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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2020

A N A C T

RELATING TO FOOD AND DRUGS

Introduced By: Representatives Corvese, Canario, Vella-Wilkinson, Azzinaro, and Ucci

Date Introduced: January 16, 2020

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby amended by adding thereto the following chapter:

CHAPTER 38

DRUG TAKE BACK PROGRAM

21-38-1. Definitions.

As used in this chapter, unless the context clearly requires otherwise:

(1) "Authorized collector" means:

(i) A person, company, corporation or other entity that is registered with the United States Drug Enforcement Administration to collect controlled substances for the purposes of safe disposal and destruction;

(ii) A law enforcement agency; or

(iii) A person, company, corporation or other entity authorized by the department to provide alternative collection methods for covered drugs that are not controlled substances.

(2) "Covered drug" means any substance recognized as a drug under 21 USC § 321(g)(1), as amended, and any regulations promulgated thereunder that is sold, offered for sale or dispensed in the state, whether directly or through a wholesaler, in any form including prescription and nonprescription drugs, drugs in medical devices and combination products, brand and generic drugs and drugs for veterinary use; provided however, covered drug shall not include:

(i) Vitamins or supplements;

(ii) Herbal-based remedies and homeopathic drugs, products or remedies;

(iii) Cosmetics, soap (with or without germicidal agents), laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants or other personal care products that are regulated as both cosmetics and nonprescription drugs under the Federal Food, Drug, and Cosmetic Act;

(iv) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms;

(v) Drugs that are biological products as defined in § 5-19.1-2;

(vi) Drugs for which a manufacturer provides a take back program as part of a Federal Food and Drug Administration managed risk evaluation and mitigation strategy;

(vii) Emptied injector products or emptied medical devices and their component parts or accessories; and

(viii) Drugs that are used solely in a clinical setting.

(3) "Department" means the department of health.

(4) "Drug take back organization" means an organization designated by a manufacturer or a group of manufacturers to act as an agent on behalf of the manufacturer or group of manufacturers to operate and implement a drug take back program as authorized by this chapter.

(5) "Manufacturer" means a person, company, corporation or other entity engaged in the manufacture of covered drugs sold in the state and governed by chapter 19.1 of title 5. Manufacturer does not include a repackager or wholesaler.

(6) "Pharmacies" means all pharmacies governed by chapter 19.1 of title 5, and all nonresident pharmacies authorized by law to provide covered drugs to state residents by mail.

(7) "Wholesaler" means any person, company, corporation or other entity that sells or distributes drugs and covered drugs for resale to an entity in the state governed by chapter 19.1 of title 5, other than a consumer.

(8) "Repackager" means an entity that owns or operates an establishment that repacks and relabels a product or package containing a covered drug for further sale or for distribution without further transaction.

21-38-2. Drug take back program.

(a) Any manufacturer of a covered drug shall:

(1) Operate a drug take back program approved by the department individually or jointly with other manufacturers;

(2) Enter into an agreement with a drug take back organization which shall operate a drug

take back program approved by the department; or

(3) Enter into an agreement with the department to operate a drug take back program on its behalf.

(b) Any manufacturer of a covered drug, individually or jointly, or a drug take back organization contracted by a manufacturer of a covered drug shall within ninety (90) days from the effective date of this section submit to the department, in a manner and form established by the department, a proposed drug take back program that meets, at a minimum, the following requirements:

(1) Certifies the drug take back program will accept all covered drugs regardless of who produced them;

(2) Provides contact information for the person submitting the planned drug take back program with whom the department shall direct all inquiries;

(3) Details a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs pursuant § 21-38-3;

(4) Describes other collection methods by which covered drugs will be collected by authorized collectors;

(5) Explains how covered drugs will be safely and securely tracked and handled from collection through final disposal and destruction, policies to ensure security and compliance with all applicable laws and regulations, including disposal and destruction at a permitted waste disposal facility meeting federal requirements;

(6) Describes the public education and outreach activities that will be undertaken which shall include advertising of collection locations on a website and through use of signage and other written materials, and how effectiveness will be evaluated;

(7) Details how the costs of pharmacy collection and other authorized collectors will be reimbursed which shall include costs retroactive to the effective date of this chapter, and where more than one manufacturer will be involved in the planned drug take back program, a plan for the fair and reasonable manner of allocated costs among the participants in such program such that the costs paid by each manufacturer is reasonably related to the volume or value of covered drugs sold in the state; and

(8) Provides any further information deemed appropriate by the department.

