HB 2645-5
(LC 1437)
3/31/17 (MBM/ps)

Requested by Representative MALSTROM

PROPOSED AMENDMENTS TO
HOUSE BILL 2645

On page 1 of the printed bill, delete lines 4 through 28 and delete pages 2 through 10 and insert:

"SECTION 1. Definitions. As used in sections 1 to 20 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.

"(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 prescription drugs, as defined in ORS 689.005, that are sold within this state.

"(b) 'Covered manufacturer' does not include:

"(A) A person that:

"(i) Packages or repackages prescription drugs that are sold within this state or who labels or relabels the containers of prescription drugs that are sold within this state; and

"(ii) Does not produce, prepare, propagate, compound, convert or process prescription drugs that are sold within this state; or

"(B) A prepaid group practice described in ORS 441.229.

"(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 participating in 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 Department of Environmental Quality 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 department.

"(14) 'Retail drug outlet' means a retail drug outlet, as defined in ORS 689.005, that is open to and accessible by the public.

"(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) Except as provided in subsection (2) of this section, each covered manufacturer shall participate in a drug take-back program that complies with the requirements of sections 1 to 20 of this 2017 Act. A covered manufacturer may participate in 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 20 of this 2017 Act to a drug take-back organization.

"(2) A covered manufacturer is not required to participate in a drug take-back program as described in subsection (1) of this section if the covered manufacturer manufactures prescription drugs for fewer than 50 patients in this state. A covered manufacturer that manufactures prescription drugs for fewer than 50 patients in this state must provide mail back services to those patients instead.

"(3) If a covered manufacturer does not participate in a drug take-back program as described in subsection (1) of this section, and does not qualify for exemption under subsection (2) of this section, the State Board of Pharmacy may assess a fine against the covered manufacturer in an amount not to exceed $1,000 for each day that prescription drugs manufactured by the covered manufacturer are sold in this state.

"SECTION 3. Organization of Program Operator. The program operator of a drug take-back program must be organized as an entity that is exempt from income taxes under section 501(c)(3) of the Internal Revenue Code, as amended and in effect on the effective date of this 2017 Act.

"SECTION 4. Plans and Updated Plans for Drug Take-Back Programs. (1) In a form and manner prescribed by the Department of Environmental Quality, a program operator must submit to the department a plan for participating in a drug take-back program. The department shall approve a proposed drug take-back program plan 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 department under section 15 of this 2017 Act.

"(2) To be approved by the department, a proposed drug take-back program plan 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 and 8 of this 2017 Act;

"(c) Provide for a disposal system that complies with section 9 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 cover all costs associated with 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 prescription drugs within this state;

"(g) Set forth short-term 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) Describe how the drug take-back program will provide convenient service in every county in this state, including how under the drug take-back program the program operator will:

"(A) Establish at least one drop-off site in each county in this state;

"(B) Establish at least one drop-off site in each city in this state that has 20,000 or more residents; and

"(C) Establish additional drop-off sites in each city in this state at a rate of one drop-off site per 20,000 residents.

"(3)(a) The drop-off site required under subsection (2)(h)(A) of this section may be the same drop-off site as the drop-off site required under subsection (2)(h)(B) of this section.

"(b) The department may waive the requirement of subsection (2)(h)(A) of this section with respect to an individual county if the drug take-back program plan describes how the drug take-back program will provide mail back service in the county.

"(4)(a) Not later than 90 days after receiving a plan under subsection (1) of this section, the department shall issue an order either approving or rejecting the plan. If the department rejects the plan, the department 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 department a revised plan for participating in a drug take-back program. Not later than 90 days after receiving a revised plan under this paragraph, the department shall issue an order either approving or rejecting the revised plan. If the department rejects the

revised plan, the department shall include in the order the reason or reasons for the rejection.

"(c) If the department issues an order rejecting a revised plan under paragraph (b) of this subsection, the department 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 14 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 department 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 under subsection (2) of this section. An updated plan is subject to the approval processes set forth in this subsection.

"(5) The department shall make each plan submitted under subsection (1) of this section and each revised or updated plan submitted under subsection (4) of this section available to the public.

"SECTION 5. Changes to Drug Take-Back Programs. (1) In a form and manner prescribed by the Department of Environmental Quality, a program operator must request preapproval from the department 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 department, a program operator must notify the department 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; and

"(b) Changes to the schedule or location of collection events held pursuant to section 8 of this 2017 Act.

"(3) In a form and manner prescribed by the department, a program operator must notify the department, 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) Before submitting to the Department of Environmental Quality 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 all willing authorized collectors for the purpose of collecting covered drugs under the drug take-back program.

"(2) 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.

"(3) 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 State Board of Pharmacy by rule.

"(4) 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 department 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. 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:

"(1) In accordance with the applicable regulations and protocols of the Drug Enforcement Administration of the United States Department of Justice; and

"(2) In coordination with the local solid waste management officials who have jurisdiction over the impacted area.

"SECTION 9. Disposal of Covered Drugs. Covered drugs collected at a drop-off site must be disposed of:

"(1) 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; or

"(2) At a municipal solid waste incinerator that is permitted to accept pharmaceutical waste.

