State of Oregon Department of Environmental Quality

Oregon Environmental Quality Commission meeting

Sept. 17-18, 2020

Rulemaking, Action Item C

Drug Take Back Program 2020

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DEQ Recommendation to EQC

DEQ recommends that the Environmental Quality Commission adopt the proposed rules as seen on pages 39 through 42 of this report as part of Chapter 340 of the Oregon Administrative Rules.

Language of proposed EQC motion:
"I move that the commission adopt the proposed rule amendments as seen on pages 39 through 42 of this report as part of chapter 340 of the Oregon Administrative Rules."

Overview

In 2019, the Oregon Legislature approved a statewide drug take-back program, funded by pharmaceutical manufacturers. Drug take-back programs provide a safe way for people to dispose of unneeded prescription drugs.

The proposed rule amendments will support DEQ's administration of the drug take-back law, under ORS 459A.200, which sets forth the requirements for statewide drug take-back programs in Oregon. In addition to requiring drug manufacturers' participation, the law directs these programs to provide convenient service to Oregon residents and offer safe and secure collection, transportation, and disposal of prescription, over-the-counter, brand, and generic drugs. Program operators must follow program plans that DEQ approves when developing and implementing their programs.

The proposed rule amendments will support implementing the Drug Take-Back Program by:

- Establishing criteria for evaluating a program operator's request to provide services, such as mail-back services, in lieu of establishing and maintaining a drop-off site the drug take-back law requires;
- Requiring program plans and updated plans to include the Oregon Board of Pharmacy-issued registration number of each participating manufacturer;
- Designating DEQ to enforce rules, discipline, and otherwise act on the Environmental Quality Commission's behalf, for the purposes of ORS 459A.239; and
- Establishing DEQ's fees for administering the Drug Take-Back Program.

Statement of Need

What need would the proposed rule address?

The proposed rules are needed to:

- Ensure that drug take-back programs, when providing services and collection events in place of a drop-off site required by law, will continue offering convenient statewide service;
- Ensure compliance with the drug take-back law through effective oversight and enforcement; and
- Ensure fee revenue covers DEQ's costs of administering the Drug Take-Back Program.

How would the proposed rule address the need?

The proposed rules would address the identified needs by:

- Requiring program operators to provide information for DEQ to use in waiving required drop-off sites in a county or approving services and collection events in place of a required drop-off site;
- Requiring drug take-back program plans to include the Board of Pharmacy-issued registration numbers for participating manufacturers, which would aid compliance oversight by enabling DEQ to readily identify registered manufacturers not participating in a drug take-back program;
- Designating DEQ to act on EQC's behalf for enforcement and compliance under ORS 459A.239; and
- Establishing fees reasonably calculated to cover DEQ's administrative costs, as required by ORS 459A.242.

How will DEQ know the rule addressed the need?

DEQ will know the proposed rules have addressed the needs if:

- An effective Drug Take-Back program is established;
- Services provided in lieu of required drop-off sites are providing convenient service to residents in affected areas;
- DEQ has the authority and DEQ and the Board of Pharmacy have additional information to effectively assure compliance and enforce the Drug Take-Back Program's requirements; and
- Fee revenue covers DEQ's costs for administering the Drug Take-Back Program.

Rules Affected, Authorities, Supporting Documents

Lead division
Land Quality

Program or activity
Materials Management

Chapter 340 action

Adopt				
340-098-0300	340-098-0350	340-098-0370	340-098-0390	
Amend				
340-098-0000	340-098-0010			

Statutory Authority – ORS				
468.020	468.065	459A.266		

Statutes Implemented – ORS				
459A.203	459A.209	459A.212	459A.215	459A.218
459A.239	459A.242			

Legislation
House Bill 3273 (2019)

Documents relied on for rulemaking

Document title	Document location
House Bill 3273 (2019)	https://olis.leg.state.or.us/liz/2019R1/Downloads/MeasureDocument/HB3273

Fee Analysis

These proposed rules would establish new fees to cover DEQ's costs for administering the Drug Take-Back Program under ORS 459A.200 to ORS 459A.266. ORS 459A.242 provides the authority for EQC to act on the proposed fees.

Brief description of proposed fees

The proposed rules would establish:

- A one-time fee for reviewing a drug take-back program plan or program plan update;
- An annual fee for expenses associated with DEQ's ongoing costs of administering the Drug Take-Back Program; and
- An hourly fee for any other work DEQ must do on behalf of a drug take-back program.

DEQ will charge the proposed fees to program operators. If DEQ approves multiple programs, DEQ will divide its annual fee evenly among the number of approved programs. DEQ will report its projected program expenditures and revenue annually.

Reasons

ORS 459A.242 directs DEQ to establish the fees described above. The fees are intended to cover DEQ's costs in administering this new Drug Take-Back Program under ORS 459A.200 to 459A.266.

Fee proposal alternatives considered

DEQ considered the following alternatives:

- **Maintain the status quo by not establishing fees.**
  This alternative would fail to provide the funding from manufacturers required by the Oregon Legislature for DEQ to administer the Drug Take-Back Program.

- **Apportion the annual and hourly fees, if multiple drug take-back programs exist, by charging costs associated with a particular program to that program and dividing the remainder evenly among the number of approved programs.**
  After some consideration, DEQ determined that apportioning the annual and hourly fees in this manner would be unnecessary, costly, and administratively difficult. The annual fee covers the cost of DEQ's ongoing administration, which is likely to benefit all drug take-back programs. Dividing the annual fee evenly among those programs would be efficient and provide more certainty for program operators. Hourly fees will cover other work DEQ performs on behalf of a drug take-back program and will be charged to that program or programs. Apportioning hourly fees as this alternative provides is thus unnecessary.

- **Apportion the annual and hourly fees, if multiple drug take-back programs exist, by the market share of the drug manufacturers participating in the respective programs.**
  This alternative would require programs to disclose the market data of their

participants and may be administratively burdensome for both DEQ and program operators. This would also be difficult to implement if manufacturers switch programs.

Fee payer

A program operator will pay the one-time plan review fee for each proposed plan or updated plan. A program operator of a DEQ-approved drug take-back program will pay annual and hourly fees on behalf of the drug manufacturers participating in its program.

Affected party involvement in fee-setting process

DEQ convened a rulemaking advisory committee that included appointees representing a variety of interests the proposed rules directly and indirectly affect. The committee met on March 24, 2020, and April 28, 2020, to discuss ways to establish fees that would allow DEQ to cover program costs.

Summary of impacts

The impacts of the proposed rules include the following:

- Program operators will pay a one-time fee of $75,000 for DEQ to review their proposed plan. Program operators will also pay the plan review fee when they submit proposed updates to their plans, required at least every four years. The fee is due with the plan submission. Due to the complexity of operating a drug take-back program, DEQ anticipates receiving only one or two program plans.
- Program operators with approved drug take-back programs will pay an annual fee of $345,000 in the first year, $210,000 in the second year, and $125,000 in subsequent years. If multiple drug take-back programs exist, DEQ will charge each drug take-back program an equal share of the annual fee. DEQ may reduce the annual fee for a given year to ensure fee revenue closely matches DEQ's costs. If the revenue collected from the plan review fee and annual fee exceeds DEQ's actual costs for the program in a given year, DEQ will reduce the annual fee by the excess amount in a subsequent year. DEQ will report its projected program expenditures and revenue annually.
- Program operators with approved drug take-back programs will pay an hourly fee for any other work DEQ determines is necessary on behalf of a drug take-back program. The hourly fee will not exceed $250 per hour and will be reasonably calculated to reflect the actual costs of the work.

