) "Product stewardship program" means a program financed and operated by producers to collect, transport, and safely dispose of unwanted drugs.

(13) "Regulated drug" means any substance described in subdivision 4201(29) of this title or listed in 21 U.S.C. § 812 or 813.

(14) "Residential generators" means single and multiple family residences and other locations where household drugs are unused, unwanted, disposed of, or abandoned. The term does not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the Department as a nonresidential source.

(15) "Stewardship organization" means an organization designated by a producer or a group of producers to act as an agent on behalf of one or more producers to develop and operate a product stewardship program.

(16) "Unwanted drug" means any covered drug that is no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

§ 4102. PRODUCT STEWARDSHIP PROGRAM

(a) This chapter shall apply only to a producer whose covered drug is sold or distributed in Vermont. The Department of Health shall administer and implement the provisions of this chapter.

(b) Each producer shall:

(1) operate, either individually or jointly with other producers, a product stewardship program approved by the Department; or

(2) enter into an agreement with a stewardship organization to operate on the producer's behalf a product stewardship program approved by the Department.

(c)(1) A producer, group of producers, or stewardship organization shall pay all administrative and operational fees associated with the product stewardship program, including the cost of collecting, transporting, and safely disposing of unwanted drugs collected from residential generators and the recycling or disposal, or both, of packaging collected with the unwanted drug.

(2) A person or producer shall not charge a specific point-of-sale fee to consumers to recoup the costs of the product stewardship program, nor charge a specific point-of-collection fee at the time the unwanted drugs are collected from residential generators or delivered for disposal.

(3) A producer, group of producers, or stewardship organization shall pay all costs incurred by the State of Vermont, including the Department of Health, in the administration and enforcement of the product stewardship program. Other than fines and penalties, the State of Vermont shall recover only its actual costs for administration and enforcement pursuant to this chapter and shall not charge any amounts under this chapter in excess of the actual costs.

§ 4103. PRODUCT STEWARDSHIP PLAN

(a) Plan content. Each product stewardship program shall have a product stewardship plan that contains the following:

(1) Certification that the product stewardship program will accept all unwanted drugs regardless of who produced them.

(2) Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program.

(3) A description of the methods by which the product stewardship program will collect unwanted drugs from residential generators in all areas of Vermont and an explanation of how the collection system will be convenient to the public and adequate to meet the needs of all Vermont residents.

(4) The location of each collection site and locations where envelopes will be available for a mail-back program, if applicable.

(5) A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five years by each person that will be involved in transporting unwanted drugs and each medical waste or hazardous disposal facility proposed to participate in the product stewardship program.

(6) A description of how the unwanted drugs will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security.

(7) A description of the public education and outreach activities required under this chapter and how their effectiveness will be evaluated.

(8) A description of how the scope and extent of the product stewardship program are reasonable related to the amount of covered drugs sold in Vermont by the producer or group of producers.

(9) The date on which collection of unwanted drugs will begin.

(10) A description of how support will be provided to any law enforcement agencies in Vermont that have, or later agree to have, a collection program for regulated drugs, including:

(A) the provision of a collection kiosk with appropriate accessories and signage;

(B) the ability to accept regulated drugs and other covered drugs; and

(C) technical support, including an appropriate individual to provide on-site assistance with sorting and separating controlled substances at no cost to a participating law enforcement agency.

(11) A description of how collection sites for unwanted drugs may be placed at appropriate retail stores in Vermont, including a description of the

involvement of the retail store. Nothing in this chapter shall be construed to require retail stores to host collection sites.

(12) If more than one producer will be involved in a proposed product stewardship plan, a fair and responsible manner for allocating the costs of the program among its participants based on the relative amount of covered drugs each producer sells in this State.

(b) Department review and approval.

(1) No producer, group of producers, or stewardship organization shall begin collecting unwanted drugs in compliance with this chapter until it has received written approval of its product stewardship plan from the Department.

(2) Product stewardship plans shall be submitted to the Department for approval.

