State of Oregon Department of Environmental Quality

Drug Take Back Program Rulemaking Notice of Proposed Rulemaking and Draft Rules

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State of Oregon Department of Environmental Quality

Notice of Proposed Rulemaking

June 1, 2020

Drug Take-Back Program 2020 Rulemaking

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Introduction

DEQ invites public input on proposed permanent rule amendments to chapter 340 of the Oregon Administrative Rules.

Request for Other Options

During the public comment period, DEQ asks for public comment on whether there are other options for achieving the rules' substantive goals while reducing the rules' negative economic impact on business.

Overview

In 2019, Oregon became one of a handful of states to require drug manufacturers to fund and participate in a statewide drug take-back program. The proposed rule amendments will support DEQ's administration of the drug take-back law as found in ORS 459A.200. That statute 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 DEQ approves in 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.

Procedural Summary

More information

Information about this rulemaking is on this rulemaking's web page: Drug Take-Back Rulemaking.

Public Hearings

DEQ plans to hold one public hearing. Anyone can attend the hearing by webinar or teleconference.

The hearing will be online only.

Date: Wednesday, July 15, 2020
Start time: 2 p.m.
Teleconference phone number: 971-319-4991
Participant code: 202 884 820#
Webinar link: Join Microsoft Teams Meeting

Instructions on how to join webinar or teleconference: MS Teams Instructions

How to comment on this rulemaking proposal

DEQ is asking for public comment on the proposed rules. Anyone can submit comments and questions about this rulemaking. A person can submit comments through this rulemaking's web page, by regular mail, or at the public hearing.

Comment deadline

DEQ will only consider comments on the proposed rules that DEQ receives by 4 p.m., on Friday, July 17, 2020.

Submit comment online

Drug Take-Back Rulemaking

Note for public university students:

ORS 192.345(29) allows Oregon public university and OHSU students to protect their university email addresses from disclosure under Oregon's public records law. If you are an Oregon public university or OHSU student you may omit your email address when you complete the online form to submit a comment.

By mail

Oregon DEQ
Attn: Michael Lee
700 NE Multnomah St.
Room 600
Portland, OR 97232-4100

At hearing
Wednesday, July 15, 2020, at 2 p.m.

Sign up for rulemaking notices

Get email or text updates about this rulemaking by either:

- Signing up through this link: Drug Take-Back Rulemaking Email List;
- Signing up on the rulemaking web site: Drug Take-Back rulemaking web page.

Get email or text updates about other, future DEQ rulemakings by signing up through this link: DEQ Email Notice List.

What will happen next?

DEQ will include a written response to comments in a staff report DEQ will submit to EQC. DEQ may modify the rule proposal based on the comments.

Proposed rules become effective only if EQC adopts them. DEQ's intended action is to present the proposed rule changes to the EQC as soon as possible after the earliest date on which the rule changes could take effect. DEQ intends to submit the proposed rule changes to the EQC on or after September 17, 2020.

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 the EQC's behalf for enforcement and discipline under ORS 459A.239; and
- Establishing fees reasonably calculated to cover DEQ's administrative costs, as required by ORS 459A.242.

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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	340-098-0310	340-098-0330	340-098-0350	340-098-0370
340-098-0390				
Amend				
340-098-0000				

Statutory Authority – ORS				
468.020	468.065	459A.266	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 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 allay 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.

DEQ will consider comments received during the public comment period in developing final rules to present to the Environmental Quality Commission.

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?

Fees to fund this new program have not yet been established. 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 November 1, 2020. First annual fee is due August 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
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% 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% and 3.1% 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, such as 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.

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.

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.

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

How to comment on this rulemaking proposal

DEQ is asking for public comment on the proposed rules. Anyone can submit comments and questions about this rulemaking. A person can submit comments through an online web page, by regular mail or at the public hearing.

An issue was raised about the proposed rule provision requiring program operators to submit manufacturers' Oregon Board of Pharmacy registration numbers. DEQ particularly invites the public to submit comments on this rule provision.

Comment deadline

DEQ will only consider comments on the proposed rules that DEQ receives by 4 p.m., on Friday, July 17, 2020.

