An Act To Support Collection and Proper Disposal of Unwanted Drugs

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §2700, sub-§8 is enacted to read:

8. Drug take-back stewardship program participation. Nothing in this section prohibits a law enforcement agency from participating as an authorized collector in a drug take-back stewardship program implemented under Title 38, section 1611.

Sec. 2. 38 MRSA §1611 is enacted to read:

§ 1611. Drug take-back stewardship program

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Authorized collector" means:

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

(2) A law enforcement agency; or

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

B. "Brand" means a name, symbol, word or mark that identifies a covered drug, rather than its components, and attributes a covered drug to the owner of the brand.

C. "Closed-shop pharmacy" means a pharmacy that purchases drugs for and dispenses drugs to a limited, institutional patient population.

D. "Covered drug" means any substance recognized as a drug under 21 United States Code, Section 321(g)(1), as amended, and any regulations adopted pursuant to that provision 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.

(1) "Covered drug" does not include:

(a) Vitamins or supplements;

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

(c) Cosmetics, soap with or without germicidal agents, 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;

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

(e) Drugs that are biological products as defined in 21 Code of Federal Regulations, Section 600.3(h) if the manufacturer provides a program to take back that drug;

(f) Drugs for which a manufacturer provides a program to take back those drugs as part of a United States Department of Health and Human Services, Food and Drug Administration managed risk evaluation and mitigation strategy;

(g) Emptied syringes or emptied medical devices or the component parts or accessories of those products or devices; and

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

E. "Drug take-back stewardship organization" or "stewardship organization" means a corporation, nonprofit organization or other legal entity created by one or more manufacturers to implement a drug take-back stewardship program.

F. "Drug take-back stewardship plan" or "plan" means a plan designed by a manufacturer or drug take-back stewardship organization for the establishment of a drug take-back stewardship program.

G. "Drug take-back stewardship program" or "stewardship program" means a system implemented for the collection, transportation and disposal of covered drugs in accordance with a drug take-back stewardship plan approved by the department under subsection 4.

H. "Mandatory pharmacy collector" means a pharmacy registered with the Maine Board of Pharmacy that is part of a group of 10 or more establishments that conduct business under the same name or operate under a common ownership or management or pursuant to a franchise agreement

with the same franchisor and a nonresident pharmacy registered with the Maine Board of Pharmacy that provides covered drugs to residents in the State by mail. "Mandatory pharmacy collector" does not include a closed-shop pharmacy.

I. "Manufacturer" means an entity that:

(1) Has legal ownership of the brand of a covered drug sold in or into the State;

(2) Imports a covered drug branded by a person that meets the requirements of subparagraph (1) and has no physical presence in the United States; or

(3) Sells a covered drug in the State at wholesale or retail, does not have legal ownership of the brand of the covered drug and elects to fulfill the responsibilities of the manufacturer for that covered drug.

J. "Operator" means a manufacturer or drug take-back stewardship organization that implements and operates a drug take-back stewardship program.

2. Drug take-back stewardship program. A manufacturer shall:

A. Individually or jointly with one or more manufacturers, operate a drug take-back stewardship program approved by the department;

B. Enter into an agreement with a drug take-back stewardship organization to operate a drug take-back stewardship program; or

C. Enter into an agreement with the department to operate a drug take-back stewardship program on behalf of the manufacturer.

3. Submittal of drug take-back stewardship plan. A manufacturer, individually or jointly with one or more manufacturers, or a drug take-back stewardship organization contracted by one or more manufacturers shall submit to the department a proposed drug take-back stewardship plan. The plan must, at a minimum, include:

A. A certification that the drug take-back stewardship program will accept all covered drugs regardless of who produced them;

B. Contact information for the person submitting the drug take-back stewardship plan with whom the department shall direct all inquiries related to the plan and a listing of participating manufacturers with contact information for each participating manufacturer;

C. A description of how the drug take-back stewardship program will provide free, convenient and ongoing collection of covered drugs to all persons seeking to dispose of covered drugs and how the collection will be geographically distributed in a way to ensure access in rural and underserved areas based on the use of geographic information modeling;

