A bill for an act

relating to solid waste; requiring drug producers to register and pay a fee; providing for a drug collection program funded by drug producers; requiring reports; creating an account; providing penalties; expanding categories of persons allowed to possess legend and nonprescription drugs to include those disposing of them; modifying definitions; prohibiting flushing drugs into sewer system by health care facilities; appropriating money; amending Minnesota Statutes 2008, sections 151.37, subdivisions 6, 7; 151.44; proposing coding for new law in Minnesota Statutes, chapters 115A; 144.

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

ARTICLE 1

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

Sections 115A.1410 to 115A.1420 may be cited as the "Minnesota Safe Drug Disposal Act of 2010."

EFFECTIVE DATE. This section is effective the day following final enactment.

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

Subdivision 1. **Scope.** For the purposes of sections 115A.1410 to 115A.1420, the terms in this section 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. **Controlled substance.** "Controlled substance" means a substance listed in section 152.02 or a substance designated by the Minnesota State Board of Pharmacy under section 152.02, subdivision 7, 8, or 12.

Subd. 4. **Drug wholesaler.** "Drug wholesaler" has the meaning given wholesale drug distributor in section 151.44, paragraph (b).

Subd. 5. **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;

(3) substances, other than food, intended to affect the structure or any function of the body of humans; 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. 6. **Entity.** "Entity" means a person other than an individual.

Subd. 7. **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. 8. **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. 9. **Nonprescription drug.** "Nonprescription drug" means any drug that may be lawfully sold without a prescription.

Subd. 10. **Notification.** "Notification" means a document required under section 115A.1413 that describes the elements of a program and the manner in which it will be provided.

Subd. 11. **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. 12. **Prescription drug.** "Prescription drug" has the meaning given in section 151.44, paragraph (d).

Subd. 13. **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. 14. **Product stewardship organization.** "Product stewardship organization" means an organization designated by a group of producers to act as an agent on behalf of each producer to operate a program in this state.

Subd. 15. **Program.** "Program" means a program operated by a county, a producer, a group of producers, or a product stewardship organization to collect, transport, and provide for the final disposition of unwanted products.

Subd. 16. **Residential generators.** "Residential generators" means single- and multiple-family residences and locations where drugs are unused, unwanted, discarded, or abandoned, such as hospice services, nursing homes, boarding care homes, schools, foster care, day care, and other locations where people 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. 17. **Unwanted product.** "Unwanted product" means a covered product no longer wanted by its owner or that has been abandoned, discarded, or is intended to be discarded by its owner.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 3. **[115A.1412] REGISTRATION; FEE.**

Subdivision 1. **Requirement for sale.** On or after January 1, 2011, a producer may not sell or offer for sale in this state a covered product unless the producer has filed a registration with the agency under subdivision 2 and paid a registration fee, unless the producer is exempt from the fee under subdivision 3, paragraph (c).

Subd. 2. **Producer's registration.** (a) A producer of covered products must, before January 1, 2011, submit a registration to the agency that includes:

(1) a list of the producer's brands of drugs offered for sale in this state;

(2) the name, address, and contact information of a person responsible for ensuring compliance with sections 115A.1410 to 115A.1420; and

(3) an estimate of the revenues from sales of covered products in this state during the previous calendar year.

(b) A producer who begins to sell or offer for sale covered products in this state after January 1, 2011, and has not filed a registration under this subdivision must submit a

registration to the agency within ten days of beginning to sell or offer for sale covered products.

(c) A registration must be updated within 60 days after a change in the producer's brands of covered products sold or offered for sale in this state.

(d) A registration is effective upon receipt by the agency and is valid until January 1 of each year.

(e) The agency must review each registration and notify the producer of any information required by this section that is omitted from the registration. Within 30 days of receipt of a notification from the agency, the producer must submit a revised registration providing the information noted by the agency.

Subd. 3. **Producer's registration fee.** (a) Each producer that registers under this section must, by January 1, 2011, and each year thereafter, pay to the commissioner an annual registration fee of $..... to cover estimated agency costs to administer the program and the program costs of counties that elect to offer a program during that calendar year, unless exempted under paragraph (c). The commissioner must deposit the fee in the account established in section 115A.1416.

