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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. 2010

A N A C T

RELATING TO HEALTH AND SAFETY -- UNUSED PHARMACEUTICAL DISPOSAL PROGRAM

Introduced By: Senators Blais, and Maher

Date Introduced: February 11, 2010

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

SECTION 1. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby amended by adding thereto the following chapter:

CHAPTER 25.5

DISPOSAL OF UNWANTED DRUGS

23-25.5-1. Disposal of unwanted drugs. -- After January 1, 2011, a manufacturer shall participate in a program for the disposal of unwanted drugs in accordance with this section.

23-25.5-2. Definitions. – As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings:

(1) "Covered drug" means any drug included in a manufacturer's program.

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

(3) "Drug" means:

(i) An article recognized in the United States Pharmacopoeia and National Formulary or the Homeopathic Pharmacopoeia of the United States or any supplement of those pharmacopoeias;

(ii) A substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals;

(iii) A substance, other than food, intended to affect the structure or any function of the body of humans or animals; or

(iv) A substance intended for use as a component of any substances specified in subparagraph (i), (ii) or (iii), but not including medical devices or their component parts or accessories.

"Drug" includes all prescription drugs and nonprescription over-the-counter drugs and veterinary drugs in any form, including pill, tablet, capsule, suppository, liquid, cream, ointment, lotion, transdermal patch, powder or aerosol form and both name brand and generic drugs but does not include vitamins or herbal-based remedies.

(4) "Manufacturer" means a person or entity that:

(i) Manufactures a covered drug or has legal ownership of the brand, brand name or co-brand under which a covered drug is sold; or

(ii) Imports a covered drug manufactured by a person or entity that has no physical presence in the United States; or

(iii) Sells at wholesale or retail a covered drug and does not have legal ownership of the brand or brand name, but that elects to fulfill the manufacturer's responsibilities for that covered drug.

(5) "Reporting period" means a calendar year.

(6) "Residential source" includes single-family and multiple-family residences and locations where unwanted drugs may be found such as hospice facilities, nursing homes, boarding homes, schools, foster care facilities, day care facilities and other locations where either people or their pet animals, or both, reside on a temporary or permanent basis. "Residential source" does not include a pharmacy or a business or any other nonresidential source identified by the department.

(7) "Unwanted drug" means any covered drug from a residential source that its owner no longer wants or that has been abandoned or discarded or is intended to be discarded by the owner.

23-25.5-3. Manufacturer responsibility. -- A manufacturer of covered drugs sold in the State shall participate in a program with other manufacturers of covered drugs, unless approved by the department to operate an independent program. The manufacturer shall:

(1) Except as otherwise provided in this subsection, submit to the department the manufacturer's proposed program to operate and finance the collection, transportation and recycling or disposal of unwanted drugs either independently or in conjunction with other manufacturers;

(2) Pay all the administrative and operational costs associated with implementation of the program, including the cost of the collection, transportation, management and disposal of the unwanted drugs that are collected from residential sources and the recycling or disposal of the

related packaging;

(3) Implement the program without charging a fee at the time of sale of the covered drugs or at the time the unwanted drugs are delivered or collected for disposal from residential sources; and

(4) Operate the program as approved by the department and in accordance with this subsection and other applicable state and federal laws.

The department may approve an independent program only if it meets all requirements of this section and accepts covered drugs from any manufacturer.

After January 1, 2011, a manufacturer new to the state shall submit a proposed program to the department or join an approved program prior to initiating sales in the state.

