

Requested by Representative SCHOUTEN

**PROPOSED AMENDMENTS TO
HOUSE BILL 3273**

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

3 **“SECTION 1. Definitions. As used in sections 1 to 23 of this 2019**
4 **Act:**

5 **“(1) ‘Authorized collector’ means a person that enters into an**
6 **agreement with a program operator for the purpose of collecting cov-**
7 **ered drugs under a drug take-back program.**

8 **“(2) ‘Biologics’ means a virus, therapeutic serum, toxin, antitoxin**
9 **or analogous product applicable to the prevention, treatment or cure**
10 **of human diseases or injuries.**

11 **“(3)(a) ‘Covered drug’ means a drug that a covered entity has dis-**
12 **carded or abandoned or that a covered entity intends to discard or**
13 **abandon.**

14 **“(b) ‘Covered drug’ includes:**

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

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

17 **“(C) Drugs marketed under a brand name, as defined in ORS**
18 **689.515;**

19 **“(D) Drugs marketed under a generic name, as defined in ORS**
20 **689.515; and**

21 **“(E) Combination products.**

1 **“(c) ‘Covered drug’ does not include:**
2 **“(A) Vitamins or supplements;**
3 **“(B) Herbal-based remedies or homeopathic drugs, products or**
4 **remedies;**
5 **“(C) Products that are regulated as both cosmetics and**
6 **nonprescription drugs by the federal Food and Drug Administration;**
7 **“(D) Drugs and biological products for which a covered manufac-**
8 **turer administers a drug take-back program as part of a risk evalu-**
9 **ation and mitigation strategy under the oversight of the federal Food**
10 **and Drug Administration;**
11 **“(E) Drugs administered in a clinical setting;**
12 **“(F) Drugs that are used for animal medicines, including but not**
13 **limited to parasiticide drugs for animals;**
14 **“(G) Exposed sharps, as defined in ORS 459.386, or other used drug**
15 **products that are medical waste;**
16 **“(H) Emptied injector products or medical devices and their com-**
17 **ponents;**
18 **“(I) Dialysis concentrates and solutions used for kidney dialysis in**
19 **a patient’s home; or**
20 **“(J) Biologics.**
21 **“(4)(a) ‘Covered entity’ means:**
22 **“(A) A resident of this state;**
23 **“(B) A nonbusiness entity located in this state; or**
24 **“(C) An ultimate user as defined by 21 U.S.C. 802 (27).**
25 **“(b) ‘Covered entity’ does not include a law enforcement agency or**
26 **an entity that generates pharmaceutical waste, such as a hospital,**
27 **health care clinic, office of a health care provider, veterinary clinic**
28 **or pharmacy.**
29 **“(5)(a) ‘Covered manufacturer’ means a person that manufactures**
30 **covered drugs that are sold within this state, including, but not lim-**

1 ited to, a person that manufactures covered drugs for another man-
2 ufacturer pursuant to an agreement.

3 “(b) ‘Covered manufacturer’ does not include:

4 “(A) A person that:

5 “(i)(I) Packages covered drugs that are sold within this state or that
6 labels the containers of covered drugs that are sold within this state;
7 or

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

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

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

15 “(6) ‘Drop-off site’ means the location where an authorized collector
16 operates a secure repository for collecting covered drugs.

17 “(7) ‘Drug’ has the meaning given that term in ORS 689.005.

18 “(8) ‘Drug take-back organization’ means an organization desig-
19 nated by a covered manufacturer or a group of covered manufacturers
20 to act as an agent of the covered manufacturer or group of covered
21 manufacturers for the purpose of participating in a drug take-back
22 program.

23 “(9) ‘Drug take-back program’ means a program developed and im-
24 plemented by a program operator for the collection, transportation
25 and disposal of covered drugs for which a plan has been approved un-
26 der section 4 of this 2019 Act.

27 “(10) ‘Mail-back service’ means a method of collecting covered
28 drugs from a covered entity by using prepaid, preaddressed mailing
29 envelopes.