(b) A producer who begins to sell or offer for sale covered products in this state after January 1, 2011, must pay the registration fee required by this subdivision when the producer submits a registration to the agency.

(c) A producer that operates its own program under section 115A.1413 individually or participates in a program in concert with other producers or through a product stewardship organization is not required to pay a registration fee.

Subd. 4. **Emergency exception.** The commissioner of health may grant producers a public health exemption to subdivisions 1 to 3 for prescription drugs if the commissioner of health determines it is necessary to carry out the duties of sections 144.05, 144.4197, 144.4198, and 151.37, subdivisions 2 and 10.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 4. **[115A.1413] UNWANTED PRODUCTS COLLECTION PROGRAM.**

Subdivision 1. **Program requirements.** A program established under this section must:

(1) accept all unwanted products presented to the program by a residential generator, regardless of the producer;

(2) offer program services at no cost to a residential generator;

(3) offer convenient collection options;

(4) comply with applicable state and federal health, safety, controlled substance, and environmental laws, rules, and regulations regarding handling, transporting, and arranging for the final disposition of all unwanted products collected, including the required presence of law enforcement officials;

(5) promote the program to residential generators, pharmacists, retailers of covered products, and health care practitioners as the proper and safe method for the final disposition of unwanted products;

(6) prepare education and outreach materials that publicize the location and operation of collection locations throughout the county and disseminate them to health care facilities, pharmacies, and other interested parties. The program may 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; and

(7) obtain written assurance from the federal Drug Enforcement Agency that the program complies with the federal Controlled Substances Act and regulations adopted thereunder.

Subd. 2. **Notification.** Each county, producer, group of producers, or product stewardship organization offering a program under this section must submit a notification before beginning to collect unwanted products. A notification must contain:

(1) contact information for the individual directing the program;

(2) a description of the methods by which unwanted products from residential generators will be collected in all areas of the county, including the location of each collection site, 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;

(3) a description of how the unwanted products will be safely and securely tracked and handled from collection through final disposition and the policies and procedures to be followed to ensure security and compliance with state and federal health, safety, controlled substance, and environmental laws and regulations;

(4) a description of public education and outreach activities and how their effectiveness will be evaluated; and

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

Subd. 3. **Election.** The Western Lake Superior Sanitary District may elect to offer a program under this section. If the district elects to offer a program, it has identical authority and responsibilities given to a county under sections 115A.1410 to 115A.1420 to operate a program within its legal boundaries.

EFFECTIVE DATE. This section is effective the day following final enactment.

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

Each county, producer, group of producers, or product stewardship organization operating a collection program under a notification that has been filed under section 115A.1413 must arrange for final disposition of all unwanted products from residential generators in accordance with all applicable state and federal laws.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 6. **[115A.1415] REPORTS.**

(a) On or before June 30, 2012, and in each subsequent year, each county, producer, group of producers, or product stewardship organization operating a program under section 115A.1413 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) the amount, by weight, of unwanted products collected from residential generators at each drop-off site and the total amount by weight collected through a mail-back program, if applicable;

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

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

(4) the amount and proportion, by weight, of controlled substances collected at each drop-off site and through a mail-back program, if applicable;

(5) whether policies and procedures for collecting, transporting, and final disposition of unwanted products, as established in the notification, were followed and a description of any noncompliance;

(6) whether any safety or security problems occurred during the collection, transportation, or final disposition of unwanted products 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;

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

(8) 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.

(b) By January 1, 2013, the agency shall submit a report to the chairs and ranking minority members of the senate and house of representatives committees with jurisdiction over solid waste policy and solid waste finance that examines options and makes recommendations regarding methods to estimate the amount of unwanted products collected and disposed of under all active programs as a proportion of the total amount of unwanted products extant in this state during that year. The report shall suggest financial and other incentives that may be offered to producers or counties to increase the proportion of unwanted products collected.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 7. **[115A.1416] ACCOUNT; APPROPRIATION.**

(a) The pharmaceutical waste account is created in the environmental fund. The commissioner must deposit all revenue from the fee established in section 115A.1412, subdivision 3, in the account. Any interest earned on the account must be credited to the account. Money from other sources may be credited to the account.

(b) Until June 30, 2012, money in the account is annually appropriated to the commissioner to implement sections 115A.1410 to 115A.1420.