(c) Within thirty (30) days of the effective date of this section, each wholesaler that sells covered drugs in or into the state shall provide the department with a list of manufacturers that produce covered drugs. The department may request updated lists at its discretion.

(d) A manufacturer, individually or jointly, must pay all administrative and operational

fees associated with the drug take back program, including the cost of collecting, transporting and disposing of covered drugs from pharmacies and other authorized collectors and the recycling or disposal, or both, of packing collected with the covered drug. Manufacturers shall also pay costs incurred by the state in the administration and enforcement of the drug take back program. Exclusive of fines and penalties, the state shall only recover its actual cost of administration and enforcement. In instances where manufacturers jointly conduct a drug take back program, the costs of administration and enforcement shall be fairly and reasonably allocated such that the portion of costs is reasonably related to the volume or value of covered drugs the manufacturers sell in the state. No manufacturer may charge a point-of-sale or other fee to consumers, or a fee that could be passed on to consumers, to recoup the cost of their drug take back program.

(e) Within sixty (60) days of receipt of a proposed drug take back program, the department, in consultation with the department of environmental management, shall determine whether such proposed drug take back program complies with the requirements of this chapter and notify the applicant. The department may conduct a noticed public hearing prior to approval. If the drug take back program is approved, the department shall notify the applicant in writing. If the drug take back program is not approved, the department shall notify the applicant in writing and the applicant shall submit a revised drug take back program proposal within thirty (30) days. If the department rejects the subsequent proposal, the manufacturer or manufacturers at issue shall be out of compliance with this chapter and subject to the enforcement provisions referenced in § 21-38-4. The department shall provide, and update annually, on its website a list of all manufacturers participating in a drug take back program approved by the department. At least every three (3) years, a manufacturer, jointly or individually, or a drug take back organization shall update its drug take back program and submit an updated proposal to the department for approval. A manufacturer who begins to offer a covered drug in the state after the effective date of this chapter, shall provide evidence of joining an existing approved drug take back program or submit a proposal for a drug take back program within ninety (90) days following the initial offer for sale of a covered drug. Any proposed change to a drug take back program shall be submitted in writing and approved by the department prior to any change. Each approved drug take back program shall report to the department at a date and manner set by the department. The department shall submit an annual report to the governor, speaker of the house of representatives and president of the senate by January 1 detailing all program activities, the weight collected by each program, a description of collection activities, the name and location of all collection sites, public education and outreach activities, an evaluation of the efficacy of the program and each collection method, and any manufacturer out of compliance or subject to penalties pursuant to §

21-38-4.

21-38-3. Collection.

(a) All pharmacies shall provide for the safe collection of drugs, which shall include:

(1) Offering drug collection by one or more of the following methods:

(i) On-site collection, dropbox, or receptacle meeting federal standards;

(ii) Mail-back collection by prepaid envelopes as authorized by federal law and regulation; or

(iii) Other federal drug enforcement agency approved methods of collection;

(2) Signage prominently displayed advertising such drug collection to consumers.

(b) All drug take back program operators shall notify other potential authorized collectors of the opportunity to serve as an authorized collector for the drug take back program. Participation of authorized collectors besides pharmacies shall be voluntary.

(c) All costs of pharmacies and other authorized collectors shall be paid or reimbursed by the manufacturer, jointly or individually, as part of the drug take back programs required by this chapter.

(d) Pharmacies providing for mail-back collection as part of the drug take back program shall provide a voucher for a prepaid envelope upon dispensing a covered drug. Such voucher shall include information on drug take back and safe drug disposal methods.

21-38-4. Violations.

Violation of this chapter shall be subject to a schedule of fines to be established by the department. Each day in which the violation continues shall constitute a separate violation.

21-38-5. Jurisdiction.

Jurisdiction of all matters pertaining to drug disposal by this chapter is vested exclusively in the state. Any provision of any local law or ordinance, or any rule or regulation promulgated prior to, or upon the effective date of this section, shall be preempted.

SECTION 2. This act shall take effect on January 1, 2021.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO FOOD AND DRUGS

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This act would mandate drug manufacturers to establish, fund, and manage a state-approved drug take back program for the safe collection and disposal of unused covered drugs. It would also provide consumers with pre-approved methods of collection and disposal, free of charge to the consumer and pharmacy.

This act would take effect on January 1, 2021.

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