HB 3273-5
(LC 986)
4/2/19 (SCT/ps)

Requested by Representative SCHOUTEN

PROPOSED AMENDMENTS TO
HOUSE BILL 3273

On page 1 of the printed bill, delete lines 4 through 24 and delete pages 2 through 10 and insert:

"SECTION 1. Definitions. As used in sections 1 to 23 of this 2019 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) 'Biologics' means a virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of human diseases or injuries.

"(3)(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; and

"(E) 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;

"(E) Drugs administered in a clinical setting;

"(F) Drugs that are used for animal medicines, including but not limited to parasiticide drugs for animals;

"(G) Exposed sharps, as defined in ORS 459.386, or other used drug products that are medical waste;

"(H) Emptied injector products or medical devices and their components;

"(I) Dialysis concentrates and solutions used for kidney dialysis in a patient's home; or

"(J) Biologics.

"(4)(a) 'Covered entity' means:

"(A) A resident of this state;

"(B) A nonbusiness entity located in this state; or

"(C) An ultimate user as defined by 21 U.S.C. 802 (27).

"(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.

"(5)(a) 'Covered manufacturer' means a person that manufactures covered drugs that are sold within this state, including, but not lim-

ited to, a person that manufactures covered drugs for another manufacturer pursuant to an agreement.

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

"(A) A person that:

"(i)(I) Packages covered drugs that are sold within this state or that labels the containers of covered drugs that are sold within this state; or

"(II) Repackages covered drugs that are sold within this state or that relabels the containers of covered drugs that are sold within this state, if the person informs the Department of Environmental Quality of the name of the original manufacturer of the covered drug; and

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

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

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

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

"(8) '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.

"(9) '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 2019 Act.

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

"(11) 'Manufacture' has the meaning given that term in ORS

689.005.

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

"(13) '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.

"(14) '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 of Environmental Quality.

"(15)(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 that does not have an on-site pharmacy or a health care clinic that does not have an on-site pharmacy.

"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 23 of this 2019 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 23 of this 2019 Act to a drug take-back organization.

"(2)(a) 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 provides sufficient proof to the Department of Environmental Quality that the covered manufacturer manufactures covered drugs for fewer than 50 patients in this state.

"(b) The Environmental Quality Commission may adopt rules regarding this subsection.

"(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 for each day that covered drugs manufactured by the covered manufacturer are sold in this state.

"SECTION 3. Organization of program operator. A 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 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 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 subsections (2), (4) and (5) of this section and the program operator 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:

"(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 2019 Act;

"(c) Provide for a disposal system that complies with section 9 of this 2019 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 and compliance with any applicable federal laws and regulations;

"(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;

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

"(h) Provide public outreach and education in compliance with section 10 of this 2019 Act;

"(i) 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 establish at least one drop-off site:

"(A) In each county in this state; and

"(B) Per population center, plus an additional drop-off site for every 50,000 residents of the city or town located within a population center;

"(j) Identify the transporters and waste disposal facilities that the program will use;

"(k) In a nonurban county, as defined in ORS 653.026, provide upon request of a covered entity a mail-back service option that is prepaid

by the program; and

"(L) Provide to a person who provides in-home hospice services, upon the person's request, mail-back service supplies to be used by the hospice services patient.

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

"(4) Drop-off sites described in subsection (2)(i) of this section must be located throughout a population center to provide reasonably convenient and equitable access to all residents of the population center.

"(5) 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.

"(6)(a) A modification to the manner in which a proposed drug take-back program will provide the public outreach and education described in subsection (2)(h) of this section is not subject to the requirements of section 5 of this 2019 Act if the modification is in response to federal, state or local regulatory changes, or to changes in industry best practices that are made in good faith to improve the quality and outcomes of the outreach and education.

"(b) A modification to the transporters and waste disposal facilities described in subsection (2)(j) of this section is not subject to section 5 of this 2019 Act if the modification is made in response to federal, state or local regulatory changes, or to changes in industry best practices or contractors that are made in good faith and do not knowingly have a negative impact on the efficacy of the plan.

"(7)(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. If the department rejects the plan, the department shall

provide the reason or reasons for the rejection.

"(b) Not later than 60 days after the department rejects 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 either approve or reject the revised plan. If the department rejects the revised plan, the department shall provide the reason or reasons for the rejection.

"(c) If the department rejects 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 2019 Act.

"(d) Not later than four years after the department approves 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.

"(8) The department shall make each plan submitted under subsection (1) of this section and each revised or updated plan submitted under subsection (7) of this section available to the public.