Other proposed rules will result in a small increase in administrative costs for drug take-back programs. One rule requires a program operator to include, in its plan or updated plan submittal to DEQ, the Oregon Board of Pharmacy registration number of each drug manufacturer participating in its proposed drug take-back program. This may result in an incidental administrative cost to program operators and drug manufacturers. Another proposed rule establishes the criteria for DEQ's waiving drop-off sites in a particular county and approving services in lieu of required drop-off sites. A program operator will have administrative costs associated with demonstrating how it meets these criteria, which will require a program operator to:

- Demonstrate good-faith efforts to solicit and enter into agreements with potential authorized collectors to host drop-off sites;
- Demonstrate why it cannot establish or maintain a required drop-off site;
- Demonstrate concurrence by affected local governments with services being proposed or reasons why the operator could not obtain such concurrence with good faith efforts;
- Describe how the operator will design and implement proposed services to provide convenient service for all residents in the affected county or population center; and
- Agree to solicit potential authorized collectors for the affected county or population center on at least an annual basis.

Fee payer agreement with fee proposal

DEQ shared its fee proposal with the advisory committee in its meetings on March 24, 2020, and April 28, 2020. In the first meeting, two advisory committee members expressed concern that there was no cap on the amount DEQ may charge under the hourly fee. The law does not require that a cap be set but requires fees to be reasonably calculated to cover DEQ's costs of administration. DEQ believes that sharing its projected revenue and expenditures on a yearly basis can help address concerns.

In the second meeting, one committee member asked about the basis of the plan review and annual fees. DEQ indicated that the fees are based on resources spent on reviewing a plan under the existing paint product stewardship program and estimates of ongoing staff costs as well as consultation with the Department of Justice. Another committee member asked if the proposed $250 maximum hourly fee would be charged for all qualifying work. DEQ indicated that the rate charged would vary depending on the type of other work done. If actual costs for other work on behalf a drug take-back program are lower, DEQ will charge a lower fee.

After the committee meetings, DEQ revised its proposed apportionment of fees in the event of multiple drug take-back programs. DEQ now proposes to divide the annual fee evenly in the event of multiple drug take-back programs. DEQ considers its previously proposed apportionment to be unnecessary, costly, and administratively difficult, as stated in fee alternatives considered, above.

Links to supporting documents for proposed fees

ORS 459A.200 to ORS 459A.266: Oregon Revised Statutes

How long will the current fee sustain the program?

These fees are new because the program is new. The proposed fees are intended to cover DEQ's cost for implementing the Drug Take-Back Program. DEQ's estimated revenue needs are below.

Table 1 Drug Take-Back Program Revenue Need				
Program Costs	**FY21***	**FY22**	**FY23**	**FY24**
Annual operating costs	$184,000	$191,000	$106,000	$111,000
Repay loan and create operating balance		$154,000**	$104,000	$ 14,000
Revenue need	$184,000	$345,000	$210,000	$125,000

* "FY" indicates fiscal year beginning July 1. For instance, "FY21" refers to the period from July 1, 2020, to June 30, 2021.
** The $154,000 amount includes an estimated $109,000 of operating costs from FY21 not covered by plan review fee revenue (assuming one payment of $75,000). If actual plan review fee revenue exceeds $75,000 in FY21, the revenue need for FY22 will be reduced by the excess.

Table 2 Current Fees	
Program costs covered by fees	0%
Program costs covered by General Fund	0%
Program costs covered by other Materials Management funds	100%

Table 3 Proposed Fees		
Expected change in revenue in FY 2021 and FY 2022 (+/-)	$420,000	100%
Main GF required by statute/rule to fund program	$0	0%
Proposed fee allows General Fund replacement	$0	0%
Expected effective date	Plan review fee is due Nov. 1, 2020. First annual fee is due Aug. 1, 2021.	

Based on inquiries DEQ has received and the complexity of operating drug take-back programs, DEQ anticipates that two entities, at most, will submit plans to operate a drug take-back program in Oregon. DEQ expects two drug take-back programs, at most, will be approved. Below are estimates for one or two fee payers.

Table 4
Transactions and Revenue

Biennium	Number of transactions	Number of fee Payers	Impact on revenue (+/-)	Total revenue (+/-)
Current biennium	1-2	1-2	$75,000-$150,000	$75,000-$150,000
Next biennium	2-4	1-2	$480,000-$555,000	$480,000-$550,000

DEQ assumes one-to-two program operators submitting program plans in the current biennium, resulting in one-to-two transactions. In the next biennium, DEQ will assess the first and second annual fees. If DEQ approves multiple programs, DEQ will divide the annual fee evenly among all programs.

Table 5
Fee Schedule
Drug Take-Back Program Fees

Description	Amount
Plan Review Fee	
Due upon submission of proposed plan or updated plan; updated plans must be submitted at least once every four years	$75,000
Annual Fee	
First annual fee	$345,000
Second annual fee	$210,000
Subsequent annual fees	$125,000
If multiple drug take-back programs exist, DEQ will divide the annual fee evenly among all programs.	
Hourly Fee for Other Work on Behalf of a Drug Take-Back Program	
Maximum hourly fee	$250

Table 5 Fee Schedule Drug Take-Back Program Fees	
Description	**Amount**
DEQ will invoice each program operator quarterly for hourly fee work associated with their drug take-back program. The hourly fee charged will be calculated to reasonably reflect DEQ's expenses for the work performed.	

Statement of Fiscal and Economic Impact

The proposed rules would have a direct fiscal impact on entities submitting a plan to DEQ for operating a drug take-back program, approved drug take-back program operators, and the drug manufacturers participating in approved programs. The direct fiscal impact will be in the form of fees paid to DEQ and additional administrative costs for complying with proposed rules. These proposed rules and their associated costs are described above under Summary of Impacts.

The large number of participating drug manufacturers that share the cost will reduce the fiscal burden on each affected manufacturer and program operator. Based on inquiries DEQ has received and the complexity of operating drug take-back programs, DEQ anticipates that at most two program operators will submit plans to operate drug take-back programs in Oregon. DEQ expects it will approve at most two drug take-back programs. These potential and approved program operators are likely to be small businesses, but drug manufacturers will fund the programs. DEQ estimates there will be hundreds of participating drug manufacturers that can share the fees and additional administrative costs. For context, the proposed drug take-back program for Washington State lists over 450 participating drug producers. The Oregon Board of Pharmacy's website lists over 2,000 drug manufacturers registered to sell drugs into Oregon, but not all of these manufacturers will be required to participate in drug take-back programs.

The proposed rules likely will not have a significant adverse impact on program operators and drug manufacturers that are small businesses, as DEQ's costs are likely to be small compared to a drug take-back program's annual operating costs. These costs may also be spread among a large number of participating manufacturers. A recently submitted drug take-back program plan for Washington State estimated its annual operating costs at $4 million. Assuming operating costs of a drug take-back program in Oregon are comparable and only one drug take-back program is approved in Oregon, DEQ's combined one-time plan review fee and first annual fee, or $420,000, would represent approximately 10.5 percent of a drug take-back program's annual operating costs. After the first annual fee, which is intended to help capture startup costs, the annual fee will be reduced to $210,000 and then to $125,000 thereafter, or approximately 5.3 percent and 3.1 percent of the estimated overall annual cost, respectively. As described in Summary of Impacts above, DEQ expects administrative costs associated with DEQ's other proposed rules to be incidental or small.

DEQ expects that an increase in costs in the supply or distribution chain or in drug prices as a result of costs related to DEQ's proposed fees and rules would likely be negligible. In terms of indirect fiscal impact, participating drug manufacturers may pass their direct costs to other entities in the drug supply and distribution chains or to consumers. Entities in the drug supply and distribution chains include wholesalers, insurance providers, distributors such as pharmacies, and healthcare providers. The U.S Government Accountability Office's "Report to Congressional Requesters: Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals (GAO-18-40)" suggests that costs associated with DEQ's proposed rules, including fees, would be a small portion of a drug manufacturer's operating costs. The report is available at: GAO Report. DEQ estimates

there will be hundreds of participating drug manufacturers among whom the fees and additional administrative costs could be shared.

Statement of Cost of Compliance

State agencies, local governments and the public

The proposed rules and fees do not have a direct impact on state agencies, local governments, or the public, unless they are drug take-back program operators. Such operators must be 501(c)(3) organizations.

State agencies, local governments, and the public might experience an indirect impact if the drug manufacturers participating in a drug take-back program pass the cost of DEQ's fees or of complying with DEQ's proposed rules to consumers through increased drug prices. As mentioned above, an increase in drug prices due to fees or additional administrative costs associated with complying with the proposed rules would likely be negligible.