23-25.5-4. Program requirements. – The program required under section 2 must include at a minimum:

(1) A list of all manufacturers participating in the collection, handling and disposal proposed in the program and the manufacturers' contact information;

(2) Performance goals, including recovery goals for the first, 2nd and 3rd years of the program, expressed as pounds of unwanted drugs disposed of per capita and an explanation of how the recovery goals have been set to recover a significant percentage of unwanted drugs from residential sources relative to the quantity of unwanted drugs that may be available for disposal;

(3) A description of a proposed collection system that, at a minimum, must include the use of prepaid mailing envelopes addressed to the department, unless other collection methods are approved by the United States Drug Enforcement Agency. The collection system must be convenient and adequate to serve the needs of residents in both urban and rural areas; and

(4) A handling and disposal system, including:

(i) Identification of and contact information for hazardous waste disposal facilities and other entities to be used by the program to collect and destroy the unwanted drugs;

(ii) The policies and procedures to be followed by persons in charge of unwanted drugs collected pursuant to the program;

(iii) A description of how the collected unwanted drugs are tracked through to final disposal and how safety and security is maintained; and

(iv) A description of the public education effort and communications strategy as required in section 5.

23-25.5-5. Program review and approval. – A program submitted to the department pursuant to section 23-25.5-3 must be approved by the department, with concurrence of the agency, before a manufacturer may engage in the collection of unwanted drugs from residential

sources within the state. A manufacturer shall implement the program within three (3) months of the program's approval unless the department approves an extension of the implementation date.

(1) The department shall review each program in consultation with the agency.

(2) The department shall determine whether a program complies with this chapter. If the department is satisfied that a program complies, the department shall issue an approval. If a program is rejected, the department shall provide the applicant with the reasons in writing for rejecting the program. The department may also approve the program with modifications.

(3) A manufacturer or the manufacturer's agent operating an approved program may not make any substantive changes to the program without obtaining the department's prior written approval of the proposed changes, except that:

(i) Additions and changes to the list of hazardous waste facilities and other entities under contract for drug collection or destruction may be made without the department's or agency's prior written approval. The manufacturer or manufacturer's agent responsible for implementing the program must inform the department and agency of such an addition or change fifteen (15) days prior to the effective date of the addition or change. If there is no objection by the department or agency, the manufacturer may implement the addition or change; and

(ii) Additional manufacturers may participate in an approved program without the department's and agency's prior written approval. The manufacturer or manufacturer's agent responsible for implementing the program must provide the department with an updated manufacturer participant list within fifteen (15) days after a manufacturer begins participation in the program.

(4) If the department or agency determines that a program is not being operated in accordance with this section and rules adopted to implement this section, or if the department or agency determines that there is an imminent danger to the public, the department or agency may:

(i) Amend the approval of the program by clarifying terms or conditions to ensure full implementation of the program; or

(ii) Suspend or cancel the approval of the program.

At least fifteen (15) days prior to amending, suspending or canceling an approval, the department shall inform the manufacturer or the manufacturer's agent operating the program of the action and provide the manufacturer or the manufacturer's agent an opportunity to respond.

(5) Notwithstanding section 5, if the department or agency determines that it is necessary in order to protect the public from imminent danger, the department or agency may immediately amend, suspend or cancel an approval without giving the manufacturer or the manufacturer's agent operating the program an opportunity to be heard, but must give that manufacturer or the

manufacturer's agent an opportunity to be heard within fifteen (15) days after the date on which the department or agency takes any of those actions.

23-25.5-6. Education and outreach. – A manufacturer must:

(1) Promote the use of a program and the proper disposal of unwanted drugs so that collection options are widely understood by customers, pharmacists, retailers of covered drugs and health care practitioners including doctors and other prescribers;

(2) Establish a toll-free telephone number and publicly accessible website where collection options are made available; and

(3) Provide educational and outreach materials describing where and how to return unwanted drugs. These materials must be provided to pharmacies, health care facilities and other interested parties at no cost.

Pharmacies must make available to their customers the educational information and prepaid mailing envelopes supplied by the manufacturer or manufacturer's agent pursuant to subsection 3, paragraph C for unwanted drug collection.