Sec. 8. **[115A.1417] AGENCY DUTIES.**

(a) The agency shall administer sections 115.1410 to 115A.1420.

(b) The agency shall review notifications submitted under section 115A.1413.

(c) The agency shall manage the account established in section 115A.1416 and shall reimburse counties for reasonable program costs incurred by the counties. If the revenues in the account exceed the amount that the agency determines is necessary for efficient and effective operation and administration of the program, including any amount for contingencies, the agency must recommend to the legislature that the producer fee be lowered in order to reduce revenues collected in the subsequent program year by the estimated amount of the excess.

(d) The agency shall provide on its Web site a list of all producers that have filed a complete registration and paid a registration fee to the agency and a list of all producers the agency has identified as noncompliant with section 115A.1412 or 115A.1415.

(e) The agency shall consult with counties and producers to estimate the costs of collection, transportation, and final disposition of drugs and may set maximum rates, on a per-pound or other basis, at which counties may be reimbursed for program activities.

(f) The agency shall provide technical assistance to counties seeking to develop a program or to improve an existing program's operations, including producing a program template.

(g) The agency shall research alternative options for the final disposition of unwanted products.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 9. **[115A.1418] OTHER COLLECTION PROGRAMS.**

(a) Nothing in sections 115A.1410 to 115A.1420 prohibits or restricts the operation of any program collecting, transporting, and providing for final disposition of covered products in addition to those approved by the agency under section 115A.1413 or prohibits or restricts any persons from receiving, collecting, transporting, or providing for final disposition of covered products, provided that those persons are registered with the agency under section 115A.1412 and comply with the reporting requirements under section 115A.1415, paragraph (a), and all other applicable state and federal laws.

(b) A county or other public agency may not require households to use public facilities to collect, transport, and arrange for final disposition of covered products to the exclusion of other lawful programs available.

Sec. 10. **[115A.1419] ANTICOMPETITIVE CONDUCT.**

(a) A producer, group of producers, or product stewardship organization that organizes a system to collect, transport, and arrange for the final disposition of unwanted products under sections 115A.1410 to 115A.1420 may engage in anticompetitive conduct to the extent necessary to plan and implement its chosen organized collection system and is immune from liability under state laws relating to antitrust, restraint of trade, unfair trade practices, and other regulation of trade or commerce.

(b) An organization of producers, an individual producer, and its officers, members, employees, and agents who cooperate with a political subdivision that organizes a system to collect, transport, and arrange for the final disposition of unwanted products under sections 115A.1410 to 115A.1420 may engage in anticompetitive conduct to the extent necessary to plan and implement the organized collection system, provided that the political subdivision actively supervises the participation of each entity. An organization, entity, or person covered by this paragraph is immune from liability under state law relating to antitrust, restraint of trade, unfair trade practices, and other regulation of trade or commerce.

Sec. 11. **[115A.1420] ENFORCEMENT.**

Subdivision 1. **Generally.** Sections 115A.1410 to 115A.1420 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 has not filed a complete registration with the agency, or has not paid a registration fee, the agency shall send the producer a written warning that the producer is in violation of section 115A.1412.

(b) A producer that has not filed a complete registration or paid a registration fee to the agency and 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) All penalties levied under this section must be deposited into the pharmaceutical waste account established under section 115A.1416.

Subd. 3. **Wholesaler penalties.** (a) 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.1412 and 115A.1415. 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.

(b) 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 section 115A.1412 or 115A.1415.

(c) A drug wholesaler that continues to sell a covered product from a producer that is not in compliance with section 115A.1412 or 115A.1415 60 days after receiving a written notice from the agency must be assessed a penalty of $1,000 for each day of noncompliance.

(d) All penalties levied under this section must be deposited into the pharmaceutical waste account established under section 115A.1416.

EFFECTIVE DATE. This section is effective the day following final enactment.

ARTICLE 2

Section 1. **[144.569] HANDLING OF PHARMACEUTICAL WASTE IN HEALTH CARE FACILITIES.**

Subdivision 1. **Pharmaceutical waste disposal.** Health care facilities licensed or regulated by the commissioner of health, including but not limited to nursing homes,

home care and hospice entities, boarding care homes, and supervised living facilities, must not destroy or dispose of any drug by flushing the drug into the sewer or septic system. Health care facilities licensed or regulated under chapters 144, 144A, 144D, and 144G must comply with the requirements of sections 115A.1410 to 115A.1420 for the final disposition of unused or contaminated drugs.