30 “(11) ‘Manufacture’ has the meaning given that term in ORS

1 **689.005.**

2 **“(12) ‘Pharmacy’ has the meaning given that term in ORS 689.005.**

3 **“(13) ‘Potential authorized collector’ means:**

4 **“(a) A person that:**

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

7 **“(B) Qualifies under federal law to collect and dispose of controlled**
8 **substances, or qualifies under federal law to have the person’s regis-**
9 **tration modified in such a way that authorizes the person to collect**
10 **and dispose of controlled substances.**

11 **“(b) A law enforcement agency.**

12 **“(14) ‘Program operator’ means a covered manufacturer, group of**
13 **covered manufacturers or drug take-back organization that develops**
14 **and implements, or plans to develop and implement, a drug take-back**
15 **program approved by the Department of Environmental Quality.**

16 **“(15)(a) ‘Retail drug outlet’ means a retail drug outlet, as defined**
17 **in ORS 689.005, that is open to and accessible by the public.**

18 **“(b) ‘Retail drug outlet’ does not include a hospital that does not**
19 **have an on-site pharmacy or a health care clinic that does not have**
20 **an on-site pharmacy.**

21 **“SECTION 2. Requirement to participate in drug take-back pro-**
22 **gram. (1) Except as provided in subsection (2) of this section, each**
23 **covered manufacturer shall participate in a drug take-back program**
24 **that complies with the requirements of sections 1 to 23 of this 2019 Act.**
25 **A covered manufacturer may participate in a drug take-back program**
26 **independently, as part of a group of covered manufacturers or by de-**
27 **legating the covered manufacturer’s duties under sections 1 to 23 of**
28 **this 2019 Act to a drug take-back organization.**

29 **“(2)(a) A covered manufacturer is not required to participate in a**
30 **drug take-back program as described in subsection (1) of this section**

1 if the covered manufacturer provides sufficient proof to the Depart-
2 ment of Environmental Quality that the covered manufacturer man-
3 ufactures covered drugs for fewer than 50 patients in this state.

4 “(b) The Environmental Quality Commission may adopt rules re-
5 garding this subsection.

6 “(3) If a covered manufacturer does not participate in a drug take-
7 back program as described in subsection (1) of this section, and does
8 not qualify for exemption under subsection (2) of this section, the
9 State Board of Pharmacy may assess a fine against the covered man-
10 ufacturer in an amount not to exceed \$10,000 for each day that covered
11 drugs manufactured by the covered manufacturer are sold in this
12 state.

13 **“SECTION 3. Organization of program operator.** A program opera-
14 tor of a drug take-back program must be organized as an entity that
15 is exempt from income taxes under section 501(c)(3) of the Internal
16 Revenue Code, as amended and in effect on the effective date of this
17 2019 Act.

18 **“SECTION 4. Plans and updated plans for drug take-back programs.**

19 (1) In a form and manner prescribed by the Department of Environ-
20 mental Quality, a program operator must submit to the department a
21 plan for participating in a drug take-back program. The department
22 shall approve a proposed drug take-back program plan if the program
23 operator submits a completed application, the proposed drug take-back
24 program meets the requirements of subsections (2), (4) and (5) of this
25 section and the program operator pays the fee established by the de-
26 partment under section 15 of this 2019 Act.

27 “(2) To be approved by the department, a proposed drug take-back
28 program plan must:

29 “(a) Identify and provide contact information for the program op-
30 erator and each covered manufacturer participating in the proposed

1 **drug take-back program;**

2 **“(b) Provide for a collection system that complies with sections 6,**
3 **7 and 8 of this 2019 Act;**

4 **“(c) Provide for a disposal system that complies with section 9 of**
5 **this 2019 Act;**

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

8 **“(e) Include policies and procedures to ensure the security of pa-**
9 **tient information that may be printed on the packaging of a covered**
10 **drug and compliance with any applicable federal laws and regulations;**

11 **“(f) Set forth a plan to cover all costs associated with the proposed**
12 **drug take-back program, with the costs of the proposed drug take-back**
13 **program apportioned among each covered manufacturer participating**
14 **in the proposed drug take-back program;**

15 **“(g) Set forth goals with respect to the amount of drugs collected**
16 **under the proposed drug take-back program and with respect to fos-**
17 **tering full public awareness of the proposed drug take-back program;**

18 **“(h) Provide public outreach and education in compliance with**
19 **section 10 of this 2019 Act;**

20 **“(i) Describe how the drug take-back program will provide conven-**
21 **ient service in every county in this state, including how under the**
22 **drug take-back program the program operator will establish at least**
23 **one drop-off site:**

24 **“(A) In each county in this state; and**

25 **“(B) Per population center, plus an additional drop-off site for every**
26 **50,000 residents of the city or town located within a population center;**

27 **“(j) Identify the transporters and waste disposal facilities that the**
28 **program will use;**

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

1 by the program; and

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

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

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

12 “(5) The drop-off site required under subsection (2)(i)(A) of this
13 section may be the same drop-off site as the drop-off site required
14 under subsection (2)(i)(B) of this section.

