House Bill 2065

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of Governor Kate Brown for Department of Environmental Quality)

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 covered drugs that are sold within this state to participate in drug take-back program for purpose of collecting from certain persons those drugs for disposal.

Directs Department of Environmental Quality to administer Act. Requires stewardship organizations subject to Act to first submit plan for developing and implementing drug take-back program on or before July 1, 2020. Requires drug take-back programs to be operational by February 1, 2021.

Becomes operative January 1, 2020.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

Relating to drug take-back programs; 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 2019 Act:

(1) "Authorized collector" means a person that enters into an agreement with a stewardship organization 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 person, as defined in ORS 459.005, acting in this state.

(b) "Covered entity" does not include a law enforcement agency or a business that gen-

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.

erates 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 private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store label if the manufacturer of the drug has been identified by a stewardship organization;

(B) A repackager if the manufacturer of the drug has been identified by a stewardship organization; or

(C) A nonprofit health care corporation that is exempt from federal income tax under section 501(c)(3) of the Internal Revenue Code and that repackages drugs solely for the purpose of supplying a drug to facilities or retail pharmacies operated by the health care corporation or its affiliate if the manufacturer of the drug has been identified by a stewardship organization.

(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 program" means a program developed and implemented by a stewardship organization for the collection, transportation and disposal of covered drugs for which a plan has been approved under section 4 of this 2019 Act.

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

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

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

(11) "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 to authorize 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 Environmental Quality Commission by rule.

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

(b) "Retail drug outlet" does not include a hospital or health care clinic that does not have an on-site pharmacy.

(13) "Stewardship organization" means a covered manufacturer, a group of covered manufacturers or an organization designated by a covered manufacturer or group of covered manufacturers to act as an agent for the covered manufacturer or group of covered manufacturers that develops and implements, or plans to develop and implement, a drug take-back program approved by the Department of Environmental Quality.

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 22 of this 2019 Act.

(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 and provides mail-back services to those patients.

(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 $10,000 per violation.

SECTION 3. Organization of stewardship organization. The stewardship organization 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 2019 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 stewardship organization must submit to the department a plan for establishing a drug take-back program. The department shall review and approve a proposed drug take-back program plan if the stewardship organization timely submits a completed application, the proposed drug take-back program plan meets the requirements of subsection (2) of this section and the stewardship organization pays the fee established by the department under section 15 of this 2019 Act.

(2) To be approved by the department, a proposed drug take-back program plan must describe how the drug take-back program will:

(a) Finance, manage and conduct a drug take-back program to collect covered drugs from covered entities;

(b) Cover all costs associated with participation in the proposed drug take-back program and apportion those costs to participating covered manufacturers;

(c) Identify and provide contact information for the stewardship organization management team and each covered manufacturer participating in the proposed drug take-back program;

(d) Provide for a disposal system that complies with section 9 of this 2019 Act;

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

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

(g) Promote, and provide public outreach and education about, the proposed drug take-back program as described in section 10 of this 2019 Act;

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

(i) Provide convenient service in every county in this state, including how under the proposed drug take-back program the stewardship organization will, at a minimum:

(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 10,000 residents above the threshold established in subparagraph (B) of this paragraph.

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

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

(c) A drop off site established under section 7 (2)(e) of this 2019 Act cannot be used to meet the requirements of subsection (2)(i) of this section.

(4)(a) Not later than 90 days after receiving a plan under subsection (1) of this section, the department shall either approve or reject the plan, or request additional information to supplement the plan. If the department rejects the plan or requests additional information, the department shall provide in writing to the stewardship organization the reason or reasons for the rejection or the request for additional information.

(b) Not later than 60 days after the department rejects a plan or requests additional information under paragraph (a) of this subsection, a stewardship organization must submit to the department a revised plan, or the requested additional information, for establishing a drug take-back program. Not later than 90 days after receiving a revised plan or additional information under this paragraph, the department shall either approve or reject the plan. If the department rejects the plan, the department shall inform the stewardship organization in writing of the reason or reasons for the rejection.

(c) If the department rejects a plan under paragraph (b) of this subsection, the department may:

(A) Require the stewardship organization 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, or on the stewardship organization, as described in section 14 of this 2019 Act.

(d) Not later than four years after approving a plan under this subsection, the department shall require that a stewardship organization submit to the department an updated plan for the continued operation of a drug take-back program, in which the stewardship organization 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.

(6) In approving plans and updated plans under this section, and in preapproving changes under section 5 of this 2019 Act, the department shall, insofar as is practicable, ensure that each resident of this state has adequate access to a drop off site.