"(9) As used in this section, 'population center' means a city or town and the unincorporated area of the county that is within a 10-mile radius from the center of the city or town.

"SECTION 5. Changes to drug take-back programs. (1) In a form

and manner prescribed by the Department of Environmental Quality, except as provided in subsection (3) of this section, 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 30 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 involving methods used to collect covered drugs;

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

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

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

"(e) Changes involving methods used to foster public awareness of the proposed drug take-back program;

"(f) Changes to drop-off sites that do not meet the requirements of section 4 (2)(i) of this 2019 Act;

"(g) Changes in the location of a drop-off site; and

"(h) Changes to the location or schedule of a collection event held pursuant to section 8 of this 2019 Act.

"(2) The department shall approve or reject a request submitted pursuant to subsection (1) of this section within 30 days of receiving the request. If the department does not approve or reject the request, and provide written notice to the program operator of the department's decision within 30 days of the date on which the department received the request, the proposed change shall be considered approved.

"(3)(a) If a program operator intends to make a proposed change to a drug take-back program but, for good cause as determined by the

department, is unable to make a request 30 days before the proposed change is to occur as required under subsection (1) of this section, the program operator shall notify the department of the proposed change as far in advance of the proposed change as practicable. Upon receipt of notice described in this subsection, the department shall consult with the program operator regarding the proposed change. Not later than seven business days after receiving the notice, the department may temporarily approve the proposed change.

"(b) The Environmental Quality Commission may adopt rules to carry out this subsection.

"(4) In a form and manner prescribed by the department, a program operator must notify the department:

"(a) Not later than 30 days after the change occurs of any change to the contact information for the program operator.

"(b) Not later than 60 days after the change occurs, of any change involving:

"(A) Which covered manufacturers are participating in the drug take-back program;

"(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 2019 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) 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.

"(3) In approving plans and updated plans under section 4 of this 2019 Act, 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 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 program operator must:

"(A) Ensure that each secure repository is serviced as often as necessary to avoid reaching capacity;

"(B) Ensure that collected covered drugs are transported to a location described in section 9 of this 2019 Act in a timely manner; and

"(C) Provide a method for the authorized collector to notify the program operator of the need for additional collections at the drop-off site;

"(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;

"(e) Except as provided in paragraph (f) of this subsection, a drop-off site must accept all covered drugs from covered entities; and

"(f) If a drop-off site is located at a long-term care facility, as defined in ORS 442.015, and allowed under applicable federal regulations, only individuals who reside, or have resided, at the long-term care facility may use the drop-off site.

"(3) A drug take-back program that is unable to establish and maintain a sufficient number of drop-off sites in order to meet the requirements of the plan submitted under section 4 of this 2019 Act shall provide additional services, such as mail-back services, and hold collection events to ensure the convenient service described in the plan submitted under section 4 of this 2019 Act, subject to approval by the Department of Environmental Quality.

"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 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 2019 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 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 and other covered drugs;

"(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, collection processes and any collection events;

"(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 biennial survey of covered entities and of pharmacists and health care providers 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, mail-back service and collection events 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 by a covered entity, 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 drugs collected under the drug take-back program;

"(c) The amount, by weight, of 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 total amount, by weight, of drugs collected at each drop-off site, presented in a manner that assists the department in determining the rate of use of each drop-off site;

"(f) The date and location of each collection event held pursuant to section 8 of this 2019 Act;

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

"(h) The disposal technologies or processes used pursuant to section 9 of this 2019 Act and which facilities or incinerators were used;

"(i) The total amount, by weight, of drugs disposed of by each method, presented in a manner that allows the department to conduct an audit to verify the information;

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

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

"(L) A summary of the annual expenditures of the drug take-back program, aggregated by category;

"(m) Whether service was provided in compliance with the program operator's description pursuant to section 4 (2)(i) of this 2019 Act and whether the public awareness goals have been met, including a summary of strategies and surveys used, and copies of any promotional materials developed by, the drug take-back program; and

"(n) An attestation that all covered drugs collected under the drug take-back program were disposed of in compliance with applicable laws, rules and regulations.

"(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 and the timeline for resubmittal.

"(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 Environmental Quality shall ensure compliance with sections 1 to 23 of this 2019 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 23 of this 2019 Act;

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

"(3) Auditing the records of program operators.

"SECTION 14. Enforcement and discipline. (1)(a) The Environmental Quality Commission shall send notice to a covered manufac-

turer if the covered manufacturer fails to participate in a drug take-back program as required by sections 1 to 23 of this 2019 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, 30 days after the date on which the commission 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 commission may impose a civil penalty against the covered manufacturer for an amount that does not exceed $10,000 for each day, beginning on the 31st day, that the covered manufacturer commits the violation.

