State of Minnesota

HOUSE OF REPRESENTATIVES

EIGHTY-SIXTH SESSION

HOUSE FILE NO. 1217

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Authored by Gardner, Bigham, Knuth, Sailer and Loeffler
The bill was read for the first time and referred to the Committee on Environment Policy and Oversight

A bill for an act

relating to solid waste; requiring a product stewardship program operated by drug producers to collect and dispose of unwanted drugs; providing civil penalties; creating an account; proposing coding for new law in Minnesota Statutes, chapter 115A.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[115A.1410] TITLE.**

This act may be cited as the Minnesota Safe Drug Disposal Act of 2009.

Sec. 2. **[115A.1411] DEFINITIONS.**

Subdivision 1. **Scope.** For the purposes of sections 115A.1410 to 115A.1419, the following terms have the meanings given.

Subd. 2. **Covered product.** "Covered product" means all prescription drugs and all nonprescription drugs, including both brand name and generic drugs.

Subd. 3. **Drug wholesaler.** "Drug wholesaler" means a business that sells or distributes drugs for resale to an entity other than a consumer.

Subd. 4. **Drugs.** "Drugs" means:

(1) articles recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias;

(2) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(3) substances, other than food, intended to affect the structure or any function of the body of humans or other animals; or

(4) substances intended for use as a component of any substances specified in this subdivision, but not including medical devices or their component parts or accessories.

Subd. 5. **Entity.** "Entity" means a person other than an individual.

Subd. 6. **Generic drug.** "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.

Subd. 7. **Mail-back program.** "Mail-back program" means a system whereby residential generators of unwanted products obtain prepaid and preaddressed mailing envelopes in which to place unwanted products for shipment to an entity that will dispose of them safely and legally.

Subd. 8. **Nonprescription drug.** "Nonprescription drug" means any drug that may be lawfully sold without a prescription.

Subd. 9. **Person.** "Person" means an individual, firm, sole proprietorship, corporation, limited liability company, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal entity, however organized.

Subd. 10. **Plan.** "Plan" means a product stewardship plan required under section 115A.1413 that describes the manner in which a product stewardship program will be provided.

Subd. 11. **Prescription drug.** "Prescription drug" has the meaning given in section 151.44, paragraph (d).

Subd. 12. **Producer.** (a) "Producer" means a person who has legal ownership of the brand, brand name, or co-brand of a covered product or manufactures a generic covered product sold in Minnesota.

(b) Producer does not include a retailer who:

(1) puts its store label on a covered product;

(2) imports a covered product branded or manufactured by a producer who meets the requirements of paragraph (a) and who has no physical presence in the United States; or

(3) sells at wholesale a covered product, does not have legal ownership of the brand, and elects to fulfill the responsibilities of the producer for that product.

Subd. 13. **Product stewardship program.** "Product stewardship program" means a program financed and operated by producers to collect, transport, and recycle unwanted products.

Subd. 14. **Residential generators.** "Residential generators" means single and multiple family residences and locations where household drugs are unused, unwanted, disposed of, or abandoned, such as hospice services, nursing homes, boarding care homes,

schools, foster care, day care, and other locations where people, pets, or both reside on a temporary or permanent basis. Residential generators do not include airport security, drug seizures by law enforcement, pharmacy waste, business waste, or any other source identified by the agency as a nonresidential source.

Subd. 15. **Stewardship organization.** "Stewardship organization" means an organization designated by a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

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

Sec. 3. **[115A.1412] PRODUCT STEWARDSHIP PROGRAM.**

Subdivision 1. **Requirement for sale.** On and after January 1, 2012, no producer or drug wholesaler may sell or offer for sale covered products in this state unless the producer of the covered products participates in a product stewardship program to collect and dispose of unwanted products from residential generators. Each producer must:

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

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

Subd. 2. **Product stewardship program costs.** (a) A producer, group of producers, or stewardship organization must pay all administrative and operational costs associated with their product stewardship program, including the cost of collecting, transporting, and disposing of unwanted products collected from residential generators and the recycling or disposal, or both, of packaging collected with the unwanted product.