(3) Within 180 days following receipt and review of a product stewardship plan, the Department shall conduct a public hearing and shall determine whether the plan complies with the requirements of this chapter and any rules adopted pursuant to this chapter.

(A) As part of its approval, the Department may set reasonable performance goals for the program.

(B) If the Department approves a plan, it shall notify the applicant of its approval in writing.

(C) If the Department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan. The Department may reject a plan without conducting a public hearing.

(D) An applicant whose plan has been rejected shall submit a revised plan to the Department within 60 days after receiving notice of the rejection. The Department may require the submission of a further revised plan or, in its sole discretion, the Department may develop, approve, and impose its own product stewardship plan or an approved plan submitted by one or more other producers pursuant to this chapter. The imposed plan shall be presented at the public hearing. Nothing in this section shall be construed to require the Department to create or impose a product stewardship plan.

(E) If the Department rejects a product stewardship plan or any other subsequently revised plan, the producer or producers at issue shall be deemed to be out of compliance with this chapter and shall be subject to the enforcement provisions included under this chapter. If the Department imposes its plan or another plan, the producer or producers at issue shall not be considered out of compliance with this chapter if they comply with that plan, but shall be subject to the enforcement provisions relating to compliance with an approved plan.

(4) A producer, group of producers, or stewardship organization operating a product stewardship program shall update its product stewardship

plan at least once every three years and submit the updated plan to the Department for review and approval.

(5) A producer who begins to offer a covered drug for sale in this State on or after January 1, 2017 shall submit a product stewardship plan to the Department or provide evidence of having joined an existing approved product stewardship program within 180 days following the producer's initial offer for sale of a covered drug.

(6) Any proposed changes to a product stewardship plan shall be submitted to the Department in writing and approved by the Department in writing prior to implementation of any change.

§ 4104. DISPOSAL OF UNWANTED DRUGS

(a) Each product stewardship program shall comply with all State and federal laws, rules, and regulations applicable to its operations, including those governing the disposal of medical waste and controlled substances.

(b) Each product stewardship program shall dispose of all unwanted drugs by incineration at a medical waste or hazardous waste facility in possession of all required regulatory permits and licenses.

(c) Producers with product stewardship programs may request approval from the Department to use final disposal technologies, where lawful, that provide superior environmental and human health protection to that provided by current medical waste disposal technologies for covered drugs if and when

those technologies are proven and available. The proposed technology shall provide equivalent protection in each, and superior protection in one or more, of the following areas:

(1) monitoring of any emissions or waste;

(2) worker health and safety;

(3) air, water, or land emissions contributing to persistent, bioaccumulative, and toxic pollution; and

(4) overall impact on the environment and human health.

(d) Each product stewardship program shall encourage residential generators to separate unwanted drugs from their original containers, where appropriate, prior to collection or disposal.

§ 4105. OUTREACH AND EDUCATION

(a) A product stewardship program shall promote the program to residential generators, pharmacists, retailers of covered drugs, and health care providers as a safe and appropriate method to dispose of unwanted drugs.

(b) A product stewardship program's outreach and education activities shall include developing, and updating as necessary, educational and other outreach materials aimed at retailers of covered drugs. These materials may include:

(1) signage that is prominently displayed and easily visible to the consumer;

(2) written materials and templates of materials for reproduction by retailers to be provided to the consumer at the time of purchase or delivery, or both; and

(3) advertising or other promotional materials, or both, related to the product stewardship program.

(c) A product stewardship program shall prepare education and outreach materials that publicize the location and operation of collection locations across the State and shall disseminate the materials to health care facilities, pharmacies, and other interested parties. The program shall also establish a website publicizing collection locations and program operations and a toll-free telephone number that residential generators can call to find nearby collection locations and understand how the program works.