"(2)(a) The commission shall send notice to a program operator, and any covered manufacturers that participate in the program operator's drug take-back program, if the commission determines that the program operator's drug take-back program is not in compliance with sections 1 to 23 of this 2019 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 to be out of compliance with sections 1 to 23 of this 2019 Act 30 days after the date on which the commission sent notice under paragraph (a) of this subsection, the commission may:

"(A) Impose a civil penalty against the program operator, and each covered manufacturer described in paragraph (a) of this subsection, for an amount that does not exceed $1,000 for each entity per day, beginning on the 31st day, that the program operator commits the violation; and

"(B) If the commission 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) Civil penalties imposed under this section are joint and several obligations of the program operator and each covered manufacturer that participates in the program operator's drug take-back program.

"(4) The commission 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 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 23 of this 2019 Act:

"(a) A one-time fee for reviewing a 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 23 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) If a drug take-back program has more than one program operator, each program operator is subject to the fees established under subsection (1) of this section.

"(3) Fees established under subsection (1) of this section must be reasonably calculated to cover the costs of administering sections 1 to 23 of this 2019 Act.

"(4) 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 purposes of administering sections 1 to 23 of this 2019 Act.

"(2) The 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 2019 Act; and

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

"SECTION 17. Liability. An authorized collector, covered manufacturer, drug take-back organization, drug take-back program 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 23 of this 2019 Act, unless the function, duty or power was performed with gross negligence or willful and wanton misconduct.

"SECTION 18. 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 23 of this 2019 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 23 of this 2019 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 23 of this 2019 Act.

"SECTION 19. Confidentiality. Any proprietary information or any financial, manufacturing or sales information or data that the De-

partment of Environmental Quality receives from a covered manufacturer or drug take-back organization under sections 1 to 23 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 drug take-back organization.

"SECTION 20. Nonapplicability of the Uniform Controlled Substances Act. The provisions of the Uniform Controlled Substances Act do not apply to a program operator or authorized collector, insofar as the program operator is collecting, transporting and disposing of covered drugs pursuant to sections 1 to 23 of this 2019 Act.

"SECTION 21. Moratorium. Except as expressly authorized by state law, the governing body of a city, county or other political subdivision of this state may not enact an ordinance or regulation or otherwise establish or require a program for the collection, by or on behalf of covered manufacturers, of:

"(1) Biologics;

"(2) Covered drugs;

"(3) Drugs 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;

"(4) Drugs that are used for animal medicines, including but not limited to parasiticide drugs for animals;

"(5) Drugs administered in a clinical setting; or

"(6) Dialysis concentrates and solutions used for kidney dialysis in a patient's home.

"SECTION 22. Interagency agreements. The Department of Environmental Quality may enter into agreements with other state agen-

cies for purposes including covering costs incurred in the administration of sections 1 to 23 of this 2019 Act.

"SECTION 23. Rulemaking. The Environmental Quality Commission shall adopt any rules necessary for the effective administration of sections 1 to 23 of this 2019 Act. Upon request, the State Board of Pharmacy shall assist the commission in adopting rules under this section.

"SECTION 24. Report to the Legislative Assembly. Not later than July 1, 2023, the Department of Environmental Quality shall submit a report to the Legislative Assembly, in the manner provided by ORS 192.245, describing the administration of sections 1 to 23 of this 2019 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; and

"(2) A comprehensive review of the strategies employed by drug take-back programs to achieve the requirements of sections 1 to 23 of this 2019 Act.

"SECTION 25. Sunsets. (1) Sections 1 to 23 of this 2019 Act are repealed on September 15, 2031.

"(2) Section 24 of this 2019 Act is repealed on December 31, 2023.

"SECTION 26. Required date for initial participation. (1) On or before November 1, 2020, each program operator, as defined in section 1 of this 2019 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 2019 Act.

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

"(3) A manufacturer that becomes a covered manufacturer after January 1, 2020, shall, not more than six months after the date on

which the manufacturer becomes a covered manufacturer, participate in a drug take-back program in compliance with section 2 of this 2019 Act.

"SECTION 27. Operative date. (1) Sections 1 to 23 of this 2019 Act become operative on January 1, 2020.

"(2) The Department of Environmental Quality, the Environmental Quality Commission 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, commission 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, commission or board by sections 1 to 23 of this 2019 Act.

"SECTION 28. 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 29. 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.".