Subd. 2. **Penalty.** For a violation of subdivision 1, the commissioner of health may impose a civil penalty not exceeding $10,000 for each separate violation.

EFFECTIVE DATE. This section is effective six months after the United States Drug Enforcement Administration approves an alternative system of disposal for unwanted drugs that complies with the federal Controlled Substances Act.

Sec. 2. Minnesota Statutes 2008, section 151.37, subdivision 6, is amended to read:

Subd. 6. **Exclusion for course of employment.** (a) Nothing in this chapter shall prohibit the possession of a legend drug by an employee, agent, or sales representative of a registered drug manufacturer, or an employee or agent of a registered drug wholesaler, or registered pharmacy, while acting in the course of employment.

(b) Nothing in this chapter shall prohibit the following entities from possessing a legend drug for the purpose of disposing of the legend drug as pharmaceutical waste:

(1) a law enforcement officer;

(2) a hazardous waste transporter licensed by the Department of Transportation;

(3) a facility permitted by the Pollution Control Agency to treat, store, or dispose of hazardous waste, including household hazardous waste;

(4) a facility licensed by the Pollution Control Agency or a metropolitan county as a very small quantity generator collection program or a minimal generator; or

(5) a county or other entity that collects, stores, transports, or disposes of a legend drug pursuant to a notification filed with the Pollution Control Agency under section 115A.1413 or a person authorized by one of these entities to conduct one or more of these activities.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 3. Minnesota Statutes 2008, section 151.37, subdivision 7, is amended to read:

Subd. 7. **Exclusion for prescriptions.** (a) Nothing in this chapter shall prohibit the possession of a legend drug by a person for that person's use when it has been dispensed to the person in accordance with a ~~written or oral~~ valid prescription issued by a practitioner.

(b) Nothing in this chapter shall prohibit a person, for whom a legend drug has been dispensed in accordance with a written or oral prescription by a practitioner, from designating a family member, caregiver, or other individual to handle the legend drug for the purpose of assisting the person in obtaining or administering the drug or sending the drug for destruction.

(c) Nothing in this chapter shall prohibit a person for whom a prescription drug has been dispensed in accordance with a valid prescription issued by a practitioner from transferring the legend drug to a county or other entity that collects, stores, transports, or disposes of a legend drug pursuant to a notification filed under section 115A.1413 or to a person authorized by one of these entities to conduct one or more of these activities.

EFFECTIVE DATE. This section is effective the day following final enactment.

Sec. 4. Minnesota Statutes 2008, section 151.44, is amended to read:

151.44 DEFINITIONS.

As used in sections 151.43 to 151.51, the following terms have the meanings given in paragraphs (a) to ~~(f)~~ (h):

(a) "Wholesale drug distribution" means distribution of prescription or nonprescription drugs to persons other than a consumer or patient or reverse distribution of such drugs, but does not include:

(1) a sale between a division, subsidiary, parent, affiliated, or related company under the common ownership and control of a corporate entity;

(2) the purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for its own use from the organization or from other hospitals or health care entities that are members of such organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended through December 31, 1988, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) the sale, purchase, or trade of a drug or offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) the transfer of prescription or nonprescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(8) the distribution of prescription or nonprescription drug samples by manufacturers representatives; or

(9) the sale, purchase, or trade of blood and blood components.

(b) "Wholesale drug distributor" means anyone engaged in wholesale drug distribution including, but not limited to, manufacturers; repackers; own-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and pharmacies that conduct wholesale drug distribution. A wholesale drug distributor does not include a common carrier or individual hired primarily to transport prescription or nonprescription drugs.

(c) "Manufacturer" means anyone who is engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(d) "Prescription drug" means a drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to United States Code, title 21, sections 811 and 812.

(e) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(f) "Blood components" means that part of blood separated by physical or mechanical means.

(g) "Reverse distribution" means the receipt of prescription or nonprescription drugs received from or shipped to Minnesota locations for the purpose of returning the drugs to their producers or distributors.

(h) "Reverse distributor" means a person engaged in the reverse distribution of drugs.

EFFECTIVE DATE. This section is effective the day following final enactment.