D. A description of the collection methods to be used to ensure that covered drugs will be collected by authorized collectors;

E. A listing of authorized collectors and collection sites;

F. Information on how covered drugs will be safely and securely tracked and handled from collection through final disposition and policies to ensure security and compliance with all applicable federal and state laws, rules and regulations including, but not limited to, 21 Code of Federal Regulations, Section 1317.90, which requires disposal and destruction at a licensed waste disposal facility that renders drugs nonretrievable;

G. A description of how the collection system will be designed and monitored to prevent tampering;

H. A description of how the amount of covered drugs collected and disposed of will be measured;

I. A description of the education and outreach materials that will be used to encourage consumer participation, including, but not limited to, messaging that is understood by a diverse audience, a publicly accessible website with information for both authorized collectors and consumers about the drug take-back stewardship program and printed materials for collection sites including brochures and signage. The education and outreach efforts must ensure that 60% of consumers are aware of the stewardship program after one year of stewardship program implementation, 70% after 2 years and 90% after 4 years;

J. A description of the performance goals established to measure the success of the drug take-back stewardship program and a description of how the stewardship program will be designed to meet or exceed those goals; and

K. Information on how the drug take-back stewardship program will be financed in accordance with subsection 5.

4. Approval of drug take-back stewardship plan. Within 20 business days after receipt of a proposed drug take-back stewardship plan under subsection 3, the department shall review the plan and approve, approve with conditions or deny the plan. The department shall notify the submitter in writing of the department's determination and, if the plan is approved with conditions or denied, the notification must include the reasons for the determination.

A. A manufacturer or drug take-back stewardship organization whose drug take-back stewardship plan is denied shall submit a revised plan to the department within 60 days after receiving a notice of denial. If the department denies the subsequent proposal, the manufacturer or manufacturers participating in the proposed drug take-back stewardship program are out of compliance with this section and subject to the enforcement provisions under this section. The department may hold a public hearing prior to making a decision to approve, approve with conditions or deny a proposed plan.

B. A manufacturer who begins to offer a covered drug in the State after the effective date of this section shall provide to the department evidence of joining an existing drug take-back stewardship program or submit a proposed drug take-back stewardship plan within 30 days after the manufacturer's initial offer for sale of a covered drug.

C. Prior to implementing a change to an approved drug take-back stewardship plan, an operator shall submit the proposed change to the department for review. If a change is not substantive, such as the addition of or a change to a collection site or the addition of a manufacturer to the drug take-back stewardship program, approval by the department is not needed, but the operator shall inform the department of the change within 14 days of implementing the change. The department shall review plan amendments in accordance with this section.

D. At any time, the department may require changes to a drug take-back stewardship plan or implementation of a plan to meet the requirements of this subsection.

5. Costs. A manufacturer, individually or jointly with one or more manufacturers, shall pay all administrative and operational costs associated with the manufacturer's drug take-back stewardship program, including, but not limited to:

A. The cost of collecting covered drugs from mandatory pharmacy collectors and authorized collectors, transporting covered drugs to disposal locations and disposing of covered drugs;

B. Costs related to working with authorized collectors to develop a readily recognizable, consistent design of collection receptacles, as well as clear, standardized instructions for consumers on the use of collection receptacles. The department may provide guidance to manufacturers on the development of the instructions and design;

C. Costs incurred by the State in the administration and enforcement of the drug take-back stewardship program; and

D. All costs associated with drug take-back stewardship program effectiveness and assessments under this section.

When more than one manufacturer participates in a drug take-back stewardship program, the costs of administration and enforcement must be fairly and reasonably allocated so that the portion of costs allocated to each manufacturer is reasonably related to the market share of covered drugs that manufacturer sells in the State.

Disposal of a covered drug under a drug take-back stewardship program must be free to consumers. A manufacturer may not charge a point-of-sale fee to consumers, or a fee that could be passed on to consumers, to recoup the cost of implementing the stewardship program.