(b) No fee may be charged to cover the costs of a product stewardship program at the time of sale of the covered product or when unwanted products are collected from residential generators or delivered for disposal.

Sec. 4. **[115A.1413] PRODUCT STEWARDSHIP PLAN.**

Subdivision 1. **Plan content.** A product stewardship plan must contain the following:

(1) certification that the product stewardship program will accept all unwanted products regardless of who produced them;

(2) contact information for the individual and the entity submitting the plan and for all producers participating in the product stewardship program;

(3) a description of the methods by which unwanted products from residential generators will be collected in all counties in the state, including the location of each collection site and locations where envelopes for a mail-back program are available, and an explanation of how the collection system will be convenient and adequate to serve the needs of residents in both urban and rural areas;

(4) 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 transporter and each hazardous waste disposal facility proposed to participate in the product stewardship program;

(5) a description of how the unwanted products will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;

(6) a description of the public education effort and outreach activities required under section 115A.1415 and how their effectiveness will be evaluated; and

(7) a starting date when collection of unwanted products will begin.

Subd. 2. **Agency review and approval; updates.** (a) No producer, group of producers, or stewardship organization may begin collecting unwanted products until it has received written approval of its product stewardship plan from the agency.

(b) Product stewardship plans must be submitted to the agency for approval. The initial plans must be submitted by January 1, 2011. The agency may consult with other state agencies regarding the plan.

(c) Within 90 days after receipt of a plan, the agency shall determine whether the plan complies with sections 115A.1410 to 115A.1419. If it approves a plan, the agency shall notify the applicant of its approval in writing. If it rejects a plan, the agency shall notify the applicant in writing of its reasons for rejecting the plan. An applicant whose plan has been rejected by the agency must submit a revised plan to the agency within 60 days after receiving notice of the rejection.

(d) At least every four years, a producer, group of producers, or stewardship organization operating a product stewardship program must update its product stewardship plan and submit the updated plan to the agency for review and approval.

(e) A producer who begins to offer covered products for sale in Minnesota after January 1, 2011, must submit a product stewardship plan to the agency or provide evidence of having joined an existing approved plan at least 90 days prior to the producer's initial offer of sale of covered products.

(f) Any proposed changes to a product stewardship plan must be approved by the agency in writing.

Sec. 5. **[115A.1414] DISPOSAL OF UNWANTED PRODUCTS.**

Subdivision 1. **Disposal at hazardous waste facility.** Each product stewardship program must dispose of all unwanted products from residential generators at a hazardous waste facility. Unwanted products from residential generators otherwise retain all other generator exemptions for household hazardous waste. The hazardous waste facility must be:

(1) in possession of a valid permit from the agency;

(2) authorized to manage hazardous waste by another state with a hazardous waste program approved by the United States Environmental Protection Agency; or

(3) authorized under interim status or permitted by the United States Environmental Protection Agency.

Subd. 2. **Alternative disposal technologies.** Product stewardship programs may petition the agency for approval to use final disposal technologies that provide superior environmental and human health protection compared with current hazardous waste disposal technologies for drugs. The agency may not approve the use of an alternative proposed technology unless the petitioners have presented clear and convincing evidence that the technology's performance under field conditions provides equivalent protection in each, and superior protection in one or more, of the following areas:

(1) monitoring 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 to the environment and human health.

Subd. 3. **Packaging separation.** Each product stewardship program is encouraged to separate unwanted products from their original containers, when appropriate, prior to collection or disposal.

Sec. 6. **[115A.1415] PRODUCT STEWARDSHIP PROGRAM PROMOTION AND OUTREACH.**

(a) A product stewardship program must promote the program to residential generators, pharmacists, retailers of covered products, and health care practitioners as the proper and safe method to dispose of unwanted drugs.

(b) A product stewardship program must prepare education and outreach materials that publicize the location and operation of collection locations throughout the state and disseminate them to health care facilities, pharmacies, and other interested parties. The program must also establish a Web site 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.