Large businesses - Businesses with more than 50 employees

The proposed rules and fees directly impact potential and approved drug take-back program operators and drug manufacturers participating in drug take-back programs in Oregon. ORS 459A.203 exempts manufacturers who manufacture covered drugs for fewer than 50 patients in Oregon from the requirement to participate in a drug take-back program. Many drug manufacturers are large businesses. Potential and approved program operators may also be large businesses. As mentioned in Fiscal and Economic Impact, above, fees, and any additional administrative costs associated with DEQ's proposed rules, are likely to be a small portion of a program operator's and participating drug manufacturers' operating costs.

In terms of indirect impacts on large businesses, drug manufacturers may pass the cost of the fees and administrative costs associated with proposed rules on to businesses in the drug supply and distribution chains. These businesses include wholesalers, insurance providers, and distributors, such as pharmacies and healthcare providers, and may be large businesses. As mentioned in Fiscal and Economic Impact, above, an increase in supply costs due to the cost of complying with DEQ's proposed fees and rules would likely be negligible.

Small businesses – Businesses with 50 or fewer employees

Program operators, drug manufacturers, and entities in the drug supply and distribution chains that are small businesses would experience the same impact as large businesses.

ORS 183.336 Cost of Compliance Effect on Small Businesses

1. Estimated number of small businesses and types of businesses and industries with small businesses subject to proposed rule.

At least two small businesses expressed interest in submitting plans to act as program operator for drug take-back programs. Based on available information, DEQ is unable to estimate the number of small business drug manufacturers that would be required to participate in the Drug Take-Back Program.

2. Projected reporting, recordkeeping and other administrative activities, including costs of professional services, required for small businesses to comply with the proposed rule.

Additional administrative activities related to DEQ's proposed rules include:

- A program operator submitting a program plan to operate a drug take-back program must include each participating drug manufacturer's Oregon Board of Pharmacy registration number.
- A program operator seeking a waiver from establishing drop-off sites in a particular county, or seeking DEQ approval to provide additional services and collection events where the program operator is unable to establish and maintain a required drop-off site, must provide certain information in its request for a waiver or approval. This includes why a drop-off site cannot be established or maintained and how the proposed services will continue to provide convenient service. The program operator must also seek local government concurrence and agree to solicit potential authorized collectors to host a drop-off site in the affected county or population center on at least an annual basis.

3. Projected equipment, supplies, labor and increased administration required for small businesses to comply with the proposed rule.

See previous response.

4. Describe how DEQ involved small businesses in developing this proposed rule.

DEQ included a representative of a small business with experience in operating drug take-back programs on the advisory committee. The advisory committee also included representatives from a variety of stakeholders, including small, independent pharmacies.

Documents relied on for fiscal and economic impact

Document title	Document location
MED-Project: A Product Stewardship Plan For Covered Drugs from Households, State of Washington, July 1, 2019	Washington State Department of Health website: WA DOH
Report to Congressional Requesters: Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals (GAO-18-40)	United States Government Accountability Office website: US GAO

Advisory committee fiscal review

DEQ appointed an advisory committee.

As ORS 183.33 requires, DEQ asked for the committee's recommendations on:

- Whether the proposed rules would have a fiscal impact,
- The extent of the impact, and

- Whether the proposed rules would have a significant adverse impact on small businesses; if so, then how DEQ can comply with ORS 183.540 reduce that impact.

The committee reviewed the draft fiscal and economic impact statement and its findings are stated in the approved minutes dated April 28, 2020. The meeting summary is posted on the committee's DEQ web page: Drug Take-Back Rulemaking.

The committee agreed that the proposed rules would have a fiscal impact. One committee member said that, because of the point-of-sale limitations, he did not see much fiscal impact for authorized collectors to operate drop-off sites and that the benefits of a drug take-back program would outweigh the costs. In terms of the extent of impact, three committee members said that there was not information available for them to agree that any indirect impact would likely be "negligible," and that "negligible" was a relative term. None of the other committee members disagreed with DEQ's conclusion that the indirect impact would likely be negligible. The committee determined the proposed rules would not have a significant adverse impact on small businesses in Oregon.

Housing cost

As ORS 183.534 requires, DEQ evaluated whether the proposed rules would have an effect on the development cost of a 6,000-square-foot parcel and construction of a 1,200-square-foot detached, single-family dwelling on that parcel.

DEQ determined the proposed rules would have no effect on the development costs. The proposed rules primarily impact drug take-back program operators and drug manufacturers participating in their drug take-back programs. Even if participating drug manufacturers pass associated costs and fees onto other entities in the drug supply and distribution chains or onto consumers, the resulting increase in the cost of goods to consumers would likely be negligible.

Federal relationship

ORS 183.332, 468A.327 and OAR 340-011-0029 require DEQ to attempt to adopt rules that correspond with existing equivalent federal laws and rules unless there are reasons not to do so.

The proposed rules add requirements that are in addition to those in federal requirements. The following exemption from adopting rules that correspond with equivalent federal laws and rules applies to this proposal: there is no corresponding federal regulation. See ORS 183.332(6). The proposed rules apply to a program created by Oregon statutes to address the environmental and health impacts of unused or improperly disposed drugs. No comparable federal program or requirement exists.

What alternatives DEQ considered, if any

DEQ considered the following alternatives to its fees:

1. DEQ considered maintaining the status quo by not establishing fees. DEQ did not adopt this alternative because it would not provide the funding from manufacturers that DEQ needs to administer the Drug Take-Back Program, as required by the legislature.

2. DEQ considered apportioning the annual and hourly fees, if multiple drug take-back programs exist, by charging costs associated with a particular program to that program and dividing the remainder evenly among the number of approved programs. After some consideration, DEQ determined that apportioning the annual and hourly fees in this manner would be unnecessary, costly, and administratively difficult. The annual fee covers DEQ's ongoing administration costs, which are likely to benefit all drug take-back programs, and dividing the annual fee evenly among those programs would be efficient and provide more certainty for program operators. Hourly fees will cover other work DEQ performs on behalf of a drug take-back program, and will be charged to that program or programs. Apportioning hourly fees as this alternative provides is thus unnecessary.

3. DEQ considered apportioning the annual and hourly fees, if multiple drug take-back programs exist, by the market share of the drug manufacturers participating in the respective programs. DEQ did not adopt this alternative because it would require programs to disclose the market data of their participants and may be administratively burdensome for both DEQ and program operators. This alternative would also be difficult to implement if manufacturers switch programs.

Land Use

Land-use considerations

In adopting new or amended rules, ORS 197.180 and OAR 340-018-0070 require DEQ to determine whether the proposed rules significantly affect land use. If so, DEQ must explain how the proposed rules comply with state wide land-use planning goals and local acknowledged comprehensive plans.

Under OAR 660-030-0005 and OAR 340 Division 18, DEQ considers that rules affect land use if:

- The statewide land use planning goals specifically refer to the rule or program, or the rule or program is reasonably expected to have significant effects on:
    - Resources, objects, or areas identified in the statewide planning goals, or
    - Present or future land uses identified in acknowledge comprehensive plans

DEQ determined whether the proposed rules involve programs or actions that affect land use by reviewing its Statewide Agency Coordination plan. The plan describes the programs that DEQ determined significantly affect land use. DEQ considers that its programs specifically relate to the following statewide goals:

Goal	Title
5	Natural Resources, Scenic and Historic Areas, and Open Spaces
6	Air, Water and Land Resources Quality
11	Public Facilities and Services
16	Estuarine Resources
19	Ocean Resources

Statewide goals also specifically reference the following DEQ programs:

- Nonpoint source discharge water quality program – Goal 16
- Water quality and sewage disposal systems – Goal 16
- Water quality permits and oil spill regulations – Goal 19

Determination

DEQ determined that these proposed rules do not affect land use under OAR 340-018-0030 or DEQ's State Agency Coordination Program.

EQC Prior Involvement

DEQ did not present additional information specific to this proposed rule revision.