Submit comment online
Any person can submit a written comment at this web page:

Drug Take-Back Rulemaking

Note for public university students:

ORS 192.345(29) allows Oregon public university and OHSU students to protect their university email addresses from disclosure under Oregon's public records law. If you are an Oregon public university or OHSU student you may omit your email address when you complete the online form to submit a comment.

By mail

Oregon DEQ
Attn: Michael Lee
700 NE Multnomah St., Room 600
Portland, OR 97232-4100

At hearing

July 15, 2020, at 2 p.m.

Public Hearing

DEQ plans to hold one public hearing. Anyone can attend a hearing in person, or by webinar or teleconference.

The hearing is online only.

Date: Wednesday, July 15, 2020
Start time: 2 p.m.
Teleconference phone number: 971-319-4991
Participant code: 202 884 820#
Webinar link: Join Microsoft Teams Meeting
Instructions on how to join webinar or teleconference: MS Teams Instructions

DEQ will consider all comments and testimony received before the closing date. DEQ will summarize all comments and respond to comments in the Environmental Quality Commission staff report.

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 Draft Rules – Edits Highlighted

Key to Identifying Changed Text:
~~Deleted Text~~
New/inserted text
~~Text deleted from one location~~ - and moved to another location

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

340-098-0000
Applicability
These rules relate to the statewide collection, transportation, and recycling system for electronic devices established by ORS 459A.300 to 459A.365 and to the Drug Take-Back Program established by ORS 459A.200 to 459A.266. 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. 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) "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.

(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

A proposed drug take-back program plan and updated program plan submitted under ORS 459A.209 must include the registration number issued by the Oregon Board of Pharmacy for each covered manufacturer participating in the proposed drug take-back program.

340-098-0350
Services and Collection Events in Place of a Required Drop-Off Site
To obtain a waiver from DEQ under ORS 459A.209(3), or approval to provide additional services and collection events in place of a drop-off site under ORS 459A.218(3), a program operator must, to DEQ's satisfaction:

(1) Demonstrate 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;

(2) Explain why the program operator cannot establish or maintain a drop-off site in the affected county or population center;

(3) Demonstrate how the services proposed in place of a required drop-off site will provide convenient service for all residents in the affected county or population center;

(4) Demonstrate concurrence by affected local governments with the proposed services, or explain why the program operator could not obtain such concurrence despite good faith efforts; and

(5) Agree 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. The plan review fee is a one-time fee for reviewing a program plan or an updated program plan submitted under ORS 459A.209.

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

(b) Plan review fees are due with submittal of a plan or an updated plan to DEQ.

(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.

(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 invoice each program operator quarterly for hourly fee work associated with that operator's drug take-back program. DEQ will calculate the hourly fee to reasonably reflect DEQ's expenses for the work performed. 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 Draft Rules – Edits Incorporated

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

340-098-0000
Applicability
These rules relate to the statewide collection, transportation, and recycling system for electronic devices established by ORS 459A.300 to 459A.365 and to the Drug Take-Back Program established by ORS 459A.200 to 459A.266. 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. 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) "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.

(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
A proposed drug take-back program plan and updated program plan submitted under ORS 459A.209 must include the registration number issued by the Oregon Board of Pharmacy for each covered manufacturer participating in the proposed drug take-back program.

340-098-0350

Services and Collection Events in Place of a Required Drop-Off Site
To obtain a waiver from DEQ under ORS 459A.209(3), or approval to provide additional services and collection events in place of a drop-off site under ORS 459A.218(3), a program operator must, to DEQ's satisfaction:

(1) Demonstrate 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;

(2) Explain why the program operator cannot establish or maintain a drop-off site in the affected county or population center;

(3) Demonstrate how the services proposed in place of a required drop-off site will provide convenient service for all residents in the affected county or population center;

(4) Demonstrate concurrence by affected local governments with the proposed services, or explain why the program operator could not obtain such concurrence despite good faith efforts; and

(5) Agree 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. The plan review fee is a one-time fee for reviewing a program plan or an updated program plan submitted under ORS 459A.209.

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

(b) Plan review fees are due with submittal of a plan or an updated plan to DEQ.

(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.

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