"SECTION 10. 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) Disseminate information on the inherent risks of improperly storing or disposing of opioids or opiates;

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

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

"(e) 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;

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

"(g) 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

"(h) 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)(h) of this section:

"(a) In a form and manner prescribed by the Department of Environmental Quality, a program operator must submit proposed survey questions to the department 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 11. Annual Report to the Department of Environmental Quality. (1) In a form and manner prescribed by the Department of Environmental Quality, a program operator must submit to the department 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 date and location of collection events held pursuant to section 8 of this 2017 Act;

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

"(g) The disposal technologies or processes used pursuant to section 9 of this 2017 Act;

"(h) 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;

"(i) A summary of the drug take-back program's compliance with section 10 of this 2017 Act; and

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

"(2) The department shall review reports submitted under this section and approve those that comport with the requirements of this section. If the department does not approve a report under this subsection, the department shall provide the program operator with written notice of revisions necessary for approval.

"(3) The department shall publish approved reports submitted under this section on a website of the department.

"SECTION 12. Funding Drug Take-Back Programs. Each covered manufacturer or group of covered manufacturers must pay all costs associated with participating in 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 13. Inspection and Audit. The Department of Environ-

mental Quality shall ensure compliance with sections 1 to 20 of this 2017 Act by:

"(1) Entering into an agreement with the State Board of Pharmacy whereby the board, during routine inspections of retail drug outlets:

"(a) Inspects drop-off sites located at retail drug outlets; and

"(b) Informs the department of drop-off sites that are not in compliance with sections 1 to 20 of this 2017 Act;

"(2) Inspecting drop-off sites not located retail drug outlets; and

"(3) Auditing the records of program operators.

"SECTION 14. Enforcement and Discipline. (1)(a) The Department of Environmental Quality 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 20 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, 120 days after the date on which the department 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 department may impose a civil penalty against the covered manufacturer for an amount that does not exceed $10,000 for each day, beginning on the 121st day, that the covered manufacturer commits the violation.

"(2)(a) The department shall send notice to a program operator if the department determines that the program operator's drug take-back program is not in compliance with sections 1 to 20 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 20 of this 2017 Act 30 days after the date on which

the department sent notice under paragraph (a) of this subsection, the department 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 department 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 department shall deposit moneys collected through the imposition of civil penalties under this section into the Secure Drug Take-Back Account established under section 16 of this 2017 Act.

"SECTION 15. Fees. (1) The Department of Environmental Quality shall establish the following fees for the purpose of paying the costs of administering sections 1 to 20 of this 2017 Act.

"(a) A one-time fee for reviewing a drug take-back program plan submitted under section 4 of this 2017 Act.

"(b) An annual fee for expenses associated with the ongoing costs of administering sections 1 to 20 of this 2017 Act.

"(c) An hourly fee for any other work that the department must do on behalf of a drug take-back program.

"(2) Fees established under subsection (1) of this section must be reasonably calculated to pay the expenses associated with the purpose for which the fee is collected.

"(3) The department shall deposit fee moneys collected pursuant to this section into the Secure Drug Take-Back Account established under section 16 of this 2017 Act.

"SECTION 16. 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 account shall be credited to the account. All moneys in the account

are continuously appropriated to the Department of Environmental Quality purposes of administering sections 1 to 20 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 14 and 15 of this 2017 Act; and

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

"SECTION 16a. Liability. An authorized collector, covered manufacturer, drug take-back organization, drug take-back program, potential authorized collector and program operator may not be held criminally or civilly liable for any function, duty or power performed for the purpose of complying with sections 1 to 20 of this 2017 Act, unless the function, duty or power was performed with gross negligence or willful and wanton misconduct.

"SECTION 17. Antitrust Immunity. The Legislative Assembly declares that program operators providing 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 participating in drug take-back programs as required by sections 1 to 20 of this 2017 Act shall be exempt from state antitrust laws. The Legislative Assembly further declares its intent to provide immunity for participating in drug take-back programs as required by sections 1 to 20 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 20 of this 2017 Act.

"SECTION 18. Confidentiality. Any proprietary information or any

financial, manufacturing or sales information or data that the Department of Environmental Quality receives from a covered manufacturer or drug take-back organization under sections 1 to 20 of this 2017 Act is confidential and not subject to public disclosure under ORS 192.410 to 192.505, except that the department 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 19. 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 20 of this 2017 Act.

"SECTION 19a. Moratorium. Except as expressly authorized by state law, the governing body of a city or a county may not enact an ordinance requiring, or otherwise establishing a program for, the collection of covered drugs by nongovernmental entities through the use of drop-off sites or mail back services.

"SECTION 20. Rulemaking. The Department of Environmental Quality shall adopt any rules necessary for the effective administration of sections 1 to 20 of this 2017 Act. Upon request, the State Board of Pharmacy shall assist the department in adopting rules under this section.

"SECTION 21. Report to the Legislative Assembly. Not later than September 15, 2019, the Department of Environmental Quality shall submit a report to the Legislative Assembly, in the manner provided by ORS 192.245, describing the department's administration of sections 1 to 20 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 20 of this 2017 Act.

"SECTION 21a. Repeals. (1) Sections 1 to 20 of this 2017 Act are repealed on September 15, 2029.

"(2) Section 21 of this 2017 Act is repealed on December 31, 2019.

"SECTION 22. Required Date for Initial Participation. (1) Each program operator, as defined in section 1 of this 2017 Act, shall submit to the Department of Environmental Quality a plan for participating in a drug take-back program as required by section 4 (1) of this 2017 Act on or before July 1, 2018.

"(2) Each drug take-back program must be operational by February 1, 2019.

"SECTION 23. Operative Date. (1) Sections 1 to 20 of this 2017 Act become operative on January 1, 2018.

"(2) The Department of Environmental Quality and 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 department or 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 department or board by sections 1 to 20 of this 2017 Act.

"SECTION 24. 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 25. 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.".