Advisory Committee

Background

DEQ convened the Drug Take-Back Program 2020 Rulemaking advisory committee. The committee included representatives from pharmaceutical manufacturers, pharmacies, the Board of Pharmacy, associations for local governments and a substance abuse prevention organization and met twice. The committee's web page is located at: Advisory Committee.

The committee members were:

Rulemaking Name Advisory Committee	
Name	**Representing**
Scott Barrie	Association for Accessible Medicines
Rob Bovett	Association of Oregon Counties
Marcus Cox	Klamath Health Partnership, Inc.
Allyn Cripe / Dwight Holton*	Lines for Life
Naomi Hunsaker	Washington County Department of Health and Human Services
Shawn Miller	NW Grocery Association
Steven Miller	Cascade Pharmacy
Marc Rizzo	Oregon State Pharmacy Association
Joseph Schnabel	Oregon Board of Pharmacy
Cara Simaga	Stericycle
Suzie Smith	Oregon Association of Clean Water Agencies
David Spangler	Consumer Healthcare Products Association
Donna Steward	Pharmaceutical Research and Manufacturers of America
Jim Wilson	MED-Project
Scott Winkels	League of Oregon Cities
*Allyn Cripe represented Lines for Life at the first committee meeting. At Lines for Life's request, Dwight Holton represented the organization at the second committee meeting.	

Meeting notifications

To notify people about the advisory committee's activities, DEQ:

- Sent GovDelivery bulletins, a free e-mail subscription service, to the following lists:
  - Rulemaking
- Added advisory committee announcements to DEQ's calendar of public meetings at DEQ Calendar.

Committee discussions

In addition to the recommendations described under the Statement of Fiscal and Economic Impact section above, the committee discussed implementation issues, particularly the issue of encouraging program operators to solicit and enter into agreements with existing drug take-back sites. Several committee members expressed a desire that all willing existing sites, including sites on tribal land, should have the option to join a statewide program.

Public Engagement

Public notice

DEQ provided notice of the proposed rulemaking and rulemaking hearing by:

- Filing notice with the Oregon Secretary of State for publication in the July 1, 2020, Oregon Bulletin;
- Posting the Notice of Proposed Rulemaking and draft rules on the web page for this rulemaking: Drug Take-Back Rulemaking
- Emailing interested parties on the following DEQ lists through GovDelivery:
    - Rulemaking
    - Drug Take-Back
- Emailing the following key legislators required under ORS 183.335:
    - Senator Michael Dembrow; Chair, Senate Interim Committee on Environment and Natural Resources
    - Senator Alan Olsen, Vice-Chair, Senate Interim Committee on Environment and Natural Resources
    - Senator Lynn Findley, Member, Senate Interim Committee on Environment and Natural Resources
    - Senator Floyd Prozanski, Member, Senate Interim Committee on Environment and Natural Resources
    - Senator Arnie Roblan, Member, Senate Interim Committee on Environment and Natural Resources
    - Representative Karin Power, Chair, House Interim Committee on Energy and Environment
    - Representative Daniel Bonham, Vice-Chair, House Interim Committee on Energy and Environment
    - Representative Janeen Sollman, Vice-Chair, House Interim Committee on Energy and Environment
    - Representative Ken Helm Member, House Interim Committee on Energy and Environment
    - Representative E. Werner Reschke, Member, House Interim Committee on Energy and Environment
    - Representative Andrea Salinas, Member, House Interim Committee on Energy and Environment
    - Representative Sheri Schouten, Member, House Interim Committee on Energy and Environment
    - Representative David Brock Smith, Member, House Interim Committee on Energy and Environment
    - Representative Marty Wilde, Member, House Interim Committee on Energy and Environment
    - Representative Cedric Hayden, Vice-Chair, House Interim Committee on Health Care
    - Representative Rachel Prusak, Vice-Chair; House Interim Committee on Health Care

    - Representative Teresa Alonso Leon, Member, House Interim Committee on Health Care
    - Representative Christine Drazan, House Republican Leader and Member, House Interim Committee on Health Care
    - Representative Mitch Greenlick, Member, House Interim Committee on Health Care
    - Representative Alissa Keny-Guyer, Member, House Interim Committee on Health Care
    - Representative Raquel Moore-Green, Member, House Interim Committee on Health Care
    - Representative Ron Noble, Member, House Interim Committee on Health Care
    - Representative Rob Nosse, Member, House Interim Committee on Health Care
- Posting on the DEQ event calendar: DEQ Calendar

Public Hearing

DEQ held one public hearing. DEQ received two comments at the hearing. Later sections of this document include a summary of the two comments received during the open public comment period, DEQ's responses, and a list of the commenters. Original comments are on file with DEQ.

Presiding Officers' Record

Hearing 1

Date	July 15, 2020
Place	Online only
Start Time	2:25 p.m.
End Time	2:40 p.m.
Presiding Officer	Michael Lee

Presiding Officer's report

The presiding officer convened the hearing, summarized procedures for the hearing, and explained that DEQ was recording the hearing. The presiding officer asked people who wanted to present verbal comments to sign the registration list, or if attending by phone, to indicate their intent to present comments. The presiding officer advised all attending parties interested in receiving future information about the rulemaking to sign up for GovDelivery email notices.

As Oregon Administrative Rule 137-001-0030 requires, the presiding officer summarized the content of the rulemaking notice.

Twenty-four people attended by teleconference or webinar. Two people commented orally and no one submitted written comments at the hearing.

Summary of Public Comments and DEQ Responses

Public comment period

DEQ accepted public comment on the proposed rulemaking from June 17, 2020, until 4 p.m. on July 17, 2020.

For public comments received by the close of the public comment period, the following table organizes comments into categories with cross references to the commenter number. DEQ's response follows the summary. Original comments are on file with DEQ.

DEQ changed the proposed rules in response to comments described in the response sections below.

List of Comments		
Comment #	**Comment Summary**	**Commenter Numbers**
General Support		
1	*Commenter supports the Drug Take-Back Program.* **DEQ response:** DEQ appreciates the review of proposed rules and feedback.	1, 2
Comments on OAR 340-098-0300: Requiring Board of Pharmacy-issued registration numbers for participating manufacturers in a drug take-back plan or updated plan		
2	*Requiring the registration numbers for covered manufacturers goes beyond the scope of the statute, which only requires that a program plan "identify and provide contact information" for each participating manufacturer. See ORS 459A.209(2)(a). Furthermore, Oregon Board of Pharmacy regulations may not require all covered manufacturers to register with the Board of Pharmacy, and may also require entities not qualifying as covered manufacturers under the Drug Take-Back Law to register with the Board of Pharmacy.* **DEQ response:** The Drug Take-Back Law requires that a program identify itself. It also authorizes the EQC to adopt any rules necessary for effective administration of the program. The numbers will help DEQ identify manufacturers that are not participating in a drug take-back program, but may be required to. The Board of Pharmacy has advised that all covered manufacturers required to participate in a drug take-back program are also required to register as manufacturers with the	3

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	Board of Pharmacy. The Board of Pharmacy also registers a smaller number of manufacturers not covered under the Drug Take-Back Law, such as repackagers. The Board of Pharmacy is developing data filters to exclude these non-covered manufacturers from its list of registered manufacturers. DEQ can compare the filtered list with the program operators' lists of participating manufacturers as a first step in identifying manufacturers potentially covered under the Drug Take-Back Law that are not participating in a drug-take back program. In the event that Board of Pharmacy registration requirements change or DEQ finds a more effective approach for identifying noncompliance, DEQ has modified the proposed rule to clarify that DEQ may drop the requirement to provide registration numbers in the future.	
3	*DEQ should reference the Oregon Board of Pharmacy's registration database at https://orbop.mylicense.com/verification/Search.aspx?Facility=Y in the proposed rule. DEQ should note that registration number should be included only if applicable.* **DEQ response:** DEQ declines to reference the URL in the proposed rule, as the URL may change. However, DEQ will include a link to the URL in its Drug Take-Back web page and in its Guide for Oregon Drug Take-Back Programs for program operators and covered manufacturers. DEQ plans to release the Guide in August. DEQ has modified the proposed rule so that plans and updated plans may indicate if a participating manufacturer does not have to register with the Board of Pharmacy.	3
4	*Given potential confusion and challenges around providing the Oregon Board of Pharmacy registration numbers, before the Board of Pharmacy or the EQC take any enforcement action, manufacturers not participating in a drug take-back program should be given notice and an opportunity to come into compliance or to resolve any misunderstanding over compliance.* **DEQ response:** Assuming that the EQC adopts the proposed rule authorizing DEQ to enforce the Drug Take-Back Law on the EQC's behalf, DEQ will provide notice as required under ORS	3

