House Bill 2386

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of House Interim Committee on Health Care for Association of Oregon Counties and League of Oregon Cities)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Directs each manufacturer of certain types of drugs that are sold within this state to develop and implement drug take-back program for purpose of collecting from individuals and nonbusiness entities those types of drugs for disposal.

Directs State Board of Pharmacy to administer Act. Requires manufacturers subject to Act to first submit plan for developing and implementing drug take-back program on or before December 31, 2018.

Becomes operative January 1, 2018.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to drugs; and prescribing an effective date.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Definitions. As used in sections 1 to 22 of this 2017 Act:

(1) "Authorized collector" means a person that enters into an agreement with a program operator for the purpose of collecting covered drugs under a drug take-back program.

(2)(a) "Covered drug" means a drug that a covered entity has discarded or abandoned or that a covered entity intends to discard or abandon.

(b) "Covered drug" includes:

(A) Prescription drugs, as defined in ORS 689.005;

(B) Nonprescription drugs, as defined in ORS 689.005;

(C) Drugs marketed under a brand name, as defined in ORS 689.515;

(D) Drugs marketed under a generic name, as defined in ORS 689.515;

(E) Biological products, as described in ORS 689.522;

(F) Drugs intended to be used by a licensed veterinarian; and

(G) Combination products.

(c) "Covered drug" does not include:

(A) Vitamins or supplements;

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

(C) Products that are regulated as both cosmetics and nonprescription drugs by the federal Food and Drug Administration;

(D) Drugs and biological products for which a covered manufacturer administers a drug take-back program as part of a risk evaluation and mitigation strategy under the oversight of the federal Food and Drug Administration; or

(E) Pet pesticide products.

(3)(a) "Covered entity" means a resident of this state or a nonbusiness entity located in this state.

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

(b) "Covered entity" does not include a law enforcement agency or an entity that generates pharmaceutical waste, such as a hospital, health care clinic, office of a health care provider, veterinary clinic or pharmacy.

(4)(a) "Covered manufacturer" means a person that manufactures covered drugs that are sold within this state.

(b) "Covered manufacturer" does not include a retail drug outlet whose store label appears on a covered drug or the packaging of a covered drug if the manufacturer of the covered drug is identified under section 3 of this 2017 Act.

(5) "Drop-off site" means the location where an authorized collector operates a secure repository for collecting covered drugs.

(6) "Drug" has the meaning given that term in ORS 689.005.

(7) "Drug take-back organization" means an organization designated by a covered manufacturer or a group of covered manufacturers to act as an agent of the covered manufacturer or group of covered manufacturers for the purpose of developing and implementing a drug take-back program.

(8) "Drug take-back program" means a program developed and implemented by a program operator for the collection, transportation and disposal of covered drugs for which a plan has been approved under section 4 of this 2017 Act.

(9) "Mail back service" means a method of collecting covered drugs from a covered entity by using prepaid, preaddressed mailing envelopes.

(10) "Manufacture" has the meaning given that term in ORS 689.005.

(11) "Pharmacy" has the meaning given that term in ORS 689.005.

(12) "Potential authorized collector" means:

(a) A person that:

(A) Is registered with the Drug Enforcement Administration of the United States Department of Justice; and

(B) Qualifies under federal law to collect and dispose of controlled substances, or qualifies under federal law to have the person's registration modified in such a way that authorizes the person to collect and dispose of controlled substances.

(b) A law enforcement agency or other entity not described in paragraph (a) of this subsection, as approved by the State Board of Pharmacy by rule.

(13) "Program operator" means a covered manufacturer, group of covered manufacturers or drug take-back organization that develops and implements, or plans to develop and implement, a drug take-back program approved by the board.

(14) "Retail drug outlet" has the meaning given that term in ORS 689.005.

(15) "Wholesale drug outlet" has the meaning given that term in ORS 689.005.

SECTION 2. Requirement to Participate in Drug Take-Back Program. (1) Each covered manufacturer shall develop and implement a drug take-back program that complies with the requirements of sections 1 to 22 of this 2017 Act. A covered manufacturer may develop and implement a drug take-back program independently, as part of a group of covered manufacturers or by delegating the covered manufacturer's duties under sections 1 to 22 of this 2017 Act to a drug take-back organization.