Sec. 7. **[115A.1416] REPORT.**

On or before June 30, 2013, and in each subsequent year, every producer, group of producers, or stewardship organization operating a product stewardship program must prepare and submit to the agency an annual report describing the program's activities during the previous reporting period. The report must include the following:

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

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

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

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

(5) if packaging was separated from the unwanted product prior to disposal of the unwanted product, the amount and percentage of packaging recycled and the name and location of the material recovery facility to which it was delivered;

(6) whether policies and procedures for collecting, transporting, and disposing of unwanted products, as established in the plan, were followed during the reporting period and a description of any noncompliance;

(7) 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 problem and to improve safety and security;

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

(9) how the product stewardship program complied with any other elements in the plan approved by the agency; and

(10) any other information that the agency may reasonably require.

For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year.

Sec. 8. **[115A.1417] FEES.**

The agency may establish fees to administer sections 115A.1410 to 115A.1419. The fees may be charged to producers or to a stewardship organization. Fees may be charged to fully cover but not exceed the agency's costs of administering sections 115A.1410 to 115A.1419. All fees must be paid to the commissioner for deposit in the account established in section 115A.1419.

Sec. 9. **[115A.1418] ENFORCEMENT.**

Subdivision 1. **Generally.** Sections 115A.1410 to 115A.1419 shall be enforced in the manner provided by section 115.071, subdivisions 1 to 6.

Subd. 2. **Producer penalties.** (a) Upon first determining that a producer is offering a covered product for sale in this state but is not participating in a product stewardship program approved by the agency, the agency shall send the producer a written warning that the producer is in violation of section 115A.1412, subdivision 1.

(b) A producer not participating in a product stewardship program approved by the agency whose covered product continues to be sold in this state 60 days after receiving a written warning from the agency must be assessed a penalty of $10,000 for each calendar day that the violation continues.

(c) If a plan approved under section 115A.1413, subdivision 2, is not fully implemented within 30 days of the start date contained in the plan, the agency shall assess a penalty of $5,000 along with notification to each producer associated with the product stewardship program. If, after an additional 30 days, an approved plan is not fully implemented, the agency shall assess a penalty of $10,000 to each producer associated with the product stewardship program. Subsequent violations occur each 30 days that the approved plan is not fully implemented.

(d) When the agency finds that a product stewardship program is not in compliance with the requirement to update its plan under section 115A.1413 or the reporting requirements under section 115A.1416, the agency must notify in writing each producer in the product stewardship program of the violation and must allow the producers in the product stewardship program 30 days to correct the noncompliance. After 30 days, each producer in the product stewardship program must be assessed a penalty of $5,000 for the first violation and $10,000 for each subsequent violation. A subsequent violation occurs after each 30 days of noncompliance under this paragraph.

(e) All penalties levied under this section must be deposited into the pharmaceutical product stewardship program account established under section 115A.1419.

Subd. 3. **Wholesaler penalties.** (a) The agency shall provide on its Web site a list of all producers participating in product stewardship programs the agency has approved and a list of all producers the agency has identified as noncompliant with sections 115A.1410 to 115A.1419.

(b) It is the responsibility of a drug wholesaler offering covered products for sale in this state to view the agency's Web site to determine if a producer of products the wholesaler is offering for sale in this state is in compliance with sections 115A.1410 to 115A.1419. If a drug wholesaler is unsure of the status of a producer or believes a producer is not in compliance, the drug wholesaler shall contact the agency to determine the producer's status.

(c) The agency shall send a written notice to a drug wholesaler known to be selling a product in this state from a producer who is not in compliance with sections 115A.1410 to 115A.1419.

(d) A drug wholesaler that continues to sell a covered product from a producer that is not in compliance with sections 115A.1410 to 115A.1419 60 days after receiving a written notice from the agency must be assessed a penalty of $1,000 for each day of noncompliance.

(e) All penalties levied under this section must be deposited into the pharmaceutical product stewardship program account established under section 115A.1419.

Sec. 10. **[115A.1419] ACCOUNT.**

The pharmaceutical product stewardship program account is created in the environmental fund. All receipts from fees collected under section 115A.1417 and from penalties collected under section 115A.1418 must be deposited into the account. Funds in the account at the end of a fiscal year do not cancel to the general fund, but remain in the account.

Sec. 11. **EFFECTIVE DATE.**

Sections 1 to 10 are effective the day following final enactment.