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	459A.239 and offer potential covered manufacturers an opportunity to come into compliance or resolve any misunderstanding over compliance with the Drug Take-Back Law.	
Comments on OAR 340-098-0350: Services and Collection Events in Place of a Required Drop-Off Site		
5	*Commenter supports requirement that a program operator who requests DEQ to waive drop-off sites in a particular county or to approve additional services and events in place of a required drop-off site must demonstrate good faith efforts to obtain concurrence by affected local governments with any proposed service. Commenter suggests further requiring consultation with historically impacted communities to help ensure equitable access to drug drop-off services.* **DEQ response:** DEQ appreciates the suggestion to consider clarifying what equitable access means. DEQ interprets the requirement under ORS 459A.209(4) that drop-off sites be located to provide reasonably convenient and equitable access to all residents to include access for minority, low-income, rural and other historically underserved, communities. DEQ has modified the proposed rule related to waivers and approvals to clarify that ensuring proposed services and events will provide reasonably convenient and equitable access to all residents should include engaging minority, lower-income, rural and other historically underserved communities. DEQ has also modified OAR 340-098-0300 to clarify that reasonably convenient and equitable access to a drop-off site includes access for historically underserved communities and also to require program operators to include a goal for fostering public awareness in historically underserved communities in Oregon as part of setting forth program goals.	4
6	*In areas where there are not enough potential authorized collectors to fully support the state program, requiring program operators to submit to a waiver process is unnecessarily burdensome. Instead, program operators can address possible solutions in their plans (e.g., through collection events or mail-in services) for serving these areas.*	5

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	DEQ response: Program operators can submit requests for waivers of drop-off sites, or approval of services or events in place of a drop-off site, to DEQ in a proposed plan, in an updated plan, or as a request for preapproval of a change to the program. DEQ will review such requests for waivers and approvals under processes described for reviewing plan submittals in ORS 459A.209(7) and requests for preapproval of program changes in ORS 459A.212(1). The proposed rule describes factors DEQ will consider in determining whether additional services will provide convenient services to all residents in areas that lack drop-off sites. The rule is intended to provide transparency and help program operators provide the information DEQ will need for its determination.	
7	*Commenter supports DEQ's proposed rule related to waivers and approvals of additional services and events. The rule should be revised so that a program operator will work with a local government body in an affected county upon the local government body's request.* **DEQ response:** DEQ believes drug take-back programs would better serve covered entities if a program operator actively seeks local government concurrence in population centers or counties where required drop-off sites will not be established or maintained, instead of simply responding to solicitation by local governments. DEQ has modified the proposed rule to clarify that a program operator must demonstrate good faith efforts to obtain concurrence from appropriate local government bodies.	6, 7
8	*The proposed rule should specify a timeline for when a waiver or approval request should be submitted (commenter suggests 30 days prior to implementation) and when DEQ should decide on that request (commenter suggests within 10 days of receiving a request).* **DEQ response:** Requiring DEQ to respond to requests in ten days may constrain DEQ's and the program operator's ability to work together to develop an appropriate level of services to address the absence of a required drop-off site. As described in comment 6, DEQ will review requests for waivers and approvals	7

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	under the processes and timelines set forth in ORS 459A.209(7) and ORS 459A.212(1).	
9	*DEQ should consider listing the following example as a way to demonstrate good faith efforts to solicit and enter into agreements with potential authorized collectors: "evidence of repeated outreach and the program operator providing timely and reasonable responses to any expressions of interest."* **DEQ response:** DEQ has modified the proposed rule to include outreach to identify, contact and engage with potential authorized collectors as an example of good faith efforts.	7
10	*In explaining why a program cannot establish or maintain a drop-off site, a program operator should explain any conditions for participation that potential authorized collectors refused.* **DEQ response:** DEQ has modified the proposed rule to address this suggestion.	7
11	*DEQ should remove "to DEQ's satisfaction" from the proposed rule and require DEQ to approve a request for a waiver or for additional services if DEQ determines that:* • *The request includes the information requested in the proposed rule;* • *The proposed services are a reasonable alternative to the required drop-off site(s) based on the geography, the population, the number of potential authorized collectors, the number of participating authorized collectors, and other circumstances in the affected population center or county; and* • *The proposed services will provide reasonably convenient and equitable access to all residents of the affected population center or county.* **DEQ response:** DEQ has modified the proposed rule to incorporate part of this suggestion in the factors for DEQ's consideration.	7

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Comments on OAR 340-098-0390: Fees		
12	*Suggested revision in OAR 340-098-0390(1): "Each program operator must pay ~~the~~ reasonable fees in this rule to DEQ."* **DEQ response:** This suggestion could be interpreted as requiring a program operator to pay only fees that it considers reasonable. ORS 459A.242 already requires fees to be "reasonably calculated to cover the costs of administering ORS 459A.200 to 459A.266."	5
13	*The plan review fee should be restricted to one charge per program operator, instead of for each updated plan.* **DEQ response:** DEQ has revised the proposed rule to clarify that the plan review fee applies only to the initial plan submitted to DEQ and not to an updated plan.	5
14	*DEQ should revise the fee rule to indicate that the plan review fee is "not to exceed" $75,000 and that DEQ will submit an updated review fee projection not later than 15 days prior to the due date for submittal of a plan. DEQ should also propose that its annual fees will not exceed the amounts set forth in OAR 340-098-0390(3)(a). Finally, DEQ should propose that DEQ "shall," rather than "may," reduce the annual fee for a given fiscal year to ensure fee revenue approximately matches DEQ's projected costs for that year.* **DEQ response:** The Drug Take-Back Law requires DEQ to establish fees under ORS 459A.242. Adopting these suggestions would make the fee amounts unclear and may require DEQ to engage in further rulemaking to establish the actual plan review and annual fees. DEQ intends to establish all fees with this proposed rule. DEQ has structured the fees so that fee amounts are clearly established, while still allowing DEQ flexibility to adjust the fees downward in a given year to ensure fee revenue approximately matches DEQ's costs.	5
15	*DEQ should propose that if the revenue collected from the plan review fee and annual fee exceeds DEQ's actual costs for the program in a given fiscal year, DEQ will reduce the annual fee*	5

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	by not less than the excess amount in the next subsequent year, instead of in a subsequent year. **DEQ response:** Requiring DEQ to reduce the annual fee in a given year by excess revenue collected the previous year could hinder program planning and budgeting and could cause DEQ to delay or to have to find other funds to support necessary administration in a given year. To allow for adequate program planning and budgeting, DEQ has modified the proposed rule so that DEQ will reduce the annual fee by the excess amount in a subsequent year or years.	
16	*DEQ must define what constitutes "other work" subject to the hourly fee rate. DEQ should define the hourly fee to cover any other work that DEQ "reasonably" determines is necessary on behalf of a drug take-back program "and supports with records of the time and descriptions of the activities for such other work." Program operators should not be subject to unlimited fee assessments.* *DEQ should revise the proposed rule to state that DEQ "may," instead of "will," invoice program operators on a quarterly basis; that the hourly fee will be calculated to reasonably reflect DEQ's "time and activities expenses" for the work performed; and that "DEQ must provide each program operator advance notice of any such work that amounts to greater than $10,000 in proposed hourly fees."* **DEQ response:** DEQ believes the current proposed description of the hourly fee ("any other work that DEQ determines is necessary on behalf of a drug take-back program") better reflects the description in ORS 459A.242 ("any other work that the department must do on behalf of a drug take-back program") than the suggested revision. DEQ is committed to operating an efficient and transparent program, with fees reasonably calculated to cover the costs of administration, as required by statute. The proposed rule states that DEQ will report its current and projected program expenditures and revenue every fiscal year, which will include other work expected to cost greater than $10,000. OAR 340-098-0390(5). DEQ will calculate the hourly fee to reasonably reflect	5