15 “(6)(a) A modification to the manner in which a proposed drug
16 take-back program will provide the public outreach and education de-
17 scribed in subsection (2)(h) of this section is not subject to the re-
18 quirements of section 5 of this 2019 Act if the modification is in
19 response to federal, state or local regulatory changes, or to changes
20 in industry best practices that are made in good faith to improve the
21 quality and outcomes of the outreach and education.

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

28 “(7)(a) Not later than 90 days after receiving a plan under sub-
29 section (1) of this section, the department shall either approve or re-
30 ject the plan. If the department rejects the plan, the department shall

1 provide the reason or reasons for the rejection.

2 “(b) Not later than 60 days after the department rejects a plan un-
3 der paragraph (a) of this subsection, a program operator must submit
4 to the department a revised plan for participating in a drug take-back
5 program. Not later than 90 days after receiving a revised plan under
6 this paragraph, the department shall either approve or reject the re-
7 vised plan. If the department rejects the revised plan, the department
8 shall provide the reason or reasons for the rejection.

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

11 “(A) Require the program operator to further revise the plan in
12 accordance with the processes set forth in paragraph (b) of this sub-
13 section; or

14 “(B) Impose a penalty on each covered manufacturer participating
15 in the proposed drug take-back program as described in section 14 of
16 this 2019 Act.

17 “(d) Not later than four years after the department approves a plan
18 under paragraph (a) of this subsection, a program operator must sub-
19 mit to the department an updated plan for the continued operation of
20 a drug take-back program, in which the program operator describes
21 any substantive changes to the drug take-back program that involve
22 an element required under subsection (2) of this section. An updated
23 plan is subject to the approval processes set forth in this subsection.

24 “(8) The department shall make each plan submitted under sub-
25 section (1) of this section and each revised or updated plan submitted
26 under subsection (7) of this section available to the public.

27 “(9) As used in this section, ‘population center’ means a city or
28 town and the unincorporated area of the county that is within a
29 10-mile radius from the center of the city or town.

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

1 and manner prescribed by the Department of Environmental Quality,
2 except as provided in subsection (3) of this section, a program operator
3 must request preapproval from the department for any change to a
4 drug take-back program that substantively alters the drug take-back
5 program. A program operator must make a request under this sub-
6 section not later than 30 days before the change is to occur. For pur-
7 poses of this subsection, the following types of changes substantively
8 alter a drug take-back program:

9 “(a) Changes involving methods used to collect covered drugs;

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

11 “(c) Changes to the policies and procedures for handling and dis-
12 posing of covered drugs;

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

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

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

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

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

22 “(2) The department shall approve or reject a request submitted
23 pursuant to subsection (1) of this section within 30 days of receiving
24 the request. If the department does not approve or reject the request,
25 and provide written notice to the program operator of the
26 department’s decision within 30 days of the date on which the depart-
27 ment received the request, the proposed change shall be considered
28 approved.

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

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

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

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

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

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

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

19 “(B) The contact information for a covered manufacturer partic-
20 ipating in the drug take-back program; or

21 “(C) The ownership of a covered manufacturer participating in the
22 drug take-back program.

23 “SECTION 6. Authorized collectors. (1) Before submitting to the
24 Department of Environmental Quality a plan under section 4 (1) of this
25 2019 Act, a program operator must:

26 “(a) Solicit potential authorized collectors for the purpose of col-
27 lecting covered drugs under the drug take-back program; and

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

1 “(2) An agreement entered into under this section must require an
2 authorized collector to comply with all state laws and rules and federal
3 laws and regulations governing the keeping of covered drugs, as iden-
4 tified by the State Board of Pharmacy by rule.

5 “(3) In approving plans and updated plans under section 4 of this
6 2019 Act, and in preapproving changes under section 5 of this 2019 Act,
7 the department shall, insofar as is practicable, ensure that each resi-
8 dent of this state has adequate access to a drop-off site.