6. Confidential information. Proprietary information submitted to the department in a drug take-back stewardship plan, in an amendment to a plan or pursuant to reporting requirements of this section that is identified by the submitter as proprietary information is confidential and must be handled

by the department in the same manner as confidential information is handled under section 1310-B. As used in this subsection, "proprietary information" means information that is a trade secret or production, commercial or financial information the disclosure of which would impair the competitive position of the submitter and would make available information not otherwise publicly available.

7. Audit. The department may require an operator to submit an independent financial audit of a drug take-back stewardship program.

8. Collection. This subsection applies to authorized collectors, mandatory pharmacy collectors and collection sites.

A. A mandatory pharmacy collector shall participate in each drug take-back stewardship program. A mandatory pharmacy collector shall prominently display signage advertising covered drug collection to consumers and provide for the safe collection of covered drugs through:

(1) On-site, publicly accessible and secure collection receptacles meeting federal standards;

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

(3) Other methods of collection approved by the United States Department of Justice, Drug Enforcement Administration.

B. An operator shall notify all authorized collectors of the opportunity to serve as a collection site for the drug take-back stewardship program. Except for mandatory pharmacy collectors, participation of an authorized collector is voluntary.

C. A drug take-back stewardship program must include as a collection site each retail pharmacy and hospital or clinic with an on-site pharmacy and each law enforcement agency that volunteers to participate in the stewardship program without compensation and is an authorized collector. An operator shall add the pharmacy, hospital, clinic or law enforcement agency as a collection site in the stewardship program no later than 90 days after the operator receives the offer to participate.

D. Mandatory pharmacy collectors and authorized collectors for a drug take-back stewardship program shall provide information on covered drug collection and safe drug disposal options to a consumer upon dispensing a covered drug.

E. As part of a drug take-back stewardship program, all collection requirements of mandatory pharmacy collectors and authorized collectors, including, but not limited to, collection receptacles, mail-back envelopes, educational materials and drug-disposal-specific surveillance, must be provided by the operator free of charge to the collectors.

9. Third-party outreach assessment. Every 2 years, a drug take-back stewardship organization shall fund a 3rd-party assessment of the effectiveness of education and outreach efforts under the drug take-back stewardship program. The methods and scope of the assessment must include input by the department. The stewardship organization shall make changes to the education and outreach efforts based on the results of the assessment.

10. Annual drug take-back stewardship program report. Within 90 days after the first full year of implementation, and annually thereafter, an operator shall submit to the department a report describing the implementation of the drug take-back stewardship program during the previous calendar year. The report must include at a minimum:

A. A list of manufacturers participating in the drug take-back stewardship program, including current contact information;

B. The amount by weight of covered drugs collected, including the amount by weight from each collection method used, both in total and by county;

C. Details regarding the drug take-back stewardship program's collection system, including a list of collection sites with addresses; the number of mail-back envelopes provided; locations where mail-back envelopes were provided, if applicable; dates and locations of collection events held, if applicable; and the transporters and disposal facility or facilities used;

D. Whether any safety or security problems occurred during collection, transportation or disposal of covered drugs and, if so, completed and anticipated changes to policies, procedures or tracking mechanisms to address the problem and improve safety and security;

E. A description of the public education, outreach and evaluation activities implemented to ensure that 60% of consumers are aware of the drug take-back stewardship program after one year of stewardship program implementation, 70% after 2 years, and 90% after 4 years in accordance with subsection 3, paragraph I. In order to evaluate whether the consumer awareness goals are reached, every 2 years the report must include the results of an assessment of the methods used for and effectiveness of education and outreach efforts pursuant to subsection 9;

F. A description of how collected packaging was recycled to the extent feasible;

G. A description of the methods used to collect, transport and dispose of covered drugs;

H. A summary of the drug take-back stewardship program's degree of success in meeting goals for diversion rates, if applicable, and, if any goals have not been met, what effort will be made to achieve those goals the following year;

I. An evaluation of the convenience of collection for people living in various regions of the State;

J. The total cost of implementing the drug take-back stewardship program, including, but not limited to, the stewardship program's annual expenditures, as determined by an independent financial audit; and

K. Any recommendations for changes to the drug take-back stewardship program to improve convenience of collection, consumer education and stewardship program evaluation.