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	its expenses for the work performed. OAR 340-098-0390(4)(b). Finally, DEQ will reduce the annual fee in a subsequent year or years if the plan review and annual fee revenue exceeds DEQ's actual costs for the program in a given fiscal year. OAR 340-098-0390(3)(a)(E). DEQ has modified the proposed rule to clarify that DEQ will invoice for the hourly fee only when there are charges.	
17	*OAR 340-098-0390(5) should be revised to include: "DEQ will provide a detailed breakdown of all time and activities recorded and fees charged under this section."* **DEQ response:** DEQ will provide general categories of expenses in reporting its current and projected program expenditures and revenue under OAR 340-098-0390(5).	5
Comments on Possible Additional Rules, Clarifications on Statute		
18	*To ensure full engagement of all stakeholders, DEQ should affirm, through appropriate regulatory coverage, that confidential business information will be protected from disclosure outside the state government.* **DEQ response:** DEQ will protect confidential information to the extent required by ORS 459A.254 and allowed under the Oregon Public Records Law (ORS 192.311 to 192.478). The Guide for Oregon Drug Take-Back Programs that DEQ plans to release in August will include instructions for submitting confidential information to DEQ.	5
19	*There is no practical or policy benefit to limiting program operator status solely to 501(c)(3) entities. The current limitation indicates a misunderstanding of the tax and operational features of a 501(c)(3) formation structure. Future legislative amendments could provide the additional benefits offered by for-profit providers.* **DEQ response:** This comment relates not to the proposed rules, but to the requirements of ORS 459A.206. DEQ appreciates the comment.	5

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20	*The statute contains multiple references to submission of plans, reports and other materials in "a form and manner prescribed by the Department of Environmental Quality." See, e.g. ORS 459A.209, 459A.212, 459A.227, and 459A.230. The proposed rules fail to specify the form or manner of any such submissions, or identify when this information will be available. DEQ should make public the form and manner of these submissions, beginning with the plan proposal.* **DEQ response:** DEQ will provide further guidance on the form and manner for submission of the drug take-back program plan, requests for changes to a program, biennial survey questions, and the annual report in the Guide for Oregon Drug Take-Back Programs that DEQ plans to release in August.	5
21	*DEQ should allocate sufficient state funding, and if necessary, a portion of drug take-back fees, to coordinate the program's consumer-facing aspects. For example, DEQ is best positioned to establish the consumer-facing website. Program operators can provide the information for the maintenance of this website. Requiring competing program operators to coordinate the establishment and launch of a website outside of the confines of a trade association or similar body invites a potential violation of the Sherman Act (15 U.S.C. §§ 1 and 2), for which the state would have to take multiple additional steps to provide potential federal immunity.* **DEQ response:** ORS 459A.227 requires program operators to promote and provide public outreach and education about the Drug Take-Back Program. ORS 459A.227(3) specifically requires program operators, not DEQ, to coordinate with each other to ensure that covered entities can easily identify, understand and access services provided by all drug take-back programs in Oregon. Programs, at a minimum, must provide a single toll-free telephone number and a single website address for the Program. Program operators should take necessary steps to comply with ORS 459A.227 consistent with the antitrust exemption in ORS 459A.251.	5
22	*Proposed rules should be finalized before the deadlines set forth in statute, which requires a program operator to submit its plan*	5

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	to DEQ by November 1, 2020, and a drug take-back program to be operational by July 1, 2021. Otherwise, authority to submit, consider, assess fees, or otherwise implement the program will be lacking. **DEQ response:** DEQ intends to submit proposed rules to the EQC in September 2020 for adoption.	
23	*ORS 459A.224's disposal requirements extend only to disposal in Oregon under* Daniels Sharpsmart, Inc. v. Smith, 889 F.3d 608 *(9th Cir. 2018) (upholding an injunction that prohibited California from applying its Medical Waste Management Act to disposal activities outside California as a likely violation of the Dormant Commerce Clause). Commenter would support any efforts to reconcile ORS 459A.224 with these constitutional limits through the drafting of regulations.* **DEQ response:** This comment relates not to a proposed rule, but to ORS 459A.224, which identifies the types of facilities where covered drugs may be disposed of. DEQ is not proposing a rule related to ORS 459A.224 at this time, but may consider proposing future rulemaking for ORS 459A.224 as DEQ reviews the EPA's new rule on Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (subpart P to 40 C.F.R. part 266) for potential adoption in Oregon.	7
24	*ORS 459A.224 requires covered drugs to be disposed of at either a hazardous waste disposal facility or a municipal solid waste incinerator that is permitted to accept pharmaceutical waste. EPA and Oregon DEQ air regulations use the term "municipal waste combustor," but not "municipal solid waste incinerator." DEQ should clarify this term to include incinerator options such as Hospital Medical Infectious Waste Incinerators (HMIWI). EPA regulations require HMIWI to have air pollution limits that are well below operating limits for Municipal Waste Combustors (MWC) and very close or more stringent than permitted Hazardous Waste Combustors (HWC), which are assumed to be the types of combustors referenced by ORS 459A.224. Under the EPA Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for*	8

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	Nicotine (subpart P to 40 C.F.R. part 266), controlled substances that are a hazardous waste pharmaceutical and are generated by healthcare generators, as well as household waste pharmaceuticals collected through drug take-back programs or events, can both be managed at HMIWI or MWC facilities (40 CFR 266.506). *DEQ should also consider that drugs collected through take-back programs are generated by households. Household wastes (even if a hazardous waste) are exempt from EPA and DEQ hazardous waste regulations. DEQ does not mandate that any other household hazardous wastes collected be sent to a hazardous waste disposal facility. Thus, this should not be the only option available for drug take-back program waste. HMIWI or MWC facilities should also be a viable option. Limiting disposal options to only hazardous waste disposal facilities (and potentially MWCs) will also have a tremendous cost to the drug take-back program operations. There are also environmental costs in terms of transporting such waste to the limited number of hazardous waste disposal facilities.* **DEQ response:** This comment relates not to a proposed rule, but to ORS 459A.224, which identifies the types of facilities where covered drugs may be disposed of. DEQ is not proposing a rule related to ORS 459A.224 at this time, but may consider proposing future rulemaking for ORS 459A.224 as DEQ reviews the EPA's new rule on Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (subpart P to 40 C.F.R. part 266) for potential adoption in Oregon.	
25	*Commenter is unsure what Oregon's response will be to the EPA's new final rule on Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (subpart P to 40 C.F.R. part 266) and asks for clarification. There could be a conflict between the Drug Take-Back Law and the EPA rule in how to treat hazardous waste disposal at a long-term care facilities, specifically skilled nursing facilities and intermediate care facilities. The EPA rule would seem to require that hazardous pharmaceutical waste would need to be handled separately from non-hazardous*	9

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	pharmaceutical waste, but the Drug Take-Back Law seems to allow all waste pharmaceuticals in a take-back receptacle. **DEQ response:** DEQ plans to propose rules adopting management standards for hazardous waste pharmaceuticals at least as stringent as those in EPA's new final rule. DEQ does not believe the new EPA rule and the Drug Take-Back Law are in conflict. The Drug Take-Back Law is intended for household pharmaceuticals and requires program operators to comply with all applicable federal and state laws for the disposal of covered drugs. Drop-off sites at long-term care facilities must operate under applicable federal regulations: "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." See ORS 459A.218(2)(f) (emphasis added). To the extent that federal regulations, including this EPA rule, would restrict the ability of a long-term care facility to operate a drop-off site, the facility should comply with those restrictions. Once Oregon adopts new standards for hazardous waste pharmaceuticals, the facility should comply with these standards as well.	
Other Comments		
26	*Commenter, a prospective program operator, intends to engage law enforcement agencies and existing collection sites as authorized collectors.* **DEQ response:** This comment does not relate to the proposed rules. However, DEQ appreciates the comment.	7
27	*In the event that multiple programs are approved, how can programs "share" drop-off sites? DEQ should standardize how it will evaluate each plan to ensure that approved programs are sharing the burdens and responsibilities of compliance responsibly.* **DEQ response:** DEQ will evaluate each program plan to ensure that the plan's proposed network of drop-off sites, along with other collection services, provides convenient service in every county in Oregon. DEQ does not require sharing, but is open to	7

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	programs proposing to share drop-off sites or other collection services; for instance, where the number of potential authorized collectors interested in hosting drop-off sites is limited. Program operators must determine the terms for that sharing in agreements among themselves (e.g., oversight of service provider, tracking and reporting collections, cost sharing). DEQ has allowed program operators to share sites in this manner in Oregon's E-Cycles program. DEQ intends to describe in its Guide for Oregon Drug Take-Back Programs how program plans can identify shared sites and services and ensure appropriate oversight and accurate tracking and reporting of data from them. DEQ plans to release the Guide in August.	