(2) A covered manufacturer that does not develop and implement a drug take-back program as described in subsection (1) of this section may not sell covered drugs within this state.

(3) If a covered manufacturer does not develop and implement a drug take-back program as described in subsection (1) of this section, a retail drug outlet may not sell covered drugs manufactured by the drug manufacturer. The State Board of Pharmacy may discipline a retail drug outlet that violates this section in the manner provided in ORS 689.445.

SECTION 3. Identification of Covered Manufacturers. (1) In a form and manner prescribed by the State Board of Pharmacy, a wholesale drug outlet must provide the board with a list of each covered manufacturer that sells a covered drug within this state for which the wholesale drug outlet provides wholesale services.

(2) At intervals prescribed by the board, a wholesale drug outlet must provide the board with an updated version of the list described in subsection (1) of this section, except that the board may not require a wholesale drug outlet to provide an updated version of the list more than once per year.

(3) Based on a list received by the board under subsection (1) of this section, the board may send a letter to a person inquiring as to whether the person is a covered manufacturer.

(4) A person that receives a letter of inquiry from the board under subsection (3) of this section must respond to the inquiry in writing not later than 60 days after receiving the inquiry. If the person believes that the person is not a covered manufacturer, the person must include in the response:

(a) The basis for the belief that the person is not a covered manufacturer;

(b) A list of the covered drugs that the person sells within this state; and

(c) The name and contact information of each person that manufactures a covered drug identified in paragraph (b) of this subsection.

(5) In a form and manner prescribed by the board, a retail drug outlet whose store label appears on a covered drug or the packaging of a covered drug must notify the board of the covered manufacturer from which the retail drug outlet receives the covered drug.

SECTION 4. Plans and Updated Plans for Drug Take-Back Programs. (1) In a form and manner prescribed by the State Board of Pharmacy, a program operator must submit to the board a plan for the development and implementation of a drug take-back program. The board shall approve a proposed drug take-back program if the program operator submits a completed application, the proposed drug take-back program meets the requirements of subsection (2) of this section and the program operator pays the fee established by the board under section 16 of this 2017 Act.

(2) To be approved by the board, a proposed drug take-back program must:

(a) Identify and provide contact information for the program operator and each covered manufacturer participating in the proposed drug take-back program;

(b) Provide for a collection system that complies with sections 6, 7, 8 and 9 of this 2017 Act;

(c) Provide for a disposal system that complies with section 10 of this 2017 Act;

(d) Include policies and procedures to ensure the safe and secure handling and disposal of covered drugs;

(e) Include policies and procedures to ensure the security of patient information that may be printed on the packaging of a covered drug;

(f) Set forth a plan to fund the proposed drug take-back program, with the costs of the proposed drug take-back program apportioned among each covered manufacturer participating in the proposed drug take-back program according to the share of revenue that each

covered manufacturer participating in the proposed drug take-back program earns from making sales of covered drugs within this state;

(g) Set forth short- and long-term goals with respect to the amount of covered drugs collected under the proposed drug take-back program and with respect to fostering public awareness of the proposed drug take-back program; and

(h) Take into consideration:

(A) The use of existing pharmaceutical waste transportation and disposal services;

(B) Processes whereby covered drugs may be separated from the packaging in which the covered drugs are kept to reduce transportation and disposal costs; and

(C) Processes whereby the packaging in which covered drugs are kept may be recycled.

(3)(a) Not later than 90 days after receiving a plan under subsection (1) of this section, the board shall issue an order either approving or rejecting the plan. If the board rejects the plan, the board shall include in the order the reason or reasons for the rejection.

(b) Not later than 60 days after issuing an order rejecting a plan under paragraph (a) of this subsection, a program operator must submit to the board a revised plan for the development and implementation of a drug take-back program. Not later than 90 days after receiving a revised plan under this paragraph, the board shall issue an order either approving or rejecting the revised plan. If the board rejects the revised plan, the board shall include in the order the reason or reasons for the rejection.