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

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

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

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

19 “(c) The program operator must:

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

22 “(B) Ensure that collected covered drugs are transported to a lo-
23 cation described in section 9 of this 2019 Act in a timely manner; and

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

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

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

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

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

14 “SECTION 8. Covered drug collection events. If a drug take-back
15 program provides for the periodic collection of covered drugs through
16 collection events, the collection events must be conducted:

17 “(1) In accordance with the applicable regulations and protocols of
18 the Drug Enforcement Administration of the United States Depart-
19 ment of Justice; and

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

22 “SECTION 9. Disposal of covered drugs. Covered drugs must be
23 disposed of:

24 “(1) At a hazardous waste disposal facility that meets the require-
25 ments of 40 C.F.R. parts 264 and 265, as in effect on the effective date
26 of this 2019 Act; or

27 “(2) At a municipal solid waste incinerator that is permitted to ac-
28 cept pharmaceutical waste.

29 “SECTION 10. Public awareness. (1) A program operator must pro-
30 mote, and provide public outreach and education about, the safe and

1 secure collection of covered drugs under the drug take-back program
2 through the use of a website and written materials provided at the
3 time a covered drug is delivered to a covered entity, and through the
4 use of any signage, advertising or other means of fostering public
5 awareness. At a minimum, a program operator must:

6 “(a) Promote the safe and secure storage of covered drugs by cov-
7 ered entities;

8 “(b) Disseminate information on the inherent risks of improperly
9 storing or disposing of opioids or opiates and other covered drugs;

10 “(c) Discourage the disposal of covered drugs in the garbage or
11 sewer system;

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

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

17 “(f) Publicize information on the location of drop-off sites, col-
18 lection processes and any collection events;

19 “(g) Work with authorized collectors to develop a readily recogni-
20 zable and consistent design for repositories to be used at drop-off sites
21 and to develop clear, standardized instructions to covered entities on
22 how to use those repositories; and

23 “(h) Conduct a biennial survey of covered entities and of
24 pharmacists and health care providers who interact with covered en-
25 tities.

26 “(2) For purposes of conducting a survey under subsection (1)(h) of
27 this section:

28 “(a) In a form and manner prescribed by the Department of Envi-
29 ronmental Quality, a program operator must submit proposed survey
30 questions to the department for preapproval.

1 **“(b) Surveys must:**

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

3 **“(B) Assess the extent to which drop-off sites, mail-back service and**
4 **collection events are convenient and easy to use; and**

5 **“(C) Assess knowledge of and attitudes toward the risks posed by**
6 **improperly storing covered drugs and improperly discarding or aban-**
7 **doning covered drugs.**

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

18 **“(4) Upon request by a covered entity, a retail drug outlet, hospital**
19 **with an on-site pharmacy or health care clinic with an on-site phar-**
20 **macy must provide a covered entity with written materials provided**
21 **by a program operator for the purpose of promoting the safe and se-**
22 **cure collection of covered drugs at the time that a covered drug is**
23 **delivered to a covered entity.**

24 **“SECTION 11. Annual report to the Department of Environmental**
25 **Quality. (1) In a form and manner prescribed by the Department of**
26 **Environmental Quality, a program operator must submit to the de-**
27 **partment an annual report on the development, implementation and**
28 **operation of the drug take-back program that includes:**

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

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

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

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

7 **“(e) The total amount, by weight, of drugs collected at each drop-off**
8 **site, presented in a manner that assists the department in determining**
9 **the rate of use of each drop-off site;**

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

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

14 **“(h) The disposal technologies or processes used pursuant to section**
15 **9 of this 2019 Act and which facilities or incinerators were used;**

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

19 **“(j) Whether any safety or security problems occurred during the**
20 **collection, transportation or disposal of drugs and, if a problem oc-**
21 **curred, a summary of the occurrence and possible resolutions;**

22 **“(k) A summary of the drug take-back program’s compliance with**
23 **section 10 of this 2019 Act;**

24 **“(L) A summary of the annual expenditures of the drug take-back**
25 **program, aggregated by category;**

26 **“(m) Whether service was provided in compliance with the program**
27 **operator’s description pursuant to section 4 (2)(i) of this 2019 Act and**
28 **whether the public awareness goals have been met, including a sum-**
29 **mary of strategies and surveys used, and copies of any promotional**
30 **materials developed by, the drug take-back program; and**

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

4 “(2) The department shall review reports submitted under this sec-
5 tion and approve those that comport with the requirements of this
6 section. If the department does not approve a report under this sub-
7 section, the department shall provide the program operator with
8 written notice of revisions necessary for approval and the timeline for
9 resubmittal.