List of Commenters				
#	**Name**	**Organization**	**Comment Number**	**Hearing #**
1	Sherry Statler	General Public	1	
2	Steven C. Anderson	National Association of Chain Drug Stores	1	
3	Anne Vogel-Marr	Pharmaceutical Product Stewardship Work Group	2, 3, 4	
4	Marveita Redding	City of Portland Bureau of Environmental Services	5	
5	Domingo Isasi	Inmar Rx Solutions	6, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22	
6	Victoria Travis	MED-Project USA	7	1
7	Jim Wilson	MED-Project USA	7, 8, 9, 10, 11, 23, 26, 27	

List of Commenters				
#	Name	Organization	Comment Number	Hearing #
8	Cara Simaga	Stericycle	24	1
9	Eric Lintner	Consonus Pharmacy Services	25	

Implementation

Notification

The proposed rules would become effective upon filing on approximately Sept. 21, 2020. DEQ would notify affected parties through emailing interested parties through the GovDelivery email list for Drug Take-Back and by posting an announcement on the DEQ website. DEQ is also in regular contact with companies that are likely subject to this proposed rule.

Compliance and enforcement

- Affected parties - DEQ anticipates that two to three program operators and hundreds of drug manufacturers would be subject to the proposed rules. These entities are already subject to the Drug Take-Back Law. DEQ would act on the EQC's behalf under ORS 459A.239 to work with program operators and covered manufacturers on compliance, as needed.
- DEQ staff - DEQ staff would work with DEQ's Office of Compliance and Enforcement and the Board of Pharmacy to coordinate compliance and enforcement efforts.

Measuring, sampling, monitoring and reporting

- Affected parties - The proposed rules do not require any additional measuring, sampling, or monitoring. A program operator would have to provide certain information in requesting DEQ to waive drop-off sites in a particular county or to approve additional services and events in place of a required drop-off site that the program operator is unable to establish or maintain. A program operator would also have to report, where applicable, the Oregon Board of Pharmacy-issued registration number for manufacturers participating in its drug take-back program.
- DEQ staff - DEQ staff would report its current and projected program expenditures and revenue each fiscal year.

Systems

- Website – DEQ would update its website with any new or amended information on the process for requesting DEQ to waive drop-off sites in a particular county or to approve additional services and events in place of a required drop-off site that the program operator is unable to establish or maintain; and for including the Board of Pharmacy-issued registration number for covered manufacturers participating in a drug take-back program.
- Database – DEQ would use existing software to maintain the list of covered manufacturers and their corresponding Board of Pharmacy-issued registration numbers.
- Invoicing - DEQ would use its existing database for invoicing.

Training

- Affected parties - DEQ would conduct training or offer guidance for affected parties subject to new requirements.
- DEQ staff - DEQ would schedule internal trainings if needed.

Five-Year Review

Requirement

Oregon law requires DEQ to review new rules within five years after EQC adopts them. The law also exempts some rules from review. DEQ determined whether the rules described in this report are subject to the five-year review. DEQ based its analysis on the law in effect when EQC adopted these rules.

The following rules are exempt from the five-year review under ORS 183.405(4) and 183.405 (5) of the Administrative Procedures Act because they are amendments to existing rules: OAR 340-098-0000; 340-098-0010.

Determination: Five-year rule review required

DEQ will review the following years within five years of adoption:
340-098-0300; 340-098-0350; 340-098-0370; 340-098-0390

No later five years after these rules are adopted, DEQ will review the newly adopted rules for which ORS 183.405 (1) requires review to determine whether:

- The rule has had the intended effect
- The anticipated fiscal impact of the rule was underestimated or overestimated
- Subsequent changes in the law require that the rule be repealed or amended
- There is continued need for the rule.

DEQ will use “available information” to comply with the review requirement allowed under ORS 183.405 (2).

DEQ will provide the five-year rule review report to the advisory committee to comply with ORS 183.405 (3).

Accessibility Information

DEQ can provide documents in an alternate format or in a language other than English upon request. Call DEQ at 800-452-4011 or email deqinfo@deq.state.or.us.

State of Oregon Department of Environmental Quality

Drug Take-Back Program 2020 Rules – Edits Highlighted

Key to Identifying Changed Text:
~~Deleted Text~~ (strikethough)
New/inserted text (underline)

Division 98
Solid Waste: Electronics Recycling and Drug Take-Back Program

340-098-0000
Applicability

(1) ~~These rules~~ OAR 340-098-0000 to OAR 340-098-0200 apply to manufacturers of covered electronic devices sold or offered for sale in the State of Oregon for calendar years 2012 and beyond.

(2) OAR 340-098-0000, OAR 340-098-0010, and 340-098-0300 to OAR 340-098-0390 prescribe requirements and procedures for participating in, submitting program plans for, and operating, drug take-back programs under ORS 459A.200 to 459A.266.

340-098-0010
Definitions

Terms used in OAR 340-098-0000 through 340-098-0200 have the meaning provided in ORS 459A.305. Terms used in OAR 340-098-0300 to OAR 340-098-0390 have the meanings provided in ORS 459A.200 and ORS 459A.209. Definitions for additional terms used in OAR ~~340-098-0000 through 340-098-0200~~ Chapter 340, Division 98 are:

(1) "DEQ" means the Department of Environmental Quality.

(2) "Fiscal year" means the period beginning on July 1 of any year and ending on June 30 of the next year.

(3~~2~~) "Market share" means the percentage of the total number of units of covered electronic devices sold in or into Oregon the previous calendar year or most recent four quarters for which data is available, as determined by DEQ.

(4~~3~~) "Revenue need" means the total amount of revenue DEQ must collect in registration fees in order for the registration fees to approximately match DEQ's projected costs for

implementing ORS 459A.305 to 459A.355, excluding costs incurred under ORS 459A.340(4).

340-098-0300
Requirements for a Drug Take-Back Program Plan and Updated Plan

(1) DEQ may require a proposed drug take-back program plan and updated program plan submitted under ORS 459A.209 to include the Oregon Board of Pharmacy registration number issued for each covered manufacturer participating in the proposed drug take-back program, or a statement that the manufacturer is not required to register with the Oregon Board of Pharmacy.

(2) For purposes of ORS 459A.209(4), reasonably convenient and equitable access to all residents includes access for minority, lower-income, rural and other historically underserved communities.

(3) A proposed drug take-back program plan and updated program plan submitted under ORS 459A.209 must include a goal for fostering public awareness in minority, lower-income, rural and other historically underserved communities.