(c) If the board issues an order rejecting a revised plan under paragraph (b) of this subsection, the board may:

(A) Require the program operator to further revise the plan in accordance with the processes set forth in paragraph (b) of this subsection; or

(B) Impose a penalty on each covered manufacturer participating in the proposed drug take-back program as described in section 15 of this 2017 Act.

(d) Not later than four years after issuing an order approving a plan under paragraph (a) of this subsection, a program operator must submit to the board an updated plan for the continued operation of a drug take-back program, in which the program operator describes any substantive changes to the drug take-back program that involve an element required to be developed and implemented under subsection (2) of this section. An updated plan is subject to the approval processes set forth in this subsection.

(4) The board shall make each plan submitted under subsection (1) of this section and each revised plan submitted under subsection (3)(c) of this section available to the public, and the board shall provide the public an opportunity to comment on the plan or revised plan.

SECTION 5. Changes to Drug Take-Back Programs. (1) In a form and manner prescribed by the State Board of Pharmacy, a program operator must request preapproval from the board for any change to a drug take-back program that substantively alters the drug take-back program. A program operator must make a request under this subsection not later than 60 days before the change is to occur. For purposes of this subsection, the following types of changes substantively alter a drug take-back program:

(a) Changes to which covered manufacturers are participating in the drug take-back program;

(b) Changes involving methods used to collect covered drugs;

(c) Changes involving methods used to dispose of covered drugs;

(d) Changes to the policies and procedures for handling and disposing of covered drugs;

(e) Changes to the policies and procedures for securing patient information that may be printed on the packaging of a covered drug; and

(f) Changes involving methods used to foster public awareness of the proposed drug take-back program.

(2) In a form and manner prescribed by the board, a program operator must notify the board of any change to a drug take-back program that does not substantively alter the drug take-back program. A program operator must provide notice under this subsection not later than 30 days before the change is to occur. For purposes of this subsection, the following types of changes do not substantively alter a drug take-back program:

(a) Changes to the location of a drop-off site;

(b) Changes to the administration of mail back services pursuant to section 8 of this 2017 Act; and

(c) Changes to the schedule or location of collection events held pursuant to section 9 of this 2017 Act.

(3) In a form and manner prescribed by the board, a program operator must notify the board, not later than 30 days after the change occurs, of any change involving:

(a) The contact information for the program operator;

(b) The contact information for a covered manufacturer participating in the drug take-back program; or

(c) The ownership of a covered manufacturer participating in the drug take-back program.

SECTION 6. Authorized Collectors. (1) The process by which a program operator collects covered drugs under a drug take-back program must be accessible by each resident of this state and be convenient for covered entities to use on an ongoing basis.

(2) Before submitting to the State Board of Pharmacy a plan under section 4 (1) of this 2017 Act, a program operator must:

(a) Solicit potential authorized collectors for the purpose of collecting covered drugs under the drug take-back program; and

(b) Enter into agreements with authorized collectors for the purpose of collecting covered drugs under the drug take-back program.

(3) In entering into agreements under this section, a program operator must enter into an agreement, insofar as the agreement is practicable and cost-effective, with each retail drug outlet, hospital with an on-site pharmacy, health care clinic with an on-site pharmacy and law enforcement agency that demonstrates to the program operator the capability of being an authorized collector.

(4) An agreement entered into under this section must require an authorized collector to comply with all state laws and rules and federal laws and regulations governing the keeping of covered drugs, as identified by the board by rule.

(5) In approving plans and updated plans under section 4 of this 2017 Act, and in preapproving changes under section 5 of this 2017 Act, the board shall, insofar as is practicable, ensure that each resident of this state has adequate access to a drop-off site.

SECTION 7. Drop-off sites. (1) The system by which a program operator collects covered drugs under a drug take-back program must be safe and secure to use on an ongoing basis.

(2) For purposes of a drug take-back program:

(a) A drop-off site must be available for use during the normal business hours of the authorized collector;

(b) A drop-off site must use a secure repository in compliance with all state laws and rules and federal laws and regulations governing the keeping of covered drugs in repositories, as identified by the State Board of Pharmacy by rule;

(c) The secure repository used at a drop-off site must be serviced and emptied as often as necessary to avoid reaching capacity;

(d) A sign must be affixed to the secure repository used at a drop-off site that prominently displays a toll-free telephone number and a website address that a covered entity may use to provide feedback to the program operator about the drug take-back program; and

(e) If a drop-off site is located at a long-term care facility, as defined in ORS 442.015, only individuals who reside at the long-term care facility may use the drop-off site.