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

12 “SECTION 12. Funding drug take-back programs. Each covered
13 manufacturer or group of covered manufacturers must pay all costs
14 associated with participating in a drug take-back program. A program
15 operator or authorized collector may not impose a charge, including
16 any charge imposed at the time that a covered drug is sold to or col-
17 lected from a covered entity, against covered entities for the purpose
18 of recouping the costs of a drug take-back program.

19 “SECTION 13. Inspection and audit. The Department of Environ-
20 mental Quality shall ensure compliance with sections 1 to 23 of this
21 2019 Act by:

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

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

25 “(b) Informs the department of drop-off sites that are not in com-
26 pliance with sections 1 to 23 of this 2019 Act;

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

28 “(3) Auditing the records of program operators.

29 “SECTION 14. Enforcement and discipline. (1)(a) The Environ-
30 mental Quality Commission shall send notice to a covered manufac-

1 turer if the covered manufacturer fails to participate in a drug
2 take-back program as required by sections 1 to 23 of this 2019 Act.
3 Notice sent under this subsection must explain the possible penalties
4 that may be incurred by the covered manufacturer for committing the
5 violation.

6 “(b) If, 30 days after the date on which the commission sent notice
7 under paragraph (a) of this subsection, the covered manufacturer
8 continues to sell drugs within this state without participating in a
9 drug take-back program, the commission may impose a civil penalty
10 against the covered manufacturer for an amount that does not exceed
11 \$10,000 for each day, beginning on the 31st day, that the covered
12 manufacturer commits the violation.

13 “(2)(a) The commission shall send notice to a program operator, and
14 any covered manufacturers that participate in the program operator’s
15 drug take-back program, if the commission determines that the pro-
16 gram operator’s drug take-back program is not in compliance with
17 sections 1 to 23 of this 2019 Act. Notice sent under this subsection must
18 explain the possible penalties that may be incurred by the program
19 operator for committing the violation.

20 “(b) If a drug take-back program continues to be out of compliance
21 with sections 1 to 23 of this 2019 Act 30 days after the date on which
22 the commission sent notice under paragraph (a) of this subsection, the
23 commission may:

24 “(A) Impose a civil penalty against the program operator, and each
25 covered manufacturer described in paragraph (a) of this subsection,
26 for an amount that does not exceed \$1,000 for each entity per day, be-
27 ginning on the 31st day, that the program operator commits the vio-
28 lation; and

29 “(B) If the commission determines that the violation presents a risk
30 to public health and safety, suspend, in whole or in part, operation of

1 the drug take-back program.

2 “(3) Civil penalties imposed under this section are joint and several
3 obligations of the program operator and each covered manufacturer
4 that participates in the program operator’s drug take-back program.

5 “(4) The commission shall deposit moneys collected through the
6 imposition of civil penalties under this section into the Secure Drug
7 Take-Back Account established under section 16 of this 2019 Act.

8 **“SECTION 15. Fees.** (1) The Department of Environmental Quality
9 shall establish the following fees for the purpose of paying the costs
10 of administering sections 1 to 23 of this 2019 Act:

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

13 “(b) An annual fee for expenses associated with the ongoing costs
14 of administering sections 1 to 23 of this 2019 Act.

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

17 “(2) If a drug take-back program has more than one program op-
18 erator, each program operator is subject to the fees established under
19 subsection (1) of this section.

20 “(3) Fees established under subsection (1) of this section must be
21 reasonably calculated to cover the costs of administering sections 1 to
22 23 of this 2019 Act.

23 “(4) The department shall deposit fee moneys collected pursuant to
24 this section into the Secure Drug Take-Back Account established un-
25 der section 16 of this 2019 Act.

26 **“SECTION 16. Secure Drug Take-Back Account.** (1) The Secure
27 Drug Take-Back Account is established in the State Treasury, separate
28 and distinct from the General Fund. Interest earned by the account
29 shall be credited to the account. All moneys in the account are con-
30 tinuously appropriated to the Department of Environmental Quality

1 for purposes of administering sections 1 to 23 of this 2019 Act.