11. Administration. The department shall charge a reasonable fee to be paid by a manufacturer or drug take-back stewardship organization for review of a drug take-back stewardship plan. The department may establish a reasonable annual fee to cover the actual costs for annual report review, oversight, administration and enforcement. Fees established pursuant to this subsection may not exceed the greater of $100,000 per year and one percent of total drug take-back stewardship program costs as set forth in the independent financial auditing report under subsection 10, paragraph J.

12. Private right of action. A manufacturer or a drug take-back stewardship organization implementing an approved drug take-back stewardship plan in compliance with the requirements of this section may bring a civil action against another manufacturer or stewardship organization for damages when:

A. The plaintiff manufacturer or drug take-back stewardship organization incurs more than $3,000 in actual direct costs in collecting, handling or disposing of covered drugs sold or offered for sale in the State by another manufacturer;

B. The manufacturer from whom damages are sought can be identified as the manufacturer of the collected covered drugs from a brand or marking on the discarded covered drug or from other information available to the plaintiff manufacturer or drug take-back stewardship organization and does not operate a drug take-back stewardship program in the State;

C. The plaintiff manufacturer or drug take-back stewardship organization submitted a reimbursement request to another manufacturer or stewardship organization; and

D. The plaintiff manufacturer did not receive reimbursement within:

(1) Sixty days after the request for reimbursement under paragraph C, if the plaintiff manufacturer or drug take-back stewardship organization did not request an independent audit under subparagraph (2); or

(2) Thirty days after completion of an audit, if the plaintiff manufacturer or drug take-back stewardship organization requested an independent audit and the audit confirmed the validity of the reimbursement request.

A civil action under this subsection may be brought against an individual manufacturer only if that manufacturer is individually implementing its own drug take-back stewardship program. A manufacturer participating in a stewardship program covering multiple manufacturers may not be sued individually for reimbursement. An action against a manufacturer participating in a stewardship program covering multiple manufacturers must be brought against the drug take-back stewardship organization implementing the stewardship program.

As used in this subsection, "damages" means the actual, direct costs a plaintiff manufacturer incurs in collecting, handling and disposing of covered drugs reasonably identified as having originated from a noncompliant manufacturer; punitive or exemplary damages not exceeding 3 times the costs incurred under this section; and the prevailing plaintiff manufacturer's attorney's fees and costs of bringing the action.

13. Violations. A manufacturer that is not in compliance with this section is subject to civil penalties under section 349. The department shall list on its publicly accessible website manufacturers that are participating in an approved drug take-back stewardship program and manufacturers that have been identified as being noncompliant with this section. Each day in which a violation continues is a separate violation.

14. Report to the Legislature. The department, as a part of an annual product stewardship report under section 1772, shall report to the joint standing committee of the Legislature having jurisdiction over natural resources matters on the status of drug take-back stewardship programs established pursuant to this section and shall recommend modifications to the laws governing drug take-back stewardship programs the department determines necessary or appropriate. The joint standing committee may report out a bill based on the recommendations.

15. Rules. The department shall adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 3. Submittal of drug take-back stewardship plan. Within 180 days after the effective date of this Act, a manufacturer of a covered drug under the Maine Revised Statutes, Title 38, section 1611, individually or jointly with one or more manufacturers, or a drug take-back organization contracted by one or more manufacturers shall submit to the Department of Environmental Protection a proposed drug take-back stewardship plan that meets, at a minimum, the requirements of Title 38, section 1611, subsection 3.

SUMMARY

This bill provides for the establishment of drug take-back stewardship programs. It requires certain drug manufacturers, as defined in the bill, to operate a drug take-back stewardship program to collect and dispose of certain drugs.