SECTION 8. Mail Back Services. Upon request, a program operator must provide, as part of a drug take-back program, mail back services to individuals who are incapable of travel for reasons related to age or disability, as defined in ORS 659A.104. If a request is made under this section, a program operator also must provide the requester with prepaid, pre-addressed mailing envelopes.

SECTION 9. Covered Drug Collection Events. If a drug take-back program provides for the periodic collection of covered drugs through collection events, the collection events must be conducted in accordance with the applicable regulations and protocols of the Drug Enforcement Administration of the United States Department of Justice.

SECTION 10. Disposal of Covered Drugs. (1) Covered drugs collected at a drop-off site must be disposed of at a hazardous waste disposal facility that meets the requirements of 40 C.F.R. parts 264 and 265, as in effect on the effective date of this 2017 Act. However, if cost, logistics or other factors make compliance with this subsection infeasible, a program operator may petition the Department of Environmental Quality, in a form and manner prescribed by the department, to dispose of some or all of the covered drugs collected at a drop-off site at a municipal waste disposal facility that is capable of incinerating the covered drugs.

(2) A program operator may petition the department, in a form and manner prescribed by the department, for approval to use disposal technologies or processes other than the disposal technologies and processes described in subsection (1) of this section. The department shall approve a petition under this subsection if the disposal technology or process provides a level of protection that is equivalent or superior to the level of protection provided by the technologies and processes described in subsection (1) of this section, in the following areas:

(a) Worker health and safety;

(b) Monitoring waste and air, water and land emissions that result from discarded or abandoned covered drugs;

(c) Preventing waste and air, water and land emissions that result from discarded or abandoned covered drugs;

(d) Reducing persistent, bioaccumulative and toxic pollution that results from discarded or abandoned covered drugs; and

(e) Any other impact to the environment or public health and safety deemed relevant by the department.

(3) The department shall inform the State Board of Pharmacy if the department grants a petition under subsection (1) or (2) of this section.

SECTION 11. Public Awareness. (1) A program operator must promote, and provide public outreach and education about, the safe and secure collection of covered drugs under the drug take-back program through the use of a website and written materials provided at the time a covered drug is delivered to a covered entity, and through the use of any signage, advertising or other means that the program operator determines is an effective means of fostering public awareness. At a minimum, a program operator must:

(a) Promote the safe and secure storage of covered drugs by covered entities;

(b) Discourage the disposal of covered drugs in the garbage or sewer system;

(c) Promote the disposal of covered drugs through the use of the drug take-back program;

(d) Establish a toll-free telephone number and a website address that a covered entity may use to contact the program operator about the drug take-back program;

(e) Publicize information on the location of drop-off sites and collection processes;

(f) Work with authorized collectors to develop a readily recognizable and consistent design for repositories to be used at drop-off sites and to develop clear, standardized instructions to covered entities on how to use those repositories; and

(g) Conduct a survey once every two years of covered entities and pharmacists, health care providers and veterinarians who interact with covered entities.

(2) For purposes of conducting a survey under subsection (1)(g) of this section:

(a) In a form and manner prescribed by the State Board of Pharmacy, a program operator must submit proposed survey questions to the board for preapproval.

(b) Surveys must:

(A) Measure public awareness of the drug take-back program;

(B) Assess the extent to which drop-off sites, collection events and mail back services are convenient and easy to use; and

(C) Assess knowledge of and attitudes toward the risks posed by improperly storing covered drugs and improperly discarding or abandoning covered drugs.

(3) A program operator shall coordinate with other program operators under this section to ensure that covered entities can easily identify, understand and access the services provided by all drug take-back programs that are operational in this state. At a minimum, all of the drug take-back programs that are operational in this state must provide a single toll-free telephone number and a single website address that a covered entity may use to contact program operators about the drug take-back programs and to acquire information about the location of the drop-off sites and the collection processes of the drug take-back programs.