2 “(2) The account shall consist of all moneys deposited into or cred-
3 ited to the account, including:

4 “(a) Moneys collected under and deposited into the account pursu-
5 ant to sections 14 and 15 of this 2019 Act; and

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

8 “SECTION 17. Liability. An authorized collector, covered manufac-
9 turer, drug take-back organization, drug take-back program and pro-
10 gram operator may not be held criminally or civilly liable for any
11 function, duty or power performed for the purpose of complying with
12 sections 1 to 23 of this 2019 Act, unless the function, duty or power
13 was performed with gross negligence or willful and wanton miscon-
14 duct.

15 “SECTION 18. Antitrust immunity. The Legislative Assembly de-
16 clares that program operators providing covered entities with drug
17 take-back program services, including the safe and secure collection,
18 transportation and disposal of covered drugs, is in the best interests
19 of the public. Therefore, the Legislative Assembly declares its intent
20 that participating in drug take-back programs as required by sections
21 1 to 23 of this 2019 Act shall be exempt from state antitrust laws. The
22 Legislative Assembly further declares its intent to provide immunity
23 for participating in drug take-back programs as required by sections
24 1 to 23 of this 2019 Act from federal antitrust laws. This section does
25 not authorize any person to engage in activities or to conspire to en-
26 gage in activities that constitute per se violations of state or federal
27 antitrust laws that are not authorized under sections 1 to 23 of this
28 2019 Act.

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

1 department of Environmental Quality receives from a covered manufac-
2 turer or drug take-back organization under sections 1 to 23 of this 2019
3 Act is confidential and not subject to public disclosure under ORS
4 192.311 to 192.478, except that the department may disclose summarized
5 information or aggregated data if the information or data does not
6 directly or indirectly identify the proprietary information or the fi-
7 nancial, manufacturing or sales information or data of a specific cov-
8 ered manufacturer or drug take-back organization.

9 **“SECTION 20. Nonapplicability of the Uniform Controlled Sub-**
10 **stances Act.** The provisions of the Uniform Controlled Substances Act
11 do not apply to a program operator or authorized collector, insofar as
12 the program operator is collecting, transporting and disposing of cov-
13 ered drugs pursuant to sections 1 to 23 of this 2019 Act.

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

19 **“(1) Biologics;**

20 **“(2) Covered drugs;**

21 **“(3) Drugs for which a covered manufacturer administers a drug**
22 **take-back program as part of a risk evaluation and mitigation strategy**
23 **under the oversight of the federal Food and Drug Administration;**

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

26 **“(5) Drugs administered in a clinical setting; or**

27 **“(6) Dialysis concentrates and solutions used for kidney dialysis in**
28 **a patient’s home.**

29 **“SECTION 22. Interagency agreements.** The Department of Envi-
30 **ronmental Quality may enter into agreements with other state agen-**

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

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

8 **“SECTION 24. Report to the Legislative Assembly.** Not later than
9 July 1, 2023, the Department of Environmental Quality shall submit a
10 report to the Legislative Assembly, in the manner provided by ORS
11 192.245, describing the administration of sections 1 to 23 of this 2019
12 Act. The report must include:

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

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

19 **“SECTION 25. Sunsets.** (1) Sections 1 to 23 of this 2019 Act are re-
20 pealed on September 15, 2031.

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

22 **“SECTION 26. Required date for initial participation.** (1) On or be-
23 fore November 1, 2020, each program operator, as defined in section 1
24 of this 2019 Act, shall submit to the Department of Environmental
25 Quality a plan for participating in a drug take-back program as re-
26 quired by section 4 (1) of this 2019 Act.

27 **“(2) Each drug take-back program must be operational by July 1,
28 2021.**

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

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

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

6 **“(2) The Department of Environmental Quality, the Environmental**
7 **Quality Commission and the State Board of Pharmacy may take any**
8 **action before the operative date specified in subsection (1) of this sec-**
9 **tion that is necessary to enable the department, commission or board**
10 **to exercise, on and after the operative date specified in subsection (1)**
11 **of this section, all the duties, powers and functions conferred on the**
12 **department, commission or board by sections 1 to 23 of this 2019 Act.**

13 **“SECTION 28. Captions.** The section captions used in this 2019 Act
14 are provided only for the convenience of the reader and do not become
15 part of the statutory law of this state or express any legislative intent
16 in the enactment of this 2019 Act.

17 **“SECTION 29.** This 2019 Act takes effect on the 91st day after the
18 date on which the 2019 regular session of the Eightieth Legislative
19 Assembly adjourns sine die.”.

20