23-25.5-7. Progress reports. – By February 1, 2012, and by February 1st of each subsequent year, every manufacturer or manufacturer's agent who operates a program approved under this section shall submit to the department and agency a written annual report, in a format prescribed by the department, covering the previous reporting period. The report must include:

(1) A list of manufacturers participating in a program;

(2) The amount, by weight, of unwanted drugs collected from residential sources;

(3) Documentation verifying collection and disposal of the unwanted drugs;

(4) The hazardous waste disposal facilities used, the location of those facilities and the weight of unwanted drugs collected from residential sources and disposed of at each facility;

(5) Whether policies and procedures for transporting and disposing of unwanted drugs, as established in the program, were followed during the reporting period and a description of noncompliance with those policies and procedures, if any;

(6) Whether any safety or security problems occurred during collection, transportation or disposal of unwanted drugs during the reporting period and, if so, what changes are proposed for policies, procedures or tracking mechanisms to improve safety and security in the future;

(7) A description of the public education effort and communication strategy under section 5 implemented during the reporting period;

(8) A description of research, if any, regarding disposal techniques that provides superior protection to human health and the environment beyond that provided by current hazardous waste disposal techniques;

(9) How the program met the performance standards and recovery rates as established in the program or set by the department and agency and, if the program did not meet those performance standards and recovery rates, what actions the manufacturer will take to alter the program to meet the performance standards and recovery rates; and

(10) Any other information that the department and agency may reasonably require.

23-25.5-8. Drug disposal -- rules. – A manufacturer's program must provide for the disposal of all unwanted drugs from residential sources at a hazardous waste incinerator licensed by the department. The department may adopt rules concerning approval of new disposal technology providing that a manufacturer may petition the department for, and the department may grant approval to use, a disposal technology that provides superior environmental and human health protection to that provider by a current hazardous waste disposal technology for drugs if that technology is proven and available. The proposed technology must provide equivalent protection in each, and superior protection in one or more, of:

(1) The 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) The overall environment and human health.

23-25.5-9. Performance standards. – By June 2014, the department shall establish mandated performance standards and recovery rates for the fourth (4^{th}) and subsequent program years. The department may require a manufacturer that does not meet the mandated standards and rates to modify the manufacturer's program in order to achieve performance standards and improve recovery rates. Plan modifications require the department's approval before they may be implemented.

23-25.5-10. Fines and penalties. – After January 1, 2011, a manufacturer of a covered drug that is not in compliance with this section is subject to civil penalties of one hundred dollars ($100) for each day of non-compliance. By June 1, 2010 the department shall list on its publicly accessible website manufacturers that are participating in an approved program and manufacturers that have been identified as being non-compliant with this section. All penalties and fines collected for violations of this chapter must be deposited into the Unused Pharmaceutical Disposal Program Fund, established under chapter 23-25.5.

23-25.5-11. Report to the Legislature. – By March 15, 2012 and by March 15th annually thereafter, the department, in consultation with the agency, shall report to the committees of the general assembly having jurisdiction over health matters and environmental

matters concerning the status of a program established pursuant to this section and shall recommend such modifications to the program as the department may determine necessary or appropriate.

23-25.5-12. Rules. – The department may establish rules to implement this section.

23-25.5-13. Unused Pharmaceutical Disposal Program Fund -- funding. – The Unused Pharmaceutical Disposal Program Fund, referred to in this chapter as "the fund," is established within the department to be used by the director of the department to fund or assist in funding the program. Any balance in the fund does not lapse but is carried forward to be expended for the same purposes in succeeding fiscal years. The fund must be deposited with and maintained and administered by the department. The department may accept funds into the fund from any non-general fund source, including grants or contributions of money or other things of value, that it determines necessary to carry out the purposes of this chapter. Money received by the department to establish and maintain the program must be used for the expenses of administering this chapter.

SECTION 2. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO HEALTH AND SAFETY -- UNUSED PHARMACEUTICAL DISPOSAL PROGRAM

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This act establishes a system to collect and safely dispose of unwanted drugs from households and other residential sources.

This act would take effect upon passage.

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