(4) Upon request, a retail drug outlet, hospital with an on-site pharmacy or health care clinic with an on-site pharmacy must provide a covered entity with written materials provided by a program operator for the purpose of promoting the safe and secure collection of covered drugs at the time that a covered drug is delivered to a covered entity.

SECTION 12. Annual Report to the State Board of Pharmacy. (1) In a form and manner prescribed by the State Board of Pharmacy, a program operator must submit to the board an annual report on the development, implementation and operation of the drug take-back program that includes:

(a) A list of covered manufacturers participating in the drug take-back program;

(b) The total amount, by weight, of covered drugs collected under the drug take-back program;

(c) The amount, by weight, of covered drugs collected under each method of collecting drugs under the drug take-back program;

(d) The address of each drop-off site used under the drug take-back program;

(e) The number of prepaid, preaddressed mailing envelopes distributed to requesters pursuant to section 8 of this 2017 Act;

(f) The date and location of collection events held pursuant to section 9 of this 2017 Act;

(g) The method or methods used to transport covered drugs collected under the drug take-back program;

(h) The disposal technologies or processes used pursuant to section 10 of this 2017 Act;

(i) Whether any safety or security problems occurred during the collection, transportation or disposal of covered drugs and, if a problem occurred, a summary of possible resolutions;

(j) A summary of the drug take-back program's compliance with section 11 of this 2017 Act; and

(k) A summary of the annual expenditures of the drug take-back program.

(2) The board shall publish reports submitted under this section on a website of the board.

SECTION 13. Funding Drug Take-Back Programs. Each covered manufacturer or group of covered manufacturers must pay all costs associated with developing, implementing and operating a drug take-back program. A program operator or authorized collector may not impose a charge, including any charge imposed at the time that a covered drug is sold to or collected from a covered entity, against covered entities for the purpose of recouping the costs of a drug take-back program.

SECTION 14. Inspection and audit. The State Board of Pharmacy shall ensure compliance with sections 1 to 22 of this 2017 Act by:

(1) Inspecting drop-off sites and disposal sites associated with a drug take-back program; and

(2) Auditing the records of program operators.

SECTION 15. Enforcement and Discipline. (1)(a) The State Board of Pharmacy shall send notice to a covered manufacturer if the covered manufacturer fails to participate in a drug take-back program as required by sections 1 to 22 of this 2017 Act. Notice sent under this subsection must explain the possible penalties that may be incurred by the covered manufacturer for committing the violation.

(b) If, 60 days after the date on which the board sent notice under paragraph (a) of this subsection, the covered manufacturer continues to sell drugs within this state without participating in a drug take-back program, the board may impose a civil penalty against the covered manufacturer for an amount that does not exceed $10,000 for each day, beginning on the 61st day, that the covered manufacturer commits the violation.

(2)(a) The board shall send notice to a program operator if the board determines that the program operator's drug take-back program is not in compliance with sections 1 to 22 of this 2017 Act. Notice sent under this subsection must explain the possible penalties that may be incurred by the program operator for committing the violation.

(b) If a drug take-back program continues not to be in compliance with sections 1 to 22 of this 2017 Act 30 days after the date on which the board sent notice under paragraph (a) of this subsection, the board may:

(A) Impose a civil penalty against the program operator for an amount that does not exceed $10,000 for each day, beginning on the 31st day, that the program operator commits the violation; and

(B) If the board determines that the violation presents a risk to public health and safety, suspend, in whole or in part, operation of the drug take-back program.

(3) The board shall deposit moneys collected through the imposition of civil penalties under this section into the Secure Drug Take-Back Account established under section 17 of this 2017 Act.

SECTION 16. Fees. (1) The State Board of Pharmacy shall adopt fees for the purpose of paying the costs of administering sections 1 to 22 of this 2017 Act. The fees may be imposed when a program operator submits plans, revised plans and updated plans under section 4 of this 2017 Act, requests for preapproval a change under section 5 of this 2017 Act, submits for preapproval survey questions under section 11 of this 2017 Act or submits an annual report under section 12 of this 2017 Act.