§ 4106. ANNUAL REPORT

On or before July 1, 2018, or at a later date as approved in writing by the Department of Health, and annually thereafter, each producer, group of producers, or product stewardship organization operating a product stewardship program shall prepare and submit to the Department an annual written report describing the programs activities during the preceding calendar year. The report shall include the following:

(1) a list of the producers participating in the product stewardship program;

(2) the amount, by weight, of unwanted drugs collected from residential generators at each drop-off site and statewide and, if applicable, the total amount by weight collected by a mail-back program;

(3) a description of the collection system, including the location of each drop-off site and, if applicable, locations where envelopes for a mail-back program are provided;

(4) the name and location of disposal facilities at which unwanted drugs were disposed of and the weight of unwanted drugs collected from residential generators that were disposed of at each facility;

(5) whether the policies and procedures set forth in the product stewardship plan for collecting, transporting, and disposing of unwanted drugs were followed during the reporting period and a description of any noncompliance;

(6) whether any safety or security problems occurred during collection, transportation, or disposal of unwanted products during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the program and to improve safety and security;

(7) a description of public outreach and education activities implemented during the reporting period, including the methodology used to evaluate those activities;

(8) the manner in which the product stewardship program complied with all other elements in the product stewardship plan approved by the Department, including its degree of success in meeting any performance goals set by the Department as part of its approval of the program; and

(9) any other information that the Department requires.

§ 4107. LIST OF PRODUCERS

The Department of Health shall provide on its website an updated list of all producers participating in product stewardship programs approved by the Department and a list of all producers the Department has identified as not in compliance with this chapter or any related rules.

§ 4108. RULES

The Commissioner of Health may adopt rules as needed to carry out the provisions of this chapter.

§ 4109. PENALTIES AND ENFORCEMENT

(a) The Department of Health shall administer the penalty provisions of this chapter.

(b) The Department of Health may issue a citation to a producer for a violation of this chapter or any rule adopted pursuant to this chapter. The Department shall first send a written warning to the producer with a copy of this chapter and any rules adopted pursuant to this chapter. The producer shall have 30 days after receipt of the warning to comply and correct any violations.

(c)(1) If the producer fails to comply and correct any violations, the Department may assess an administrative penalty of not more than $1,000.00 for each violation of this chapter or any rule adopted pursuant to this chapter. Each day shall constitute a separate violation.

(2) Any person in violation of this chapter or a rule adopted pursuant to this chapter shall be assessed a civil penalty of not more than $1,000.00 per day per violation. Each day in which the violation continues shall constitute a separate and distinct violation.

(3) In determining the appropriate amount of the penalty, the Department shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

(d) Any producer receiving a citation under to this chapter or any rule adopted pursuant to this chapter may appeal it to the State Board of Health pursuant to section 128 of this title within 30 days from the date the citation was issued. The request to appeal shall:

(1) be in writing;

(2) be accompanied by a deposit of the total fine amount and any fees noted on the citation;

(3) specify the basis for the appeal in detail;

(4) be postmarked within 30 days from the date the citation was issued; and

(5) be sent to the Board at the address set forth on the citation.

(e) Failure of any producer to file an appeal in accordance with this section shall constitute a waiver of that producer's right to an administrative determination of the merits of the citation and the amount of the fine and any fees and shall constitute a failure by that producer to exhaust administrative remedies.

(f) If any producer fails to comply with any requirement of this chapter or rule adopted pursuant to this chapter, the Attorney General may bring an action in the Washington County Superior Court for injunctive relief, payment of civil penalties, and any other appropriate remedy, including restraining the person from continuing any prohibited activity and compelling compliance with lawful requirements; provided that nothing in this subsection shall be construed to permit the State or the court to restrain the sale of any covered drug in this State.

(g) Any person who knowingly and willfully violates the requirements of this chapter or any rule adopted pursuant to this chapter shall be subject to a fine of not less than $50.00 nor more than $500.00 per day for each violation or to imprisonment for not more than six months, or both.

Sec. 3. FEE SCHEDULE

On or before December 1, 2016, the Department of Health shall provide to the General Assembly a proposed schedule of fees to be charged to producers of covered drugs to cover the State's costs of administering and enforcing the drug disposal programs established pursuant to 18 V.S.A. chapter 83.

Sec. 4. EFFECTIVE DATE

This act shall take effect on July 1, 2016, and shall apply to all producers offering covered drugs for sale in this State on and after January 1, 2017.