SECTION 5. Changes to drug take-back programs. (1) In a form and manner prescribed by the Department of Environmental Quality, a stewardship organization must request preapproval from the department for any change to a drug take-back program that substantively alters the drug take-back program. A stewardship organization 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 in 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;

(f) Changes involving methods used to achieve full public awareness of the drug take-back program; and

(g) Changes to the goals of the drug take-back program regarding public awareness strategies.

(2) In a form and manner prescribed by the department, a stewardship organization must notify the department of any change to a drug take-back program that does not substantively alter the drug take-back program. A stewardship organization 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) A change in location of a drop off site; and

(b) A change to the schedule, or in location, of collection events held pursuant to section 8 of this 2019 Act.

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

(a) The stewardship organization management team, including the contact information for the stewardship organization management team;

(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 of this 2019 Act, a stewardship organization must:

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

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

(2) In entering into agreements under this section, a stewardship organization 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 stewardship organization 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, and management practices set out by the stewardship organization.

SECTION 7. Drop off sites. (1) The drop off sites by which a stewardship organization collects covered drugs under a drug take-back program must be safe, secure and convenient to use on an ongoing, year-round basis and must provide equitable access for residents across this state.

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

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

(b) Each drop off site must use a secure repository in compliance with all federal laws and regulations and state laws and any rules adopted by the State Board of Pharmacy governing the keeping of covered drugs in repositories;

(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 stewardship organization about the drug take-back program;

(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; and

(f) Each drop off site must accept all covered drugs from covered entities.

(3) The board may adopt rules to identify the federal laws and regulations and state laws and rules described in subsection (2)(b) of this section.

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:

(1) Be conducted:

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

(b) In coordination with the local solid waste management officials who have jurisdiction over the impacted area; and

(2) Accept all covered drugs from covered entities.

SECTION 9. Disposal of covered drugs. Covered drugs collected at a drop off site or at a collection event must be disposed of:

(1) At a hazardous waste disposal facility that meets the requirements of 40 C.F.R. 264 and 265, as in effect on the effective date of this 2019 Act; or

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

SECTION 10. Public awareness. (1) A stewardship organization 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 stewardship organization determines is an effective means of fostering public awareness. At a minimum, a stewardship organization 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, septic 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 stewardship organization about the drug take-back program;

(f) Publicize information on the location of drop off sites and collection events;

(g) Work with authorized collectors to develop a readily recognizable and consistent design for secure 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) A survey conducted under subsection (1)(h) of this section 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 for residents of this state;

(c) Assess public knowledge of and attitudes toward the risks posed by improperly storing covered drugs and abandoning or improperly discarding covered drugs; and

(d) Be designed to collect data that may be used to improve public outreach methods.

(3) The results of a survey conducted under subsection (1)(h) of this section must be published on a website operated by or on behalf of the stewardship organization.

(4) In a form and manner prescribed by the Department of Environmental Quality, a stewardship organization must submit proposed survey design and survey questions to the department for preapproval.

(5) A stewardship organization shall coordinate with other stewardship organizations 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 stewardship organizations about drug take-back programs and to acquire information about the location of drop off sites and collection events and about the collection processes of the drug take-back programs.

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

SECTION 11. Annual report to the Department of Environmental Quality. (1) In a form and manner prescribed by the Department of Environmental Quality, a stewardship organization shall submit to the department an annual report on the development, implementation and operation of the drug take-back program that includes, but is not limited to:

(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 2019 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 2019 Act;

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

(i) A summary of the drug take-back program's compliance with section 10 of this 2019 Act;

(j) A summary of the annual expenditures of the drug take-back program; and

(k) The extent to which the drug take-back program complied with and met the goals set under the drug take-back program plan described in section 4 (2)(h) of this 2019 Act.

(2)(a) The department shall review reports submitted under this section and approve those that comport with the requirements of this section.

(b) If the department does not approve a report under this subsection, the department shall provide the stewardship organization with written notice of revisions necessary for approval. The stewardship organization shall submit a revised report to the department not more than 30 days after receiving the notice from the department.

(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 stewardship organization 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 recovering the costs of a drug take-back program.

SECTION 13. Inspection and audit; interagency agreements. (1) The Department of Environmental Quality shall ensure compliance with sections 1 to 22 of this 2019 Act by entering into an agreement with the State Board of Pharmacy whereby the board, during routine inspections of retail drug outlets and health care facilities with drop off sites:

(a) Inspects drop off sites located at retail drug outlets or health care facilities; and

(b) Informs the department of drop off sites that are not in compliance with sections 1 to 22 of this 2019 Act.