(2) Fees adopted under this section may not, taken together, exceed the costs of administering sections 1 to 22 of this 2017 Act.

(3) The board shall deposit fee moneys collected pursuant to this section into the Secure Drug Take-Back Account established under section 17 of this 2017 Act.

SECTION 17. Secure Drug Take-Back Account. (1) There is established in the State Treasury, separate and distinct from the General Fund, the Secure Drug Take-Back Account. Interest earned by the Secure Drug Take-Back Account shall be credited to the account. All moneys in the Secure Drug Take-Back Account are continuously appropriated to the State Board of Pharmacy for purposes of administering sections 1 to 22 of this 2017 Act.

(2) The Secure Drug Take-Back Account shall consist of all moneys deposited into or credited to the account, including:

(a) Moneys collected under and deposited into the account pursuant to sections 15 and 16 of this 2017 Act; and

(b) Moneys appropriated or transferred to the account by the Legislative Assembly.

SECTION 18. Antitrust Immunity. The Legislative Assembly declares that the collaboration of covered manufacturers and drug take-back organizations to provide covered entities with drug take-back program services, including the safe and secure collection, transportation and disposal of covered drugs, is in the best interests of the public. Therefore, the Legislative Assembly declares its intent that the development, implementation and operation of drug take-back programs as required by sections 1 to 22 of this 2017 Act shall be exempt from state antitrust laws. The Legislative Assembly further declares its intent to provide immunity for the development, implementation and operation of drug take-back programs as required by sections 1 to 22 of this 2017 Act from federal antitrust laws. This section does not authorize any person to engage in activities or to conspire to engage in activities that constitute per se violations of state or federal antitrust laws that are not authorized under sections 1 to 22 of this 2017 Act.

SECTION 19. Confidentiality. Any proprietary information or any financial, manufacturing or sales information or data that the State Board of Pharmacy receives from a covered

manufacturer or drug take-back organization under sections 1 to 22 of this 2017 Act is confidential and not subject to public disclosure under ORS 192.410 to 192.505, except that the board may disclose summarized information or aggregated data if the information or data does not directly or indirectly identify the proprietary information or the financial, manufacturing or sales information or data of a specific covered manufacturer or drug take-back organization.

SECTION 20. Nonapplicability of the Uniform Controlled Substances Act. The provisions of ORS chapter 475 do not apply to a program operator, insofar as the program operator is collecting, transporting and disposing of covered drugs pursuant to sections 1 to 22 of this 2017 Act.

SECTION 21. Rulemaking. The State Board of Pharmacy may adopt any rules necessary for the effective administration of sections 1 to 22 of this 2017 Act.

SECTION 22. Annual Report to the Legislative Assembly. Not later than September 15 of each year, the State Board of Pharmacy shall submit a report to the Legislative Assembly, in the manner provided by ORS 192.245, describing the board's administration of sections 1 to 22 of this 2017 Act. The report must include:

(1) An evaluation of whether the collection of covered drugs by drug take-back programs that are operational in this state is safe and secure;

(2) A summary of available data on whether the drug take-back programs are effective at reducing the risks posed by improperly stored covered drugs and improperly discarded or abandoned covered drugs; and

(3) A comprehensive review of the strategies employed by drug take-back programs to achieve the requirements of sections 1 to 22 of this 2017 Act.

SECTION 23. Required date for initial submission of plan for drug take-back program. Each program operator, as defined in section 1 of this 2017 Act, shall submit to the State Board of Pharmacy a plan for the development and implementation of a drug take-back program as required by section 4 (1) of this 2017 Act on or before December 31, 2018.

SECTION 24. Operative date. (1) Sections 1 to 22 of this 2017 Act become operative on January 1, 2018.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all the duties, powers and functions conferred on the board by sections 1 to 22 of this 2017 Act.

SECTION 25. Captions. The section captions used in this 2017 Act are provided only for the convenience of the reader and do not become part of the statutory law of this state or express any legislative intent in the enactment of this 2017 Act.

SECTION 26. Effective date. This 2017 Act takes effect on the 91st day after the date on which the 2017 regular session of the Seventy-ninth Legislative Assembly adjourns sine die.