340-098-0350
Services and Collection Events in Place of a Required Drop-Off Site

In determining whether to grant a waiver under ORS 459A.209(3), or to approve additional services and collection events in place of a drop-off site under ORS 459A.218(3), DEQ will consider whether the program operator has demonstrated:

(1) Good faith efforts to solicit and enter into agreements with potential authorized collectors in the affected county or population center for which a waiver or DEQ approval is sought, such as through outreach to identify, contact and engage with potential authorized collectors;

(2) Why a drop-off site cannot established or maintained in the affected county or population center, including an explanation of any conditions for participation on which the program operator or any potential authorized collector could not agree;

(3) How the proposed services and, as applicable, collection events will provide reasonably convenient and equitable access to all residents in the affected county or population center, and engagement with minority, lower-income, rural and other historically underserved communities to help ensure this;

(4) Concurrence by the appropriate local governments in the affected population center or county with the proposed services and, as applicable, collection events, or an explanation of why the program operator could not obtain such concurrence despite good faith efforts;

(5) Commitment to solicit potential authorized collectors for the affected county or population center on at least an annual basis.

340-098-0370
Delegation of Authority

DEQ, on behalf of the Environmental Quality Commission, may undertake any action ORS 459A.239 authorizes.

340-098-0390
Fees

(1) Each program operator must pay the fees in this rule to DEQ.

(2) Plan review fee.

(a) The plan review fee is $75,000.

(b) A program operator must pay the plan review fee for each plan it submits under ORS 459A.209(1).

(3) Annual fee.

(a) Amount of annual fee.

(A) For fiscal year beginning July 1, 2021, the annual fee is $345,000.

(B) For fiscal year beginning July 1, 2022, the annual fee is $210,000.

(C) For fiscal year beginning July 1, 2023, and for subsequent fiscal years, the annual fee is $125,000.

(D) If multiple drug take-back programs operate in a fiscal year, each drug take-back program must pay an equal share of the total annual fee for that year.

(E) If the revenue collected from the plan review fee and annual fee exceeds DEQ's actual costs for the program in a given fiscal year, DEQ will reduce the annual fee by the excess amount in a subsequent year or years.

(F) DEQ may reduce the annual fee for a given fiscal year to ensure fee revenue approximately matches DEQ's projected costs for that year.

(b) Program operators must pay the annual fee according to the schedule below:

(A) For fiscal year beginning July 1, 2021, payment is due August 1, 2021.

(B) For fiscal year beginning July 1, 2022, and for subsequent fiscal years, DEQ will notify each program operator of the program's annual fee by October 1. Payment is due not later than 30 days after the date DEQ mails the notice.

(4) Hourly fee. The hourly fee is to cover any other work that DEQ determines is necessary on behalf of a drug take-back program.

(a) The hourly fee will not exceed $250 per hour.

(b) DEQ will calculate the hourly fee to reasonably reflect DEQ's expenses for the work performed.

(c) DEQ will invoice each program operator quarterly for any hourly fee work associated with that operator's drug take-back program. The invoice will briefly describe the work performed and the cost for that work. Payment is due not later than 30 days after the date DEQ mails the invoice.

(5) Reporting. Each fiscal year DEQ will report its current and projected program expenditures and revenue.

State of Oregon Department of Environmental Quality

Drug Take-Back Program 2020 Rules – Edits Incorporated

Division 98
Solid Waste: Electronics Recycling and Drug Take-Back Program

340-098-0000
Applicability

(1) OAR 340-098-0000 to OAR 340-098-0200 apply to manufacturers of covered electronic devices sold or offered for sale in the State of Oregon for calendar years 2012 and beyond.

(2) OAR 340-098-0000, OAR 340-098-0010, and 340-098-0300 to OAR 340-098-0390 prescribe requirements and procedures for participating in, submitting program plans for, and operating, drug take-back programs under ORS 459A.200 to 459A.266.

340-098-0010
Definitions

Terms used in OAR 340-098-0000 through 340-098-0200 have the meaning provided in ORS 459A.305. Terms used in OAR 340-098-0300 to OAR 340-098-0390 have the meanings provided in ORS 459A.200 and ORS 459A.209. Definitions for additional terms used in OAR Chapter 340, Division 98 are:

(1) "DEQ" means the Department of Environmental Quality.

(2) "Fiscal year" means the period beginning on July 1 of any year and ending on June 30 of the next year.

(3) "Market share" means the percentage of the total number of units of covered electronic devices sold in or into Oregon the previous calendar year or most recent four quarters for which data is available, as determined by DEQ.

(4) "Revenue need" means the total amount of revenue DEQ must collect in registration fees in order for the registration fees to approximately match DEQ's projected costs for implementing ORS 459A.305 to 459A.355, excluding costs incurred under ORS 459A.340(4).

340-098-0300
Requirements for a Drug Take-Back Program Plan and Updated Plan

(1) DEQ may require a proposed drug take-back program plan and updated program plan submitted under ORS 459A.209 to include the Oregon Board of Pharmacy registration number issued for each covered manufacturer participating in the proposed drug take-back program, or a statement that the manufacturer is not required to register with the Oregon Board of Pharmacy.

(2) For purposes of ORS 459A.209(4), reasonably convenient and equitable access to all residents includes access for minority, lower-income, rural and other historically underserved communities.

(3) A proposed drug take-back program plan and updated program plan submitted under ORS 459A.209 must include a goal for fostering public awareness in minority, lower-income, rural and other historically underserved communities.

340-098-0350
Services and Collection Events in Place of a Required Drop-Off Site

In determining whether to grant a waiver under ORS 459A.209(3), or to approve additional services and collection events in place of a drop-off site under ORS 459A.218(3), DEQ will consider whether the program operator has demonstrated:

(1) Good faith efforts to solicit and enter into agreements with potential authorized collectors in the affected county or population center for which a waiver or DEQ approval is sought, such as through outreach to identify, contact and engage with potential authorized collectors;

(2) Why a drop-off site cannot established or maintained in the affected county or population center, including an explanation of any conditions for participation on which the program operator or any potential authorized collector could not agree;

(3) How the proposed services and, as applicable, collection events will provide reasonably convenient and equitable access to all residents in the affected county or population center, and engagement with minority, lower-income, rural and other historically underserved communities to help ensure this;

(4) Concurrence by the appropriate local governments in the affected population center or county with the proposed services and, as applicable, collection events, or an explanation of why the program operator could not obtain such concurrence despite good faith efforts;

(5) Commitment to solicit potential authorized collectors for the affected county or population center on at least an annual basis.

340-098-0370
Delegation of Authority

DEQ, on behalf of the Environmental Quality Commission, may undertake any action ORS 459A.239 authorizes.

340-098-0390
Fees

(1) Each program operator must pay the fees in this rule to DEQ.

(2) Plan review fee.

(a) The plan review fee is $75,000.

(b) A program operator must pay the plan review fee for each plan it submits under ORS 459A.209(1).

(3) Annual fee.

(a) Amount of annual fee.

(A) For fiscal year beginning July 1, 2021, the annual fee is $345,000.

(B) For fiscal year beginning July 1, 2022, the annual fee is $210,000.

(C) For fiscal year beginning July 1, 2023, and for subsequent fiscal years, the annual fee is $125,000.

(D) If multiple drug take-back programs operate in a fiscal year, each drug take-back program must pay an equal share of the total annual fee for that year.

(E) If the revenue collected from the plan review fee and annual fee exceeds DEQ's actual costs for the program in a given fiscal year, DEQ will reduce the annual fee by the excess amount in a subsequent year or years.

(F) DEQ may reduce the annual fee for a given fiscal year to ensure fee revenue approximately matches DEQ's projected costs for that year.

(b) Program operators must pay the annual fee according to the schedule below:

(A) For fiscal year beginning July 1, 2021, payment is due August 1, 2021.

(B) For fiscal year beginning July 1, 2022, and for subsequent fiscal years, DEQ will notify each program operator of the program's annual fee by October 1. Payment is due not later than 30 days after the date DEQ mails the notice.

(4) Hourly fee. The hourly fee is to cover any other work that DEQ determines is necessary on behalf of a drug take-back program.

(a) The hourly fee will not exceed $250 per hour.

(b) DEQ will calculate the hourly fee to reasonably reflect DEQ's expenses for the work performed.

(c) DEQ will invoice each program operator quarterly for any hourly fee work associated with that operator's drug take-back program. The invoice will briefly describe the work performed and the cost for that work. Payment is due not later than 30 days after the date DEQ mails the invoice.

(5) Reporting. Each fiscal year DEQ will report its current and projected program expenditures and revenue.