(2) In carrying out subsection (1) of this section, the department may:

(a) Inspect drop off sites and collection events not located at retail drug outlets or health care facilities;

(b) Audit the records of stewardship organizations; and

(c) Undertake other actions that the department determines necessary.

(3) The department may enter into interagency agreements for purposes including but not limited to covering costs incurred in administering sections 1 to 22 of this 2019 Act.

SECTION 14. Enforcement and discipline. (1) In accordance with the applicable provisions of ORS chapter 183 related to contested case proceedings, the Department of Environmental Quality may issue an order requiring compliance with the provisions of sections 1 to 22 of

this 2019 Act.

(2) The department may bring an action against any person that is in violation of the provisions of sections 1 to 22 of this 2019 Act.

(3) The department may impose a penalty not to exceed $25,000 per day against any person that is in violation of the provisions of sections 1 to 22 of this 2019 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 22 of this 2019 Act:

(a) A one-time fee for reviewing a proposed drug take-back program plan submitted under section 4 of this 2019 Act.

(b) An annual fee for expenses associated with the ongoing costs of administering sections 1 to 22 of this 2019 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 2019 Act.

SECTION 16. Secure Drug Take-Back Account. (1) The Secure Drug Take-Back Account is established in the State Treasury, separate and distinct from the General Fund. 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 for the purposes of administering sections 1 to 22 of this 2019 Act.

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

(a) Moneys collected under and deposited into the account pursuant to section 15 of this 2019 Act; and

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

SECTION 17. Liability. An authorized collector, covered manufacturer, stewardship organization, drug take-back program and potential authorized collector may not be held criminally or civilly liable for any function, duty or power performed for the purpose of complying with sections 1 to 22 of this 2019 Act, unless the function, duty or power was performed with gross negligence or willful and wanton misconduct.

SECTION 18. Antitrust immunity. (1) The Legislative Assembly declares that collaboration among authorized collectors, covered manufacturers, stewardship organizations, drug take-back programs and potential authorized collectors 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. The Legislative Assembly therefore declares its intent to exempt from state antitrust laws, and to provide immunity from federal antitrust laws through the state action doctrine, drug take-back programs that might otherwise be constrained by such laws.

(2) The Director of the Department of Environmental Quality or the director's designee shall engage in appropriate state supervision necessary to promote state action immunity under state and federal antitrust laws, and may inspect or request additional documentation to verify that the drug take-back programs established under sections 1 to 22 of this 2019

Act are implemented in accordance with the legislative intent expressed in this section.

(3) Groups that include, but are not limited to, authorized collectors, covered manufacturers, stewardship organizations, potential authorized collectors, state and local governmental entities and consumers may meet to facilitate the development, implementation and operation of drug take-back programs in accordance with the requirements of sections 1 to 22 of this 2019 Act. Any participation by the entities and individuals listed in this subsection shall be on a voluntary basis.

(4) The Department of Environmental Quality may conduct a survey of the entities and individuals specified in subsection (3) of this section concerning drug take-back programs.

(5) A survey or meeting under subsection (3) or (4) of this section is not a violation of state antitrust laws and shall be considered state action for purposes of federal antitrust laws through the state action doctrine.

SECTION 19. 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 stewardship organization under sections 1 to 22 of this 2019 Act is confidential and not subject to public disclosure under ORS 192.311 to 192.478, 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 stewardship organization.

SECTION 20. Nonapplicability of the Uniform Controlled Substances Act. The provisions of the Uniform Controlled Substances Act do not apply to a stewardship organization, insofar as the stewardship organization is collecting, transporting and disposing of covered drugs pursuant to sections 1 to 22 of this 2019 Act.

SECTION 21. 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 22. Rulemaking. The Department of Environmental Quality shall adopt any rules necessary for the effective administration of sections 1 to 22 of this 2019 Act. Upon request, the State Board of Pharmacy shall assist the department in adopting rules under this section.

SECTION 23. Required date for initial participation. (1) Each stewardship organization, as defined in section 1 of this 2019 Act, shall submit to the Department of Environmental Quality a proposed drug take-back program plan as required by section 4 (1) of this 2019 Act on or before July 1, 2020.

(2) Each drug take-back program must be operational by February 1, 2021.

SECTION 24. Operative date. (1) Sections 1 to 22 of this 2019 Act become operative on January 1, 2020.

(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 22 of this 2019 Act.

SECTION 25. Captions. The section captions used in this 2019 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 2019 Act.

SECTION 26. Effective date. This 2019 Act takes effect on the 91st day after the date on which the 2019 regular session of the Eightieth Legislative Assembly